Ministry of Health & Family Welfare

वार्षिक प्रतिवेदन
Annual Report
2018-2019

Immunodiagnostic Kit & Molecular Diagnostic Laboratory of NIB designated as WHO-COLLABORATING CENTRE for Quality Control of HIV, HCV, HBsAg and Syphilis in-vitro diagnostic assays

राष्ट्रीय जैविक संस्थान
National Institute of Biologicals

ANNUAL REPORT
2018-19

NATIONAL INSTITUTE OF BIOLOGICALS

Ministry of Health and Family Welfare
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NOIDA

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INTRODUCTION

The National Institute of Biologicals (NIB) had been set up in 1992 as an autonomous Institute under the aegis of the Ministry of Health & Family Welfare, Government of India. The Institute is located at A-32, Sector-62, NOIDA, Uttar Pradesh in an area of 74,000 Sq. M.

The scientists of the institute are committed towards their duty and follow the mandates and functions meticulously. Some of them are as hereunder:

i) to ensure quality of Biological and Biotherapeutic products, both imported and manufactured indigenously available in the Indian market.

ii) to contribute in finalizing the specifications for biological products to be incorporated in Indian Pharmacopoeia,

iii) to prepare National Reference Standards for biological products,

iv) to train technical personnel in the public and private sectors in the field of Quality Control of Biological products and Haemovigilance programme,

v) to collaborate with other National and International Scientific Institutions/ organizations in upgrading technologies and keeping abreast of scientific advances made in the field of quality assessment of Biological and Biotherapeutic products.

vi) to extend technical expertise during joint inspections of manufacturing premises of biological products with the officers of CDSCO

vii) to implement the Haemovigilance Programme of India to promote safe blood transfusion practices.

The Laboratory and Animal House facility of the Institute, constructed in February, 2006, have 42 Biosafety Level (BSL)-2 and 2 BSL-3 laboratories equipped with modern scientific equipment for testing of Biological and Biotherapeutic products. There are 20 walk-in-cold rooms and 03 walk-in-deep freezers (-20°C), and 64 bio-safety cabinets. All equipment are under Annual Maintenance Contract (AMC) or Comprehensive Maintenance Contract (CMC) and are regularly calibrated by a NABL accredited calibration laboratory.

The expenditure made by the Institute on salaries, maintenance, procurement of reagents, chemicals, scientific equipment etc., is met from the grants given by the Ministry of Health & Family Welfare, Govt. of India. The revenue generated from testing of biologicals is deposited in the consolidated fund of Government of India with Ministry of Health & Family Welfare.

REPORT FROM THE DESK OF DIRECTOR

It gives me immense pleasure to present the Annual Report of National Institute of Biologicals (NIB) for the year 2018-19 that expounds the significant work carried out at the Institute. NIB is an apex autonomous institute under the administrative control of Ministry of Health & Family Welfare (MoHFW), Government of India. The Institute is performing primary statutory function of Quality Control of Biologicals e.g. Insulin, erythropoietin, blood products, diagnostic kits e.g. HIV, HBV, HCV, therapeutic monoclonal antibodies like Trastuzumab and Rituximab used in cancer treatment etc. in accordance with provisions of Drugs & Cosmetics Act 1940 and Rule 1945 amended from time to time. The Institute is notified Central Drugs Laboratory and Central Medical Device Testing Laboratory under these statutory provisions. The biological products are tested as per statutory standards laid down in Indian Pharmacopoeia or relevant pharmacopoeia or International norms, in the NIB laboratories which are GLP compliant as laid down in Schedule L1 of Drugs & Cosmetics Rules. These Biologicals are not only highly complex molecules but also difficult to characterize involving analytical tools and small laboratory animals. Some of the NIB scientists have also been notified as Government Analysts and Medical Device Testing Officers for biological products as per Statutory Norms.

NIB is the only institute of its kind in the country and also amongst BIMSTEC (Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation) and WHO- SEAR (South-East Asia Region) countries which effectively performs Quality Control of wide spectrum of biologicals imported and indigenously manufactured - ranging from small biotherapeutic product Insulin (6kD) to complex Monoclonal Antibody (150kD) and Rapid diagnostics to Molecular diagnostics used for patient care.

Further, the Institute collaborates with Indian and other Pharmacopoeias in finalizing the specifications, prepare National Reference Standards, train technical personnel of the public and private sectors, collaborate with other National and International Scientific Institutions/ organizations in upgrading technologies and keeping abreast with scientific advances made in the field of quality assurance of various categories of Biologicals (diagnostic, therapeutic and prophylactic). The Institute also provides technical expertise to enforce Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) standards in India through joint inspections of (i) manufacturing premises in coordination with Central Drugs Standards and Control Organization (CDSCO), (ii) GLP- Laboratories conducted by National GLP Compliance Monitoring Authority (NGCMA) DST, and (iii) Animal Facilities conducted by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA).

The capacity of NIB to test different types of biologicals has increased substantially during the last decade i.e. 245 in 2018-19 from 36 in 2009-10. The Institute evaluated 1809 batches of biological samples in 2018-19 including 1616 batches under Drugs & Cosmetics Act and Rules thereunder, 178 from State Medical Procurement Agencies and 15 vaccine samples from Bangladesh. Out of total samples tested, 2.5% (i.e. 46 batches out of 1809) were found to be of Not of Standard Quality (NSQ). In a similar way NSQ biological samples were detected ranging from 0.20% (2012-13) to 14.1% (2009-10) during past ten years. This reiterates the role of the Institute in protecting and promoting public health.

National Reference Standards (NRS) for Insulin Lispro IPRS became available for purchase w.e.f September 2018 making a total of 6 National Reference Standards in NIB's repository. In addition

Institute is also in process of releasing NRS for Minimum Potency of Anti-A and Anti-B blood grouping reagents.

NIB laboratories participated in various International/ National External Quality Assurance Assessment Scheme (EQA)/ Proficiency testing by various external agencies like European Directorate for the Quality of Medicines (EDQM) - France, WHO- Geneva, National Serology Reference Laboratory (NSRL) - Australia, Christian Medical College- Vellore in order to assess and strengthen the laboratory's testing performance. NIB also collaborated with Indian Council of Medical Research (ICMR) - New Delhi to sensitize manufacturers about the Glucometer Device's Test parameters, their specifications and limits of acceptance during product development stage with respect to product design.

NIB obtained its first accreditation by National Accreditation Board for Testing and Calibration Laboratories (NABL) as per ISO/ IEC 17025: 2005 in year 2011 for 19 products with 16 Biological tests and 14 Chemical tests and thereafter has continued to maintain and enhanced this status of accreditation for the period 2018- 2020 to 120 products with 160 Biological tests and 125 Chemical tests. Occupational Health and Safety Management Systems (OHSAS) 18001:2007 is the internationally recognized standard and in this regard the Institute has successfully acquired the Bureau Veritas Certification/ UKAS (BS OHSAS 18001:2007) certification (Certificate No. IND 18.8672U/HS) vide letter No. 4090200 dated 04.06.2018 from 24.05.2018 till 11.03.2021. This certification provides a framework to identify, control and decrease the risks associated with health and safety within the workplace.

NIB has also participated in various collaborative scientific activities, both at national and international level which have enhanced Institute's visibility towards its mandates.

Immunodiagnostic kit and Molecular Diagnostic Laboratory of NIB has been designated as a WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg and Syphilis in-vitro diagnostic assays (WHO-CC No. IND-148) by WHO on 19.09.2018 and the certificate for this was conferred to NIB by the Secretary, MoHFW, Government of India during 4th WHO Global Forum on Medical Devices "Increasing access to medical devices" at AMTZ-Kalam Convention Centre, Visakhapatnam, India, in December, 2018.

NIB is the "Support Cell" for WHO Prequalification (PQ) Programme for In-vitro Diagnostics (IVD), and is providing necessary hand holding and guidance to Indian manufacturers on the WHO-PQ Programme of IVDs, enabling them to meet global quality standards with regard to quality and documentation activities as per WHO requirement. The Institute is extending technical expertise, capacity building and training & technical support to the IVD manufacturers and is working actively in co-ordination with WHO, CDSCO and stakeholders in this regard.

NIB has been a key functionary as an interface among WHO, National Center for Immunobiologicals Research and Evaluation (CRIVIB), Istituto Superiore di Sanità (ISS), Rome, Italy, Indian Pharmacopoeia Commission and Indian Vaccine Manufacturers for inclusion of WHO protocol for determination of PRP content of Hib vaccine by HPAEC-PAD in Indian Pharmacopoeia.

NIB scientist(s) participated as a member of expert team for Desktop Surveillance audit of South African National Control Laboratory (SANCL), as speakers/ faculty in various international workshops/ conferences organized by various international organizations viz. National Institute of Food and Drug Safety Evaluation NIFDS- Korea, Government of Japan, International Society of Blood Transfusion ISBT Toronto, Canada and FDA Taiwan and also for WHO SEARO GAP III Implementation Training for poliovirus laboratory containment.

NIB scientists on request from Biotechnology Industry Research Assistance Council (BIRAC) participate every month to provide expert inputs

and address the queries from Startups/ innovators in meetings of the Facilitation of Innovation and Regulations for Start-ups and Innovators (FIRST) Hub.

NIB has been contributing towards safety of blood transfusion as the National Coordinating Centre for Haemovigilance Programme of India (HvPI) which was launched on 10.12.2012 across the country. This year 05 Continued Medical Education (CMEs) and 05 National level workshops were conducted for creating awareness on importance of reporting adverse transfusion reactions. A total of 1538 participants which include blood bank officials, clinicians, nurses, blood donor motivators & blood bank technical staff were trained in these CMEs/ Workshop organized by HvPI Division of NIB. Further during 2013-14 to 2018-19 about 8700 participants were trained through 42 National level 42 CMEs (7589 participants) and 11 National level Workshops (1111 participants) organized by NIB. HvPI is a member of International Haemovigilance Network (IHN). Further, Head of HvPI- NIB, has been designated as Secretary of IHN Board.

The institute in coordination with WHO Regional Office for South East Asia (SEARO) contributed for capacity building on Haemovigilance system for quality and safety of blood donation and transfusion in Bangladesh through training under HvPI. On request of WHO- SEARO, NIB will be organizing a Regional meeting of National Focal Points of Blood Transfusion Services to Review the Progress of Implementation of Global Strategy of Safe Blood with special emphasis on Haemovigilance during 19-22 August 2019 wherein 11 Member States of South East Asia region will participate.

Considering a need of trained and skilled manpower in the country in the area of Quality Control of Biologicals, Diagnostics and Haemovigilance; NIB has trained more than 460 personnel including students, blood bank officials and technical personnel from manufacturing units during

this year. The Institute under "Pradhan Mantri Kaushal Vikas Yojna", conducted trainings on "National Skill Development & Hands- on Training on Quality Control of Biologicals" for Post – Graduate students of Biotechnology, Microbiology, Biochemistry and Pharmacy from Universities of Himachal Pradesh, Jammu, North Eastern States and JSS Ooty, Mysuru, and various National Institute of Pharmaceutical Education and Research (NIPERs) and technical personnel from manufacturing units. NIB is also expanding its National Skill Development & Hands- on Training program for Post Graduate Students of Tribal Regions of the country i.e. Chhattisgarh and Jharkhand. Trainings of blood bank officials are also organized at NIB in collaboration with Blood Cell, National Health Mission (NHM) for strengthening blood services in various states of the country. Under this programme about 1184 participants (Students and Blood bank officials) were trained by NIB during the time period of 2016-2019.

Further, NIB has generated a gross revenue of Rs.13.6 crores during 2018-19 from various sources i.e. testing fee for evaluation and Quality Control of various biological samples, training fee received from various training programmes, user charges for hostel and guest house and interest on the saving bank account etc. This is deposited in Consolidated Fund of India.

NIB continues to strive to fulfil its mandates to become a trendsetter in the field of Quality Control of biologicals in the country and meet the international benchmark. I am grateful to the Ministry of Health & Family Welfare (Government of India), Central Drugs Standards and Control Organization (CDSCO) and Indian Pharmacopoeia Commission (IPC) for their continuous support & guidance and facilitating NIB in fulfilling its endeavors. NIB is making concerted efforts to ensure the quality service in the Healthcare Sector of the country in the area of biologicals.

SCIENTIFIC ACTIVITIES

SAMPLE RECEIPT AND REPORT DISPATCH UNIT

1. Name of Head:

Rashmi Srivastava, Scientist Grade-III

2. Manpower in the Lab/Division:

I. Name of Scientific Staff

Dr. Swati Shalini, Junior Scientist

II. Name of Technical staff :

Mr. Mohit Sharma, Lab Assistant

III. No(s). of Outsourced Staff : 09

3. Aim and Scope:

SRRDU has been functional as an independent unit since 2008. The unit is main entry point for all the samples that are received in the institute as well as the exit point from where all the reports are dispatched. Samples of various Bio therapeutics, Diagnostics, and Vaccines are received from the National Drug Regulatory authorities as well as several government medical organizations like Haryana Medical Service Corporation Limited, Rajasthan Medical Services Corporation, Jammu & Kashmir Medical Services Corporation Limited etc. International samples from Bangladesh have also been received for quality evaluation at vaccine Laboratory. Requisite quantity of all samples received for testing is retained at recommended temperature up to post 3 months expiry for further use, if any.

4. Workflow of the Unit

The complete workflow of department has been well documented as per ISO 17025:2005 in approved SOPs for different categories of biologicals and is an ongoing process for continuous improvement in the efficiency of the system. All samples that are received are critically checked with respect to the essential official documents, proper temperature as per label claim, required quantities, testing fee, etc. These checks are always as per the published and revised guidelines uploaded on Institute website.

5. Sample receipt records:

The total no. of biologicals tested at NIB has

increased by 17.22% from 209 to 245 (as shown in fig 1) and their testing fees have been revised according to GST norms. A new software was developed with the help of IT department for invoice generation against submitted testing fees.

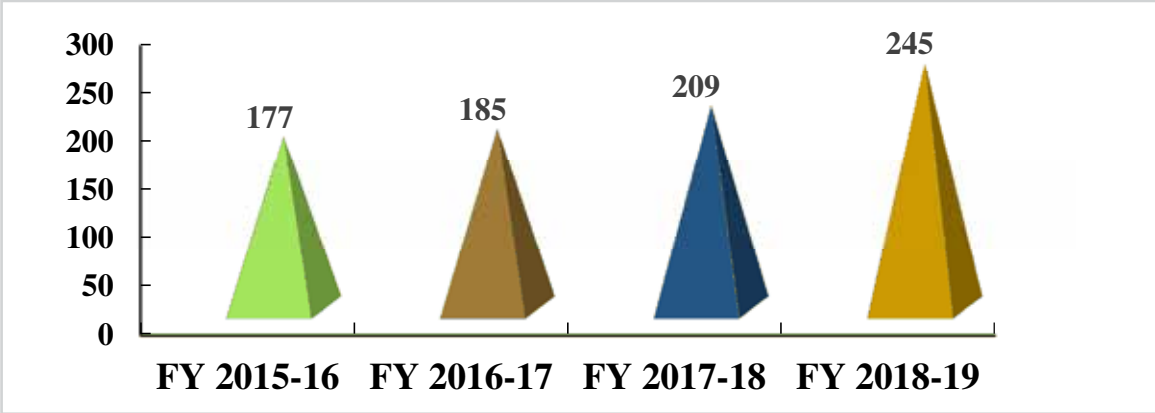


Fig 1. Capacity to test type of biologicals at NIB during last four financial years

In FY 2018-19, a total of 1848 samples have been received under various categories for testing purpose (Fig. 2). Amongst them 1515 from regulatory body, 248 from Government Medical Supplies, 16 survey samples, 23 legal samples and 46 as service samples were received. The government samples have shown a remarkable increase of 161% from 95 in FY 2017-18 to 248 in FY 2018-19.

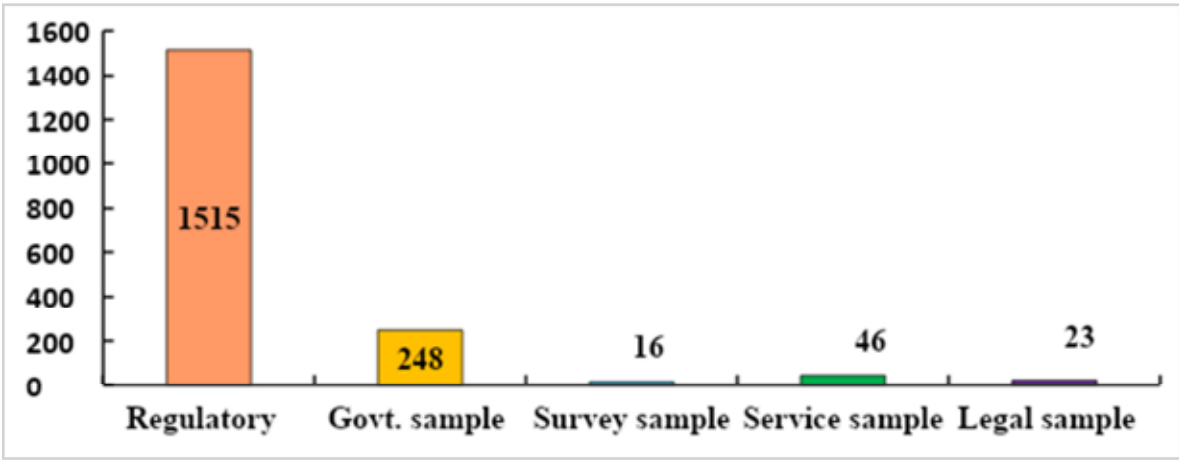


Fig 2: Total number of samples received at NIB during FY 2018-19 and their distribution in various categories

In FY 2018-19 total of 1763 (Regulatory and Govt.) samples were received for testing and their product wise distribution has been shown in fig 3. The testing fee is charged only for 1763 regulatory and Government samples received at NIB. The maximum number of samples were received for Immuno-Diagnostic Kits and Molecular Diagnostics followed by Blood Products.

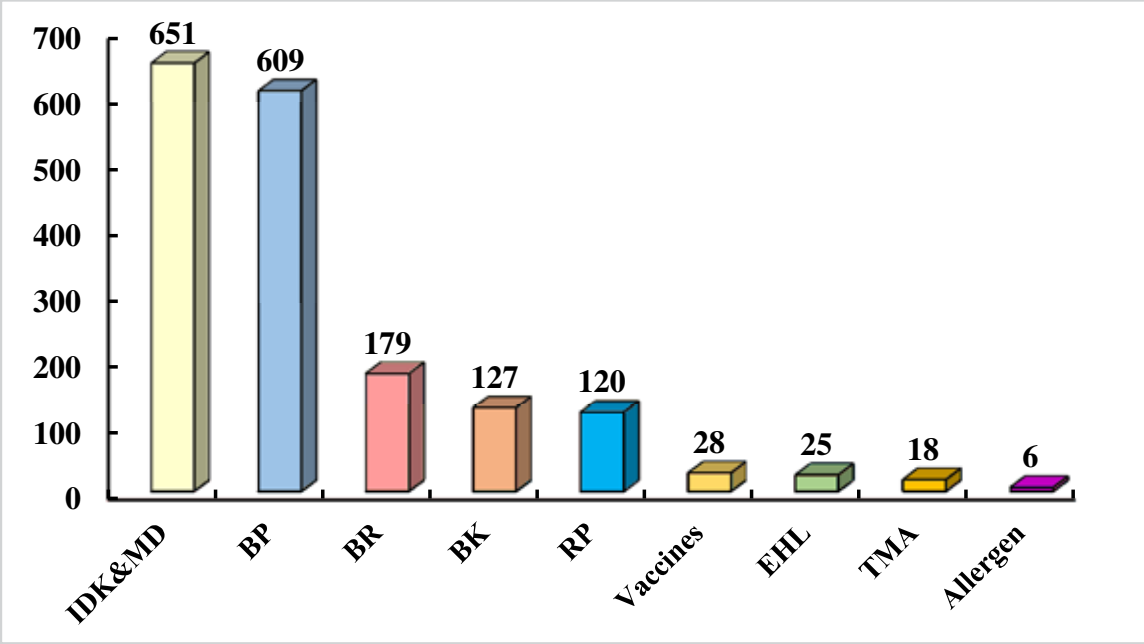


Fig 3: Number of samples received product wise for testing during FY 2018-19

IDK & MD= Immuno Diagnostic Kit and Molecular Diagnostic BP= Blood Products, BR=Blood Reagent, BK= Biochemical Kits, RP= Recombinant Product, E&H= Enzymes and Hormones, TMA= Therapeutic Monoclonal Antibody

The number of samples received in diagnostic and therapeutic categories (both indigenous and imported) were 957 and 806 respectively (Fig 4).

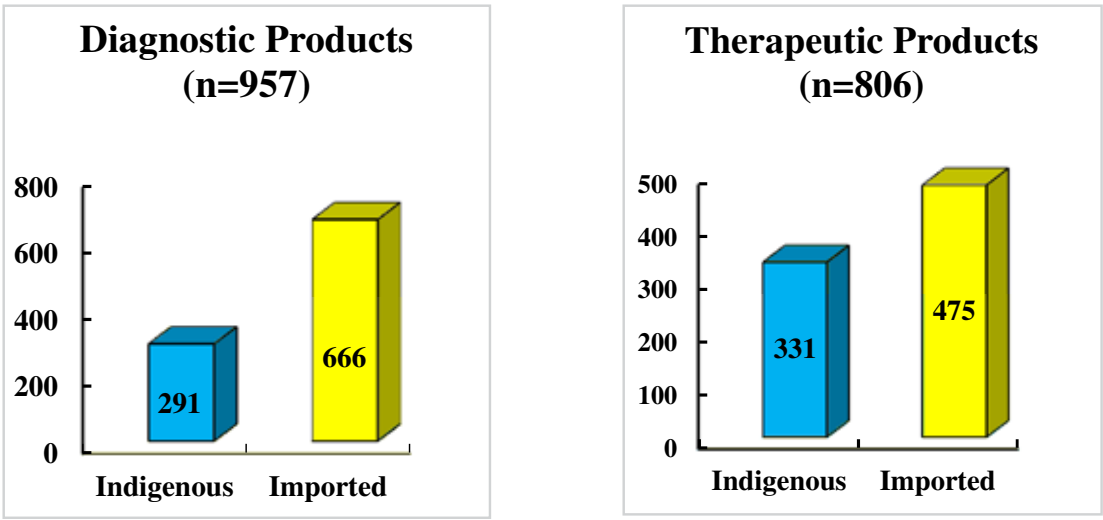


Fig 4: The number of Imported and Indigenous samples received in Therapeutics and Diagnostics categories during FY 2018-19

6. Samples Evaluated and report released:

Total 1809 reports were released in financial year 2018-19 (Fig.5). As per the regulatory guidelines applicable to samples submitted under the Drugs and Cosmetics Act, all the biologicals that fall into C and C1 class of drugs are evaluated within stipulated turnaround time except for therapeutics where 90 days may be required due to animal based testing.

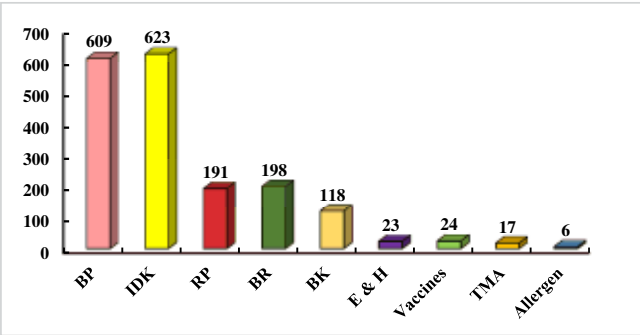


Fig 5: Total reports released product wise from the institute during FY 2018-19

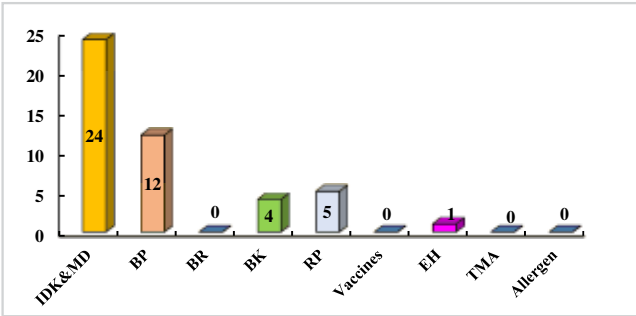


Fig 6: Data for Not of Standard Quality products released during FY 2018-19

Out of total 1809 samples, 46 samples (24 from IDK & MD, 12 from BP, 04 from BK, 5 from RP and 01 from E&H) were found to be "Not of standard Quality" (NSQ) as shown in Fig 6. The detection of NSQ samples is important for assuring quality of biological products available for patient care in Indian market.

7. Sample Storage and Record Keeping

Retained samples are stored frozen, refrigerated or at room temperature as per requirement. There are two dedicated walk-in cold rooms one each of 2-8°C and -20°C. The samples shall be stored as per the Cold Room Mapping Plan. The details of the retained samples are documented in prescribed register. Samples from the retained lot are issued to the laboratory as per request for designated purposes like repeat testing, training etc. with proper documentation. For security the complete unit is under CCTV surveillance and the samples and records are kept under lock and key.

8. Participation in Trainings/workshop/conferences

Name of Scientist/ Attended By	Name of Scientist/ Attended By Name of Program	Duration	Organizer & Place of Training
Dr. Swati Shalini	Short course on Occupational Medicine	18-02-2019 to 22-02-2019	PHFI, Gurgaon, Haryana, India
Dr. Swati Shalini	Internal training on Internal quality check	08-10-18	NIB, Noida

IMMUNODIAGNOSTIC KIT & MOLECULAR DIAGNOSTIC LABORATORY

1. Name of Head:

Dr. Rajesh K. Sharma, Scientist Grade-III
(Till 17.09.2018)

Dr. Richa Baranwal, Scientist Grade-III
(From 18.09.2018)

2. Manpower in the Lab / Division

I. Name of Scientific Staff:

Mr. N Nanda Gopal, Scientist Grade-III

Dr. Manjula Kiran, Junior Scientist

Mr. P. S. Chandranand, Junior Scientist

Mr. Rajeev Kumar, Junior Scientist

Dr. Anoop Kumar, Junior Scientist

II. Name of Technical Staff:

Ms. Deepa Sharma, Technical Officer, NRL, NACO

Ms. Bhawana Bhandari, Lab Tech, NRL, NACO (Till Nov-18)

III. No(s). of Outsourced Staff: 12

3. Scientific Activities Undertaken

a) Collaboration with other Organizations: Networking with blood banks/ hospitals of Delhi/ NCR for collection of plasma bags:

The Laboratory requires infectious plasma bags of HIV, HBV, HCV and Syphilis for Quality Control testing of indigenous and imported Immunodiagnostic and Molecular diagnostic kits received in NIB from offices of Central Drugs Standard Control Organisation (CDSCO). In this regard, DCG(I) has directed various blood banks/hospitals listed in Table 1 to provide infectious plasma bags to NIB vide letter no. Blood Bank/ Misc/ NIB/ 2015-D dated 02.12.2015. During the year 2018-19 a total number of 1220 plasma bags were collected by the Laboratory from listed blood banks/ hospitals. The total number of reactive bags of various markers viz HIV, HCV, HBV & Syphilis were 1005, however, 215 bags were non-reactive. The marker wise details of Plasma Bags collected are elaborated in Table 2.

Table 1: List of Blood Banks/Hospitals of different geographical region associated with NIB

S. No.	Name of Hospital/Blood Bank	S. No.	Name of Hospital/ Blood Bank
1.	Apollo Hospital, New Delhi	11.	Moolchand Hospital, Delhi
2.	Indian Red Cross Society, New Delhi	12.	Kailash Hospital, NOIDA
3.	G.T.B. Hospital, New Delhi	13.	Fortis Hospital, NOIDA
4.	AIIMS Hospital, New Delhi	14.	Fortis Memorial, Gurugram
5.	Safdarjung Hospital, New Delhi	15.	Medanta Hospital, Gurugram
6.	Lok Nayak Hospital, New Delhi	16.	Metro Heart Blood Bank, NOIDA
7.	Rotary Blood Bank, Delhi	17.	Prathma Blood Bank, Gujarat
8.	G.B. Pant Hospital, New Delhi	18.	B. I. M. R. Hospital, Madhya Pradesh
9.	Lady Harding Hospital, New Delhi	19.	Acharya Shri Chander College Medical Science, Jammu
10.	Ganga Ram Hospital, New Delhi		

Table 2: Total number of Plasma Bags collected during 2018-19:

Name of Hospital/ Blood Bank	Markers						
	HIV	HBsAg	HCV	Syphilis	HBV Core	Non-Reactive	Total
I.R.C.S, New Delhi	01	02	03	01	0	215	222
Kailash Hospital, Delhi	0	50	35	09	0	0	94
Fortis Hospital, Gurgaon	04	38	26	17	0	0	85
G.T.B. Hospital, New Delhi	27	192	99	74	0	0	392
Lok Nayak Hospital, New Delhi	02	04	05	51	0	0	62
Moolchand Hospital, New Delhi	01	02	05	0	0	0	08
Medanta Hospital, Gurgaon	02	13	03	0	0	0	18
Apollo Hospital, New Delhi	04	10	20	0	33	0	67
Ganga Ram Hospital, New Delhi	35	98	71	0	0	0	204
Rajiv Ghandhi Hospital, New Delhi	14	20	16	18	0	0	68
Total	**90**	**429**	**283**	**170**	**33**	**215**	**1220**

b) CDL Notification:

- The institute is notified Central Drugs Laboratory for Immunodiagnostic Kits (HIV, HCV and HBsAg) since the year 2002 and re-notified in the year 2014. NIB has also been declared as Central Medical Device Testing Laboratory from June 01, 2018, vide Gazette No.S.O.2237 (E).
- The institute is accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) in accordance with ISO/IEC 17025:2005 for testing of immunodiagnostic and molecular diagnostic kits mentioned in Table 3.

Table 3: List of Products and specific tests/type of test accredited by NABL

S. No.	Group of products/material/item tested	Specific test or type of test
Serology (N=22)		
1.	HIV 1 & / 2 Antibody	i. Rapid ii. ELISA iii. CLIA iv. ELFA v. Confirmatory

S. No.	Group of products/material/item tested	Specific test or type of test
2.	HBV	vi. Rapid vii. ELISA viii. CLIA ix. ELFA x. Confirmatory
3.	HCV	xi. Rapid xii. ELISA xiii. CLIA xiv. ELFA xv. Confirmatory
4.	Syphilis	xvi. Rapid xvii. ELISA xviii. CLIA
5.	Anti-HBc Total	xix. ELISA
6.	Anti –HBc IgM	xx. ELISA
7.	HBe Ag/ Hbe Ag-Ab/Anti -HBe	xxi. ELISA
8.	Anti-HBs	xxii. ELISA
Molecular (N=3)		
9.	Blood donor screening multiplex (HBV, HCV & HIV) molecular diagnostic test (Qualitative)	i. Nucleic Acid Amplification Test (NAT)
10.	Infection Diagnostic test for HIV-1 (Qualitative)	ii. Nucleic Acid Amplification Test (NAT)
11.	Infection Diagnostic test for HCV (Qualitative)	iii. Nucleic Acid Amplification Test (NAT)

- NIB has been designated as "Support Cell for WHO Pre-Qualification Programme" for in-vitro Diagnostics on November 22, 2017.
- Immunodiagnostic Kits and Molecular Diagnostic Laboratory of NIB has been designated as WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg & Syphilis in-vitro diagnostic assays (WHO CC No.IND-148) on September 19, 2018 and felicitated with certificate on December 15, 2018 at AMTZ-Kalam Convention Centre, Vishakhapatnam

c) Participation in International level EQAS

Immunodiagnostic Kit and Molecular Diagnostic Laboratory has been regularly participating in EQAS since 2009 which is conducted by NRL Australia, a designated WHO Centre for Diagnostics and Laboratory Support for HIV, AIDS and blood borne Infections and fully accredited Proficiency testing provider under ISO 17043: 2010. This strengthens the quality of testing and enhances the credibility of Laboratory. Laboratory has successfully participated in three rounds of EQAS 2018 and received the Certificate of Participation for Hepatitis HIV Syphilis Serology testing.

d) Government Analyst:

i. Under Gazette Notification No. S.O. 2393(E) published on September 02, 2015, Dr. Reba Chhabra, Scientist Grade-I is notified as Government Analyst for QC testing of legal samples for Human Immunodeficiency Virus, Hepatitis B Surface Antigen, Hepatitis C Virus.

ii. Under Gazette No.S.O.3400(E) published on July 11, 2018, Dr. Reba Chhabra, Scientist Grade-I is notified as Medical Device Testing Officer by Central Government in respect of medical devices (i.e. Human Immunodeficiency Virus, Hepatitis B Surface Antigen, Hepatitis C Virus)

iii. **Legal Samples Evaluated during 2018-19.** A total of five legal samples were received and reported after testing during 2018-19. All were reported to be of Standard Quality (SQ) (Table 4).

Table 4: Legal samples tested during 2018-19

S. No.	Name of the Kit	No.	Testing status
1.	HBsAg RAPID KIT	02	Standard Quality (SQ)
2.	HIV Rapid	02	Standard Quality (SQ)
3.	HCV Rapid	01	Standard Quality (SQ)

e) Publications:

Four Scientists of the Institute attended 4th WHO Global Forum on Medical Devices "Increasing access to medical devices" held at AMTZ-Kalam Convention Centre, Visakhapatnam, India from December 13-15, 2018 and presented posters. The following four abstracts of laboratory were published in the report of Fourth WHO Global forum on Medical Devices held at Andhara Medtech Zone, Vishakhapattanam, December 13-15, 2018.

i. P. S. Chandranand, Dr. Reba Chhabra, Dr. Richa Barnawal, Dr. Surinder Singh, Dr Gaby Vercauteren, Dr. Madhur Gupta, ***'Quality Control testing of Immunodiagnostic Kits'***.

ii. Manjula Kiran, Anoop Kumar, Ranjan Kumar Satapathy, Richa Baranwal, Reba Chhabra, Surinder Singh. ***'Quality Control Evaluation of Qualitative and Quantitative Molecular Diagnostic Kits'.***

iii. P.S.Chandranand, Dr. Surinder Singh, Shalini Tewari, Dhruv Srivastava, & Yasha Singh. ***'Artificial Intelligence in Cervical Cancer Prediction'.***

iv. Rajeev Kumar, N. Nanda Gopal, Richa Baranwal, Rajesh Sharma, Reba Chhabra, Surinder Singh. ***'Inclination towards high throughput advanced technique over conventional method of diagnosis'.***

4. Testing of Biologicals:

4.1 Quality Control Testing of Immunodiagnostics Kits:

During the year 2018-19, a total of 629 batches of. Write Immunodiagnostics and Molecular Diagnostic kits. (RAPID, ELISA, CLIA, ELFA, Confirmatory & PCR Kits for HIV, HCV, HBV, Syphilis & Dengue) including 63 Pooled Plasma samples were evaluated in the laboratory. A total of 24 batches were reported as Not of standard Quality (NSQ). Immunodiagnostic kits and Molecular diagnostic kits of various marker and pooled plasma samples evaluated in the laboratory during 2018-19 are tabulated in Tables 5, 6 and 7.

Table 5: Quality Control evaluation of Immunodiagnostic kits of various marker and Pooled Plasma samples evaluated in the laboratory during 2018-19.

Name of Biologicals Tested	Type of Biologicals	Number of Batches Evaluated		No. of batches found to be of Standard Quality (SQ)	No. of batches found Not of Standard Quality (NSQ)
		Imported	Indigenous		
Immuno-diagnostic kits of HIV	RAPID	24	35	55	04
	ELISA	05	34	38	01
	CLIA	34	---	34	-----
	ELFA	05	---	05	----
	Confirmatory	05	---	05	----
Immuno-diagnostic kits of HBV	RAPID	30	25	53	02
	ELISA	05	33	37	01
	CLIA	32	---	32	----
	ELFA	04	---	04	-----
	Confirmatory	09	----	09	------
Immuno-diagnostic kits of HCV	RAPID	09	20	24	05
	ELISA	13	33	42	04
	CLIA	20	---	20	---
	ELFA	03	---	03	---
	Confirmatory	----	---	---	---
Immuno-diagnostic kits of SYPHILIS	RAPID	16	18	34	----
	ELISA	---	03	03	----
	CLIA	04	---	04	----
Immuno-diagnostic kits of HIV-SYPHILIS COMBO	RAPID	02	09	11	----
Immuno-diagnostic kits of HIV-HCV COMBO	RAPID	---	03	03	----
Immuno-diagnostic kits of DENGUE	ELISA	03	-	03	----
Immuno-diagnostic kits of CHIKUN-GUNYA	ELISA	03	----	03	-----
POOLED PLASMA	ELISA	63		63	
TOTAL		289	213	485	17

4.2 Quality Control testing of HBV sub marker kits:

Out of 629 batches evaluated during 2018-19, a total of 61 batches of HBV sub marker were tested. Fifty-seven batches were reported as Standard Quality and 04 batches were of Non-Standard Quality (Table 6).

Table 6: List of HBV sub-markers tested in the year 2018-19

S. No.	Name of Product/ Marker	No. of Batches Evaluated	No. of batches found to be of Standard Quality (SQ)	No. of batches found Not of Standard Quality (NSQ)
1.	Anti- HBs Ab	13	12	01
2.	HBc IgM	14	11	03
3.	Anti-HBc	17	17	0
4.	HBsAg Quantification	03	03	0
5.	Anti- HBe	07	07	0
6.	HBe Ag	07	07	0
TOTAL		**61**	**57**	**04**

4.3 Quality control testing of molecular diagnostic kits

During 2018 -19, 66 batches of Molecular Diagnostic kits of HIV, HBV and HCV were received and tested in the laboratory. Sixty three batches were reported as of Standard Quality (SQ) and 03 batches were Not of Standard Quality (NSQ) (Table. 7).

Table 7: Molecular diagnostic kits of various markers evaluated in the laboratory during 2018-19.

Name of Biologicals Tested	Type of Biologicals	No. of Batches Evaluated		No. of batches found to be of Standard Quality (SQ)	No. of batches found Not of Standard Quality (NSQ)
		Imported	Indigenous		
Molecular Diagnostic Kit for HIV	NAT Qualitative	0	0	0	0
	NAT Quantitative	13	03	15	01
Molecular Diagnostic Kit for HBV	NAT Qualitative	0	0	0	0
	NAT Quantitative	14	03	17	0
Molecular Diagnostic Kit for HCV	NAT Qualitative	02	0	01	0
	NAT Quantitative	12	03	16	0
Multiplex Test for HIV, HCV & HBV	NAT Qualitative	11	05	14	02
Total		52	14	63	03

4.4 Inter-laboratory testing of Biologicals and Biotherapeutic Samples:

During 2018-19, the laboratory tested 628 batches of biologicals & biotherapeutics received from other NIB laboratories (Interlaboratory) viz; Blood product laboratory, Recombinant product Laboratory and Enzymes & Hormone Laboratory for Transfusion Transmitted Infection (TTIs) (HIV-Ab, HCV-Ab & HBsAg) (Figure-1).

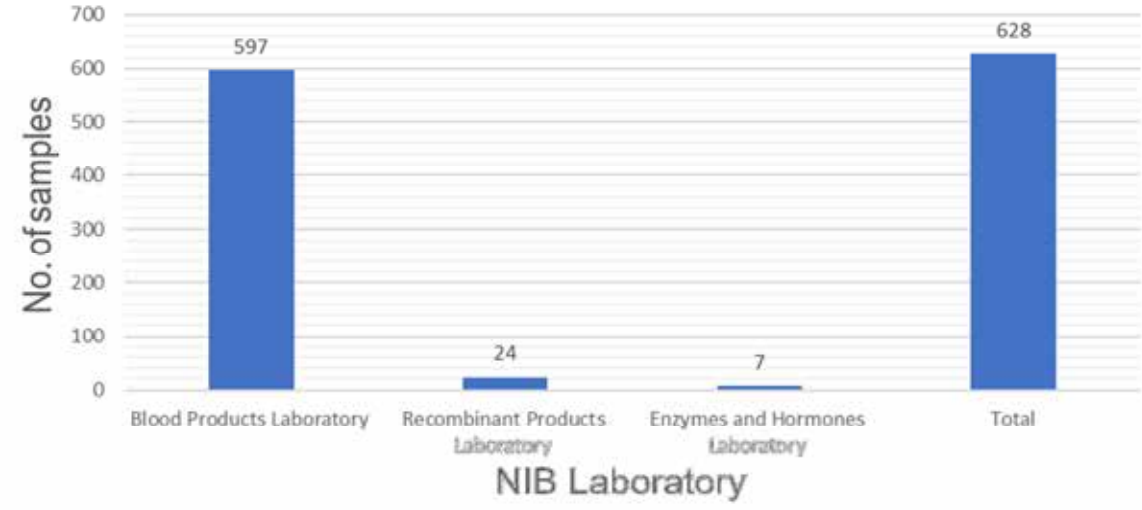


Figure 1: Number of biologicals & biotherapeutic products tested during April 2018-March 2019 for TTI testing (Inter-Laboratory Samples)

5. Preparation and Supply of National Standards, Sera Panel etc.:

5.1 Preparation and characterization of Panel

Characterization and re-characterization of the panel is a continuous laboratory activity to maintain and check quality of the panel member used for the evaluation and supply to the indigenous manufacturer.

5.2 Supply of Sera Panel

During 2018-19, the laboratory supplied total volume of ~3.1 Liters (01 Litre of HIV, 0.9 litres of HCV, 0.8 litres of HBsAg and 0.4 litres of Syphilis) Performance Panel to 11 indigenous manufacturers as mentioned in Table 8 for strengthening their Quality Control of their product during manufacturing of the products. The panel supply boxes comprise of **100 Positive & 300 Negative members of marker mentioned.** The Total Revenue generated from supply of Performance Panel during 2018-19 was ~ **13, 48, 800 INR (Thirteen lakhs forty-eight thousand and eight hundred rupees).**

Table 8: Supply of the performance panel from NIB to indigenous manufacturer

S. No.	Name of Manufacturer	Type of Panel Supplied
1.	Biolab Diagnostics Pvt. Ltd., Mumbai	Syphilis
2.	Medsource Ozone, Haryana	HIV, HCV, HBsAg, Syphilis
3.	Meril Diagnostic Ltd., Gujarat	HIV, HCV, HBsAg
4.	Aspen Laboratories Pvt. Ltd, New Delhi	HIV, HCV, HBsAg , Syphilis

5.	Transasia Biomedicals Ltd., Daman	HIV, HCV, HBsAg, Syphilis
6.	SD Biosensor Healthcare Pvt. Ltd., Gurugram	HIV, HCV, HBsAg, Syphilis
7.	Tulip Diagnostics	Syphilis
8.	Reckon Diagnostics (P) Ltd., Vadodara	HIV, HCV
9.	Qualpro Diagnostics (P) Ltd., Goa	HIV, HCV, HBsAg, Syphilis
10.	Immunoscience (I) Pvt. Ltd.,	HIV, HCV, HBsAg, Syphilis
11.	Arkray Healthcare, Surat	HIV

6. Trend in volume of work as compared to previous year:

6.1 Trend in volume of work as compared to the previous year for Quality Control Testing of Immunodiagnostic kits:

A total of 500 batches of immunodiagnostic kits of HIV, HCV, HBV, Syphilis, Dengue and Chikungunya were tested in the year 2018-19, whereas, 385 batches were evaluated in the year 2017- 2018. The details of trend for the number of respective marker kits tested in 2018-19 as compared to that tested in 2017-18 is given below in figure 2.

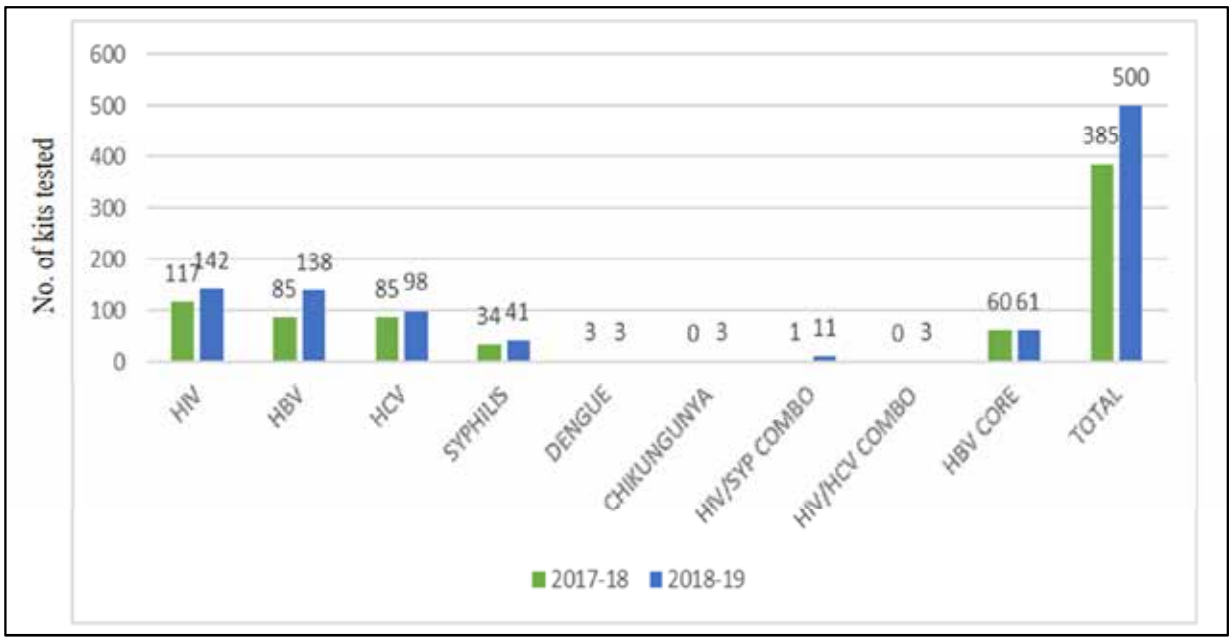


Figure 2: Trend of Immunodiagnostic kits tested in 2018-19 as compared to the previous year

6.2 Trend in volume of work as compared to the previous year for Quality Control of testing of Molecular diagnostic kits:

A total of 66 batches of molecular diagnostic kits of HIV, HCV, HBV were tested in the year 2018-19, whereas, only 13 batches were evaluated in the year 2017-18. The details of trend for the number of respective marker kits tested in 2018-19 as compared to that tested in 2017-18 is given in figure 3.

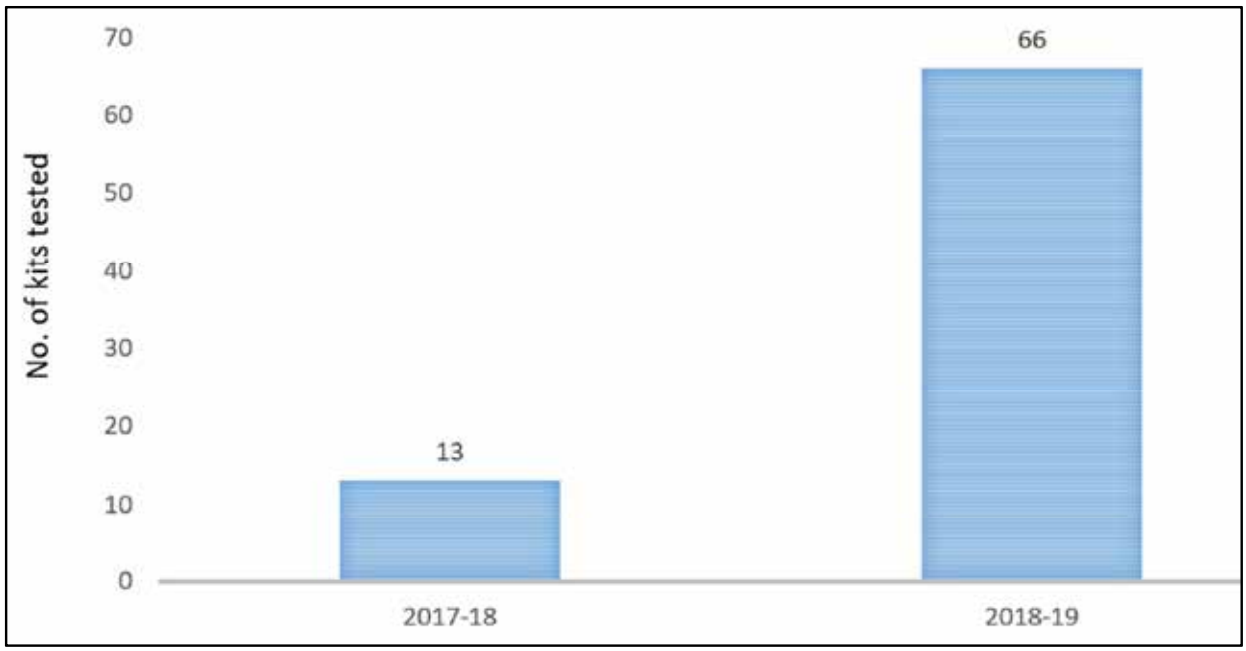


Figure 3: Trend of Molecular diagnostic kits tested in 2018-19 as compared to the previous year

6.3 Trend in volume of work as compared to the previous year for Inter-laboratory Sample Testing :

A total of 628 lot/batches of Blood Products, Recombinant Products and Enzymes and Hormones laboratory samples were tested for the TTI testing of HIV- Ab, HCV-Ab & HBsAg, in the year 2018-19 while in the year 2017-18, 508 lot/batches were tested (Figure 4).

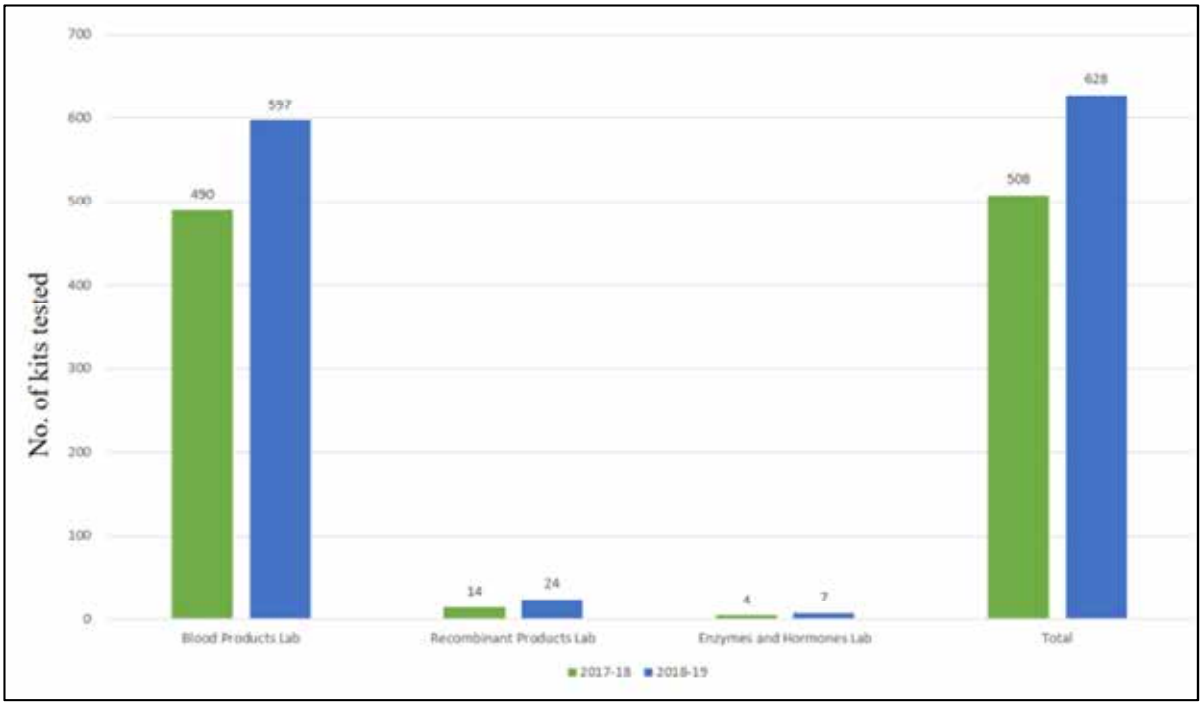


Figure 4: Trend of Inter-Laboratory Sample Testing in 2018-19 as compared to the previous year

7. Proposed targets for testing of new Biological being undertaken:

7.1 Panel reduction for the markers HIV-Ab, HCV-Ab & HBsAg: The objective is to reduce panel size for Quality Control Testing of HIV-Ab, HCV-Ab and HBsAg Rapid, ELISA and CLIA kits from the existing panel size in accordance to statistical analysis.

7.2 Lot Release testing of HIV-Rapid Diagnostic Kits (RDTs): The laboratory will prepare Kit specific dilution panels for HIV-Rapid Diagnostic Kits (RDTs) as per Paul Ehrlich Institut, Germany protocol.

7.3 NIB as a WHO Collaborating Centre would:

i. Collaborate and/or organize jointly with WHO training on Quality control of HIV, hepatitis B and Hepatitis C and Syphilis serology test Kits, in particular for India and the south East Asian region.

ii. Increase intelligence on Indian manufacturers of "WHO priority in-vitro diagnostics" through monitoring them and sharing of performance data on a periodic basis with WHO.

iii. Strengthen capacity for testing of transfusion transmissible infections in the SEARO countries.

8. Training/ Workshop/ Conference/ Meeting Organized

i. NIB as a National Reference Laboratory of NACO has organized one day EQAS Workshop for distribution of HIV Proficiency Test Panel (Round 1 of the Financial Year 2018-19) to nine State Reference Laboratories (SRLs) of Uttar Pradesh on 05.10. 2018.

ii. NIB being NRL of NACO has organized one day EQAS workshop for distribution of HIV profeciency test panel for FY 2018-19 to nine state refererence lab of Uttar Pradesh on 08.02.2019.

iii. The laboratory has organized 1st meeting with Stakeholders of in-vitro Diagnostics regarding "Support Cell for WHO Pre-Qualification Programme" on 17.08.2018 which was attended by 21 representatives from IVDx industry.

iv. The 2nd meeting with indigenous stakeholders of in-vitro Diagnostics regarding Support Cell for WHO Pre-Qualification Programme was held on 13.02.2019, at NIB to deliberate and decide upon due course of actions to be undertaken by NIB, WHO and role of respective stakeholder associations.

v. Two days training imparted to Dr. Parikipandla Sridevi, Assistant Professor, Dept. of Biotechnology, Faculty of Science, Indira Gandhi National Tribal University, Amarkantak, Madhya Pradesh, India and Dr. S. L. Balakrishna, Scientist C, MRHRU (ICMR), Datia, M.P.on "Handling and Screening of HPV samples" on December, 17-18, 2018.

8.1 Expert Committee Meetings:

The laboratory conducted the following expert committee meeting to strengthen the scientific activities of the laboratory.

- The sixth Technical Expert Committee Meeting of Immunodiagnostic Kit Laboratory was held on 04.04.2018 in the Institute under the Chairpersonship of Prof. S. P. Thyagarajan, Prof. Emeritus & Dean Research, Sh. Ramachandra University, Chennai, Tamil Nadu and

Former Vice Chancellor, University of Madras.

- The third Technical Expert Committee Meeting was held on 22.06.2018 for strengthening of Molecular Diagnostic activities of the Institute under the Chairpersonship of Prof. Raies A Qadri, Prof & Head, Department of Biotechnology, University of Kashmir, Srinagar.

Figure 5: Members of the Technical Expert Committee for strengthening of activities of Molecular Diagnostics

- The fourth Technical Expert Committee Meeting was held on 31.08.2018 for strengthening of Molecular Diagnostic activities of the Institute under the Chairpersonship of Prof. Raies A Qadri, Prof & Head, Department of Biotechnology, University of Kashmir, Srinagar.
- The seventh Technical Expert Committee Meeting of Immunodiagnostic Kit & Molecular Diagnostic Laboratory was held on 20.02.2019 in the Institute under the Chairpersonship Prof. S. P. Thyagarajan, Prof. Emeritus & Dean Research, Sh. Ramachandra University, Chennai, Tamil Nadu and Former Vice Chancellor, University of Madras.

Figure 5: Meeting of the Technical Expert Committee of Immunodiagnostic Kit and Molecular Diagnostic Laboratory was held on 20.02.2019

9. Participations in training/ Workshop/Conference:

During 2018-19, the scientists of the laboratory participated in the training, workshop & meetings as mentioned in the table 9

Table 9: Training/workshop & meetings attended by Laboratory Scientists during 2018-19

Name of the Scientist Participated	Name of the Training/ Workshop/ Conference	Duration	Place of Training
Dr. Rajesh K Sharma, Scientist Grade-III	Meeting to explore areas of collaboration with Andhra Pradesh MedTech Zone (AMTZ), Visakhapatnam as a WHO Support cell for WHO- Prequalification program for In-Vitro Diagnostics	April 16, 2018	AMTZ, Visakhapatnam
	7th Technical Research Group (TRG) meeting	August 30-31, 2018	Lab Services NACO at Pune
	Technical specification committee meeting of NACO	March 18, 2019	Nirman Bhawan, New Delhi
	Apex lab meeting of NACO	March 22-23, 2019	NARI, Pune
	Technical specification committee meeting of NACO	March 25, 2019	Nirman Bhawan, New Delhi

Name of the Scientist Participated	Name of the Training/ Workshop/ Conference	Duration	Place of Training
Dr. Richa Baranwal, Scientist Grade-III	2nd World Conference on Access to Medical Product, organized by Ministry of Health and Family welfare with the support of WHO	October 9-11, 2018	Pravasi Bharatiya Kendra, New Delhi
	2nd Technical Specification Committee meeting for finalization of technical specifications of equipment, kits and drugs under National Viral Hepatitis Control Program & Other related Programs.	January 31, 2019	Nirman Bhawan, New Delhi
	Meeting on Experts comments to conduct clinical performance evaluation of new in-vitro Diagnostics medical device to ensure safety, essentiality, desirability, effectiveness and clinical performance of new in-vitro Diagnostic ie Film Array Global Fever (GF) Panel .	February 7, 2019	Nirman Bhawan, New Delhi
	Delivered a talk in CLIN LAB India Conference at Medical Fair India 2019, from India on Evaluation of Class C & D Products	February 21-22, 2019	Pragati Maidan, New Delhi
Mr. N. Nanda Gopal, Scientist Grade-III & Mr. P. S. Chandranand, Junior Scientist	2nd Annual Regulators Conclave for Central and State Regulatory Authorities	August 23- 24 2018	Kasauli, Himachal Pradesh
Mr. N. Nanda Gopal, Scientist Grade-III & Dr Anoop Kumar, Junior Scientist	"5th National Summit on "Good & Replicable Practices & Innovations in Public HealthCare Systems in India"	October 30, 2018- November 2, 2018	Kajiranga Assam
Dr Manjula Kiran, Junior Scientist Mr. P. S. Chandranand, Junior Scientist & Mr. Rajeev Kumar, Junior Scientist	4th WHO Global Forum on Medical Devices.	December 13-15, 2018.	AMTZ Vizag

Name of the Scientist Participated	Name of the Training/ Workshop/ Conference	Duration	Place of Training
Dr. Anoop Kumar, Junior Scientist	Participated in JENESYS 2018 Inbound program under the Japan-SAARC Network program of People- to- People Exchange SAARC Countries (Theme: Health)	January 21- 29, 2019	JICE Japan
Dr. Richa Baranwal, Scientist Grade-III Dr Manjula Kiran, Junior Scientist Dr. Anoop Kumar, Junior Scientist	Meeting on Approval of specification criteria of acceptance for quality tests performed on Qualitative and Quantitative Molecular Diagnostic kits of HIV, HCV and HBV.	February 21, 2019	CDSCO, FDA Bhawan, New Delhi

10. Outstanding achievements of the Laboratory:

Director NIB along with four Scientists of the Institute attended 4th WHO Global Forum on Medical Devices "Increasing access to medical devices" held at AMTZ-Kalam Convention Centre, Visakhapatnam, India from December 13-15, 2018. During the forum, NIB was felicitated with certificate declaring Immunodiagnostic Kits & Molecular Diagnostic Laboratory, NIB as the WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg and Syphilis in-vitro Diagnostic assays by the Secretary, Ministry of Health & Family Welfare, Government of India.

Figure 6: NIB felicitated with certificate declaring IDK&MDL as the WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg and Syphilis in-vitro Diagnostic assays by the Secretary, Ministry of Health & Family Welfare, Government of India at 4th WHO Global Forum on Medical Devices at AMTZ-Kalam Convention Centre, Visakhapatnam, India from December 13-15, 2018.

BLOOD REAGENT LABORATORY

1. Name of Head:

Mrs. Kanchan Ahuja, Scientist Grade-III

2. Manpower in the lab/division:

I. Name of Scientific Staff:

Mr. Pankaj K. Sharma, Scientist Grade-III

Mrs. Vandana Tandasi, Junior Scientist

Mr. Subhash Kumar, Junior Scientist

II. Name of Technical Staff:

Ms. Priya Bhagat, Lab Assistant

III. No(s). of Outsourced Staff: 06

3. Scientific Activities Undertaken:

a) Collaboration with other organizations:

I. Collaborative study for the preparation of 1st National Reference Standard for Anti-A and Anti-B in collaboration with 8 stakeholders:

1. M/s Diagast India
2. M/s Bio-Rad Laboratories Pvt. Ltd.
3. M/s Lab Care Diagnostics
4. M/s Agappe Diagnostics Ltd.
5. M/s Immucor India Pvt. Ltd.
6. M/s Ortho Clinical Diagnostics India Pvt. Ltd.
7. M/s J. Mitra & Co. Pvt. Ltd.
8. M/s Arkray Healthcare Pvt. Ltd.

II. Networking with blood banks/ hospital of Delhi/ NCR for the collection of leftover blood samples:

DCG (I) had directed vide file no.- No.X-11026/77/14-BD dated 08.05.2014 to various blood banks/ hospitals to provide non-infective and non-clotted left over blood samples for carrying out quality control of Blood Grouping reagents, Gel Cards and Microplates.

During the year 2018-2019 a total number of 290 blood samples were collected out of which 285 were non-infected.

b) CDL Notification:

The Institute is notified Central Drugs Laboratory (CDL) by Government of India vide Gazette No. G.S.R. 601 (E), dated 27.08.2002; Gazette No. G.S.R. 908(E) dated 22.12.2014 and Gazette No. 2237 (E) dated 01.06. 2018 for Blood Grouping Reagents. The laboratory is also accredited by NABL as per the ISO/ IEC 17025:2005 for chemical and biological testing since 2011. The Blood Reagent Laboratory has the infrastructure and expertise for testing 85 different types of Blood Grouping Reagents, Rare Reagents, Gel Cards and Microplates.

c) Government Analyst:

- Mrs. Kanchan Ahuja, Head, Blood Reagent Laboratory is a notified Government Analyst for Blood Grouping Reagents as per the Gazette Notification No. S.O.-2393(E) published on 02.09.2015.
- Dr. J. P. Prasad. Scientist Grade -I and Quality Manager, NIB is a notified Government Analyst vide Gazette Notification Extraordinary Part-II. Section (3), subsection ii, published on 26.09.11

- As per the Gazette No.- S.O. 3400(E) dated 11.07.2018, Mrs. Kanchan Ahuja, Dr. J. P. Prasad are notified Medical Device Testing Officer under the sub rule (1) of rule 18 of the Medical Devices Rules, 2017.

d) Development of Monograph:

A total number of 03 monographs have been prepared and submitted to Indian Pharmacopoeia Commission for review from the Expert Group committee of Blood and Blood related Products for publication in the forthcoming edition of Indian Pharamacopoeia:

1. Anti-D IgG
2. Anti D (IgG+IgM)
3. Anti Human Globulin

e) Publication(s):

A total number of 03 monographs have been published in Indian Pharmacopoeia 2018:

1. Anti A1 Lectin
2. Anti H Lectin
3. Anti D (IgM)

f) Expert Group Committee meetings:

1. 3rd Expert Group Committee meeting was held at NIB, NOIDA for preparation of 1st National Reference Standard for Anti-A & Anti-B on 18.09.2018.

3rd Expert Group Committee meeting on 18.09.2018

2. 4th Expert Group Committee meeting was held at NIB, NOIDA for preparation of 1st National Reference Standard for Anti-A & Anti-B on 09.02.2019.

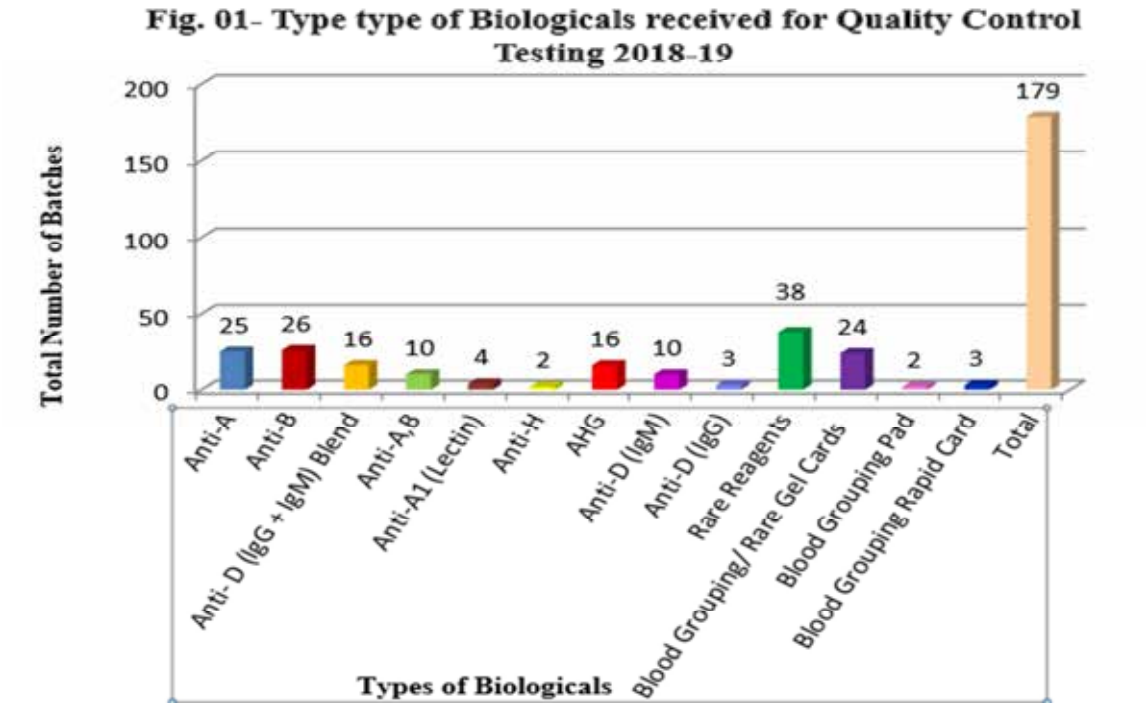
4th Expert Group Committee meeting on 09.02.2019

4. Testing of Biologicals

a) A total of number of 179 batches of Blood grouping reagents, Gel cards and blood grouping rapid cards were received for Quality Control evaluation of which 112 batches were of routine Blood Grouping reagents, 38 were rare blood grouping sera, 24 were rare & blood grouping gel cards, 02 grouping pad and 03 were grouping rapid cards. Details are given below in Table. 1 and Fig. 01

Table: 1

Name of the biologicals tested	Type of biologicals	No. of batches received & evaluated	No. of batches found to be of Standard Quality	No. batches found not to be of Standard Quality	Remarks
Anti-A	Routine and Rare Blood Grouping Reagents	25	178 + 01 (appellate sample)	Nil	01 appellate Anti-D (IgM) sample received from Chief Judicial Magistrate, Jalgaon
Anti-B		26			
Anti- D(Blend)		16			
Anti AB		10			
Anti-A1 Lectin		4			
Anti H Lectin		2			
AHG		16			
Anti D (IgM)		10			
Anti D (IgG)		3			
Rare Blood Grouping Reagents		38			
Gel Cards	Gel Cards	24			
Blood Grouping Pad	Grouping Pad	2			
Blood Grouping Rapid Cards	Rapid Cards	3			
	Total	179	179	0	01



b) Collection of samples:

The laboratory grouped, sub grouped, Rh Phenotyped 285 blood samples to be used for Quality Control evaluation of Blood Grouping Reagents. The details of the samples collected and Rh Phenotyped are given in (Figure 02 & 03).

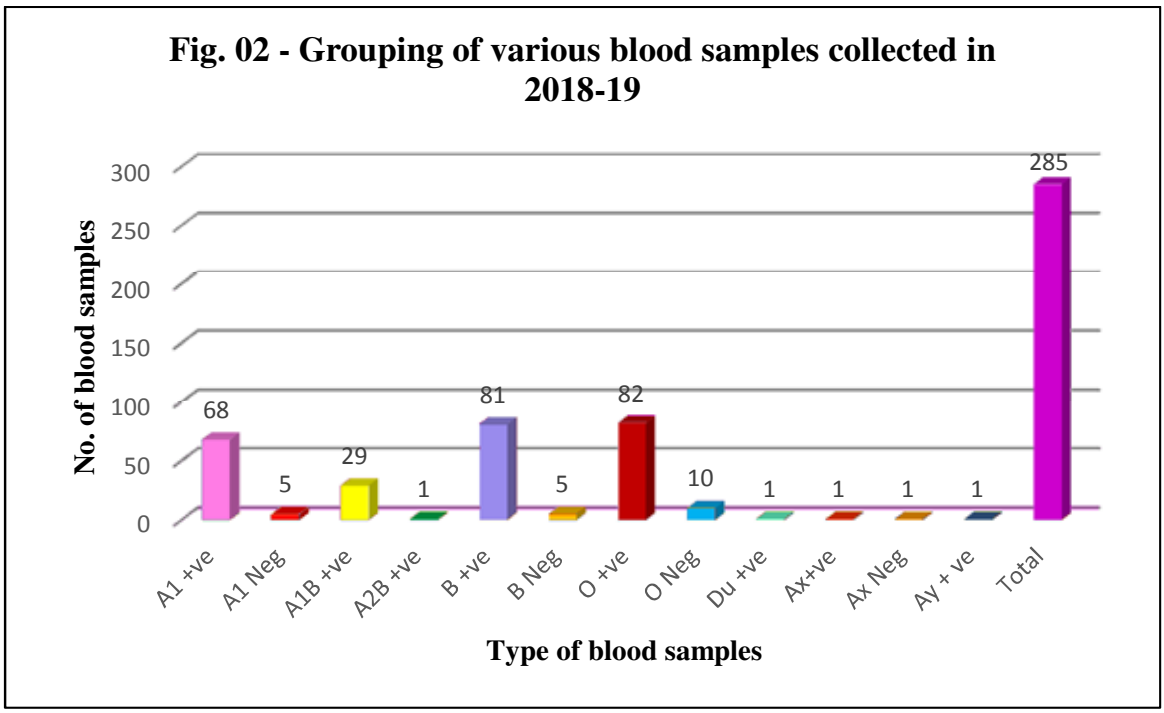
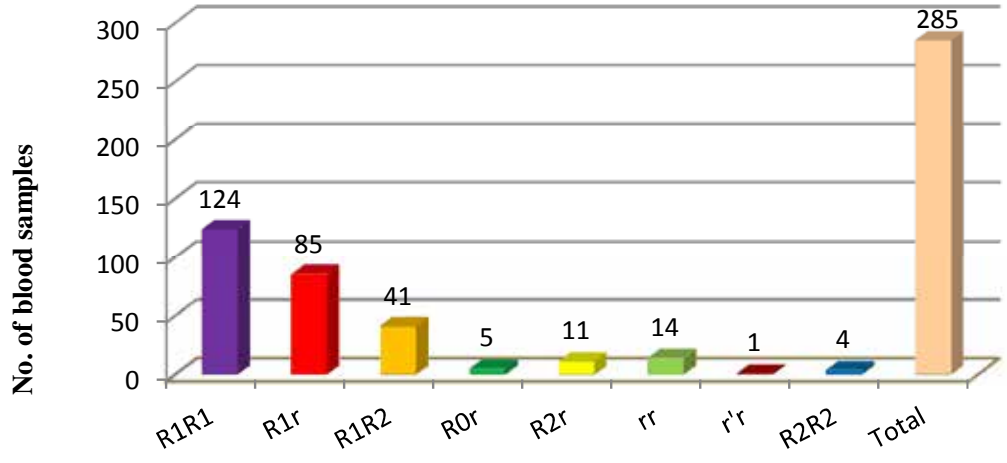


Fig.03- Phenotyping of various blood samples collected in 2018-19



5. Preparation and supply of National Standards, Sera panel etc.

a) Preparation of the 1st National Reference standard for Anti-A and Anti-B:

The laboratory is in the process for preparation of the 1st National Reference standard for Anti-A and Anti-B blood grouping reagents.

b) Preparation of in-house standards:

Calibration of working standards for Anti-A, Anti-B, Anti-AB, Anti-D (IgM), Anti-D (Blend), Anti Human Globulin, Anti-A1 (Lectin) and Anti-H (Lectin) was done using Secondary Standards (in -house controls) which were calibrated against International Reference Standards from National Institute of Biological Standards and Control (NIBSC, UK). Details of International Reference standards are given in (table 2).

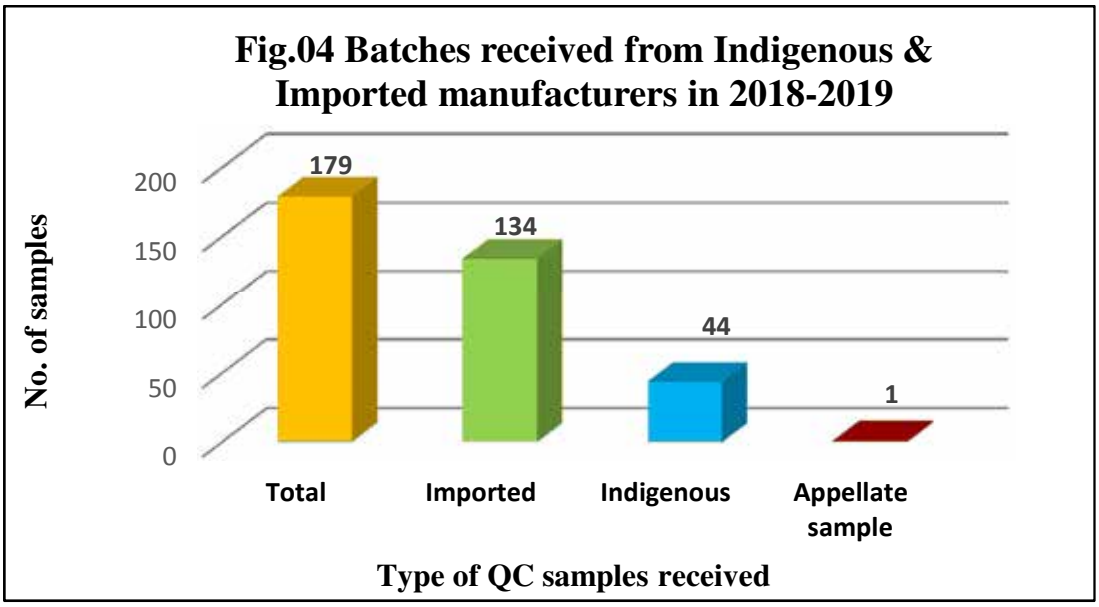
TABLE 2: Details of the International Reference Standards used

Name of Reagent	International Reference Standard	Source
Anti-A	03/188, version 2; 11/11/05	NIBSC, UK
Anti-B	03/164, version 2; 11/11/05	NIBSC, UK
Anti-AB	03/188, version 2; 11/11/05 03/164, version 2; 11/11/05	NIBSC, UK
Anti-D(IgM)	99/836, version 2; 20/5/05	NIBSC, UK
Anti-D(IgG+IgM)	99/836, version 2; 20/5/05	NIBSC, UK
Anti-Human Globulin	96/666, version 2; 19/04/04	NIBSC, UK

6. Trend in volume of work as compared to the previous year:

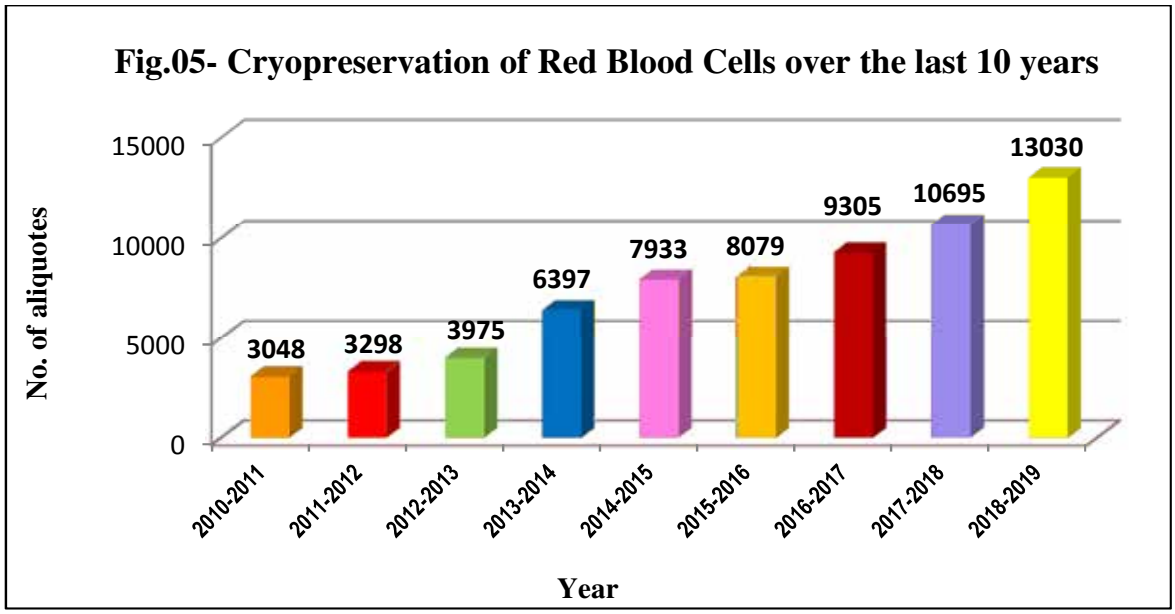
a) No. of samples received:

A total number of 179 batches were received for evaluation, 134 batches were from imported manufacturers and 44 batches were from indigenous manufacturers. A total number of 198 CoA were released during 2018-19. Details are given in Fig. 04.



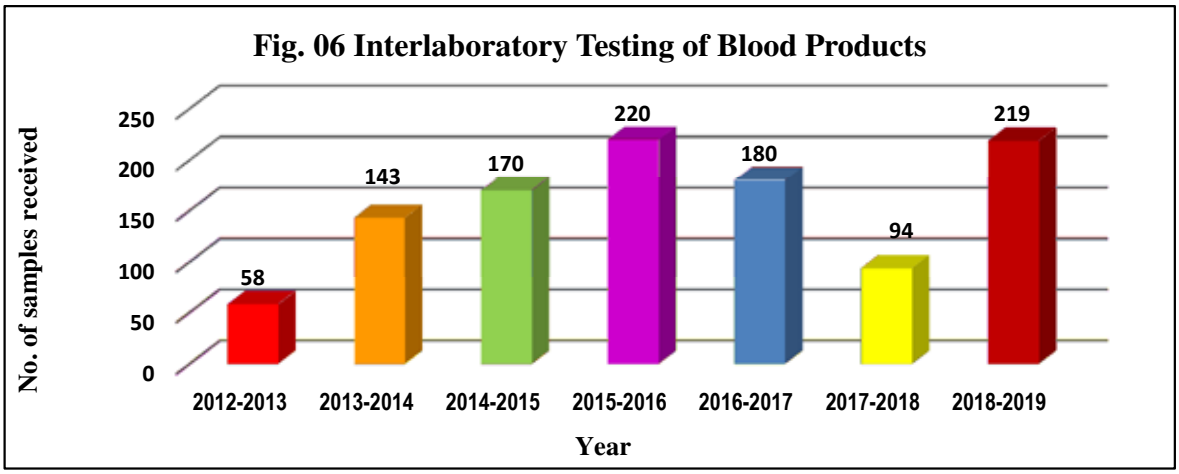
b) Cryopreservation of red blood cells:

The laboratory strengthened the repository for cryopreserved panel cells for routine and rare red blood cells from a total number of aliquots from 10695 to 13030 prepared repository for newer rare red cells (Fig.05).



c) Inter Laboratory testing of Blood Products:

The laboratory tested a total number of 219 samples of Blood Products for Anti-A and Anti-B haemagglutintion test parameter as compared to 94 batches tested in the year 2017- 18 (Fig. 6).



7. Proposed targets for testing of new biologicals being undertaken:

a) Coombs + Enzyme test

b) Reverse with Antibody Screening

8. Trainings/ Workshops/ Conferences organized:

a) Training imparted to the stakeholders:

Ms. Sangeeta Gupta from M/s J. Mitra & Co. Pvt. Ltd. was trained in Blood Reagent laboratory on 27.03.2019 for the C3d activity test for Anti Human Globulin (AHG).

b) Trainings attended by staff of Blood Reagent Laboratory at NIB, NOIDA

1. Ms. Vandana Tandasi, Junior Scientist received a training on Internal Quality Control (IQC) conducted by Quality Management Unit (QMU) at National Institute of Biologicals, NOIDA on 08.10.2018.
2. Vandana Tandasi, Junior Scientist received a training on preparation of Standard Operating Procedure (SOP) conducted by Quality Management Unit (QMU) at National Institute of Biologicals, NOIDA on 16.10.2018.
3. Training of two scientific staff on document control and control of records as per ISO:17025:2005 conducted by Quality Management Unit (QMU) at National Institute of Biologicals, NOIDA on 20.11.2018.

9. Outstanding Achievements of the laboratory:

a) Participation in proficiency testing:

The staff participated in external proficiency program for Anti-A and Anti-B blood grouping reagents conducted by Indian Red Cross Society, Delhi on 19.09.2018. The performance of the staff was found to be 100% satisfactory.

b) Preparation of 1st National Reference standard for Anti-A and Anti-B:

The laboratory has validated and prepared the 1st National Reference Standard for Anti-A and Anti-B reagents and collaborated with 8 stakeholders for assigning the minimum potency values.

BIOCHEMICAL KIT LABORATORY

1. Name of Head:

Ms. Ajanta Sircar, Scientist Grade-III

2. Manpower in the Lab/ Division:

I. Name of Scientific Staff:

Mr. Tara Chand, Scientist Grade-III

Dr. Ashwini Kumar Dubey, Scientist Grade-III

II. Name of Technical Staff:

Ms. Girija L.V., Lab Technician,

III. No(s). of Outsourced staff: 04

3. Scientific Activities Undertaken:

a) Collaboration with other organizations:

S. No.	Title	Collaborating Institutes	Period of Study	Status
1.	Performance Validation of indigenously manufactured Glucose Sensing Devices developed with ICMR support	ICMR, New Delhi and Biochemical Kit Laboratory, National Institute of Biologicals, NOIDA	09 Months	**Under Phase –I Activities:** i) Biochemical Kit Laboratory, Technical team constituting Ms. Ajanta Sircar, Scientist Grade-III & Head and Mr. Tara Chand, Scientist Grade-III, has organized an ICMR- NIB collaborative sensitization training/ workshop on requirements of ISO 15197 for the manufacturers of glucose sensing devices for eighteen member-technical staff team of M/s Biosense Technologies Pvt. Ltd., at M/s Biosense Technologies Pvt. Ltd., Thane, Mumbai. ii) Biochemical Kit Laboratory organized an ICMR-NIB Collaborative training/ workshop on 'Requirements of ISO 15197' and 'continuous validation of laboratory reference method for glucose' on 04.10.18 to 05.10.18 for 19 Participants from 05 collaborating centres, viz., All India Institute of Medical Sciences, New Delhi; Narayana Hridayalaya, Bengaluru; Dr. Mohan's Diabetes Centre, Chennai; Pondicherry Institute of Medical Sciences, Puducherry, and Biochemical Kit Laboratory, NIB- Noida at NIB-Noida.

S. No.	Title	Collaborating Institutes	Period of Study	Status
				Under Phase –II Activities: i) Technical team of National Institute of Biologicals, Noida comprising of Ms. Ajanta Sircar, Scientist Grade – III & Head, Biochemical Kit Laboratory and Tara Chand, Scientist Grade – III visited Pondicherry Institute of Medical Sciences, Pondicherry for lending their expertise for collecting data related to execution of the relevant protocols of Quality Control test parameters with respect to ICMR-NIB Collaborative project work during the period 03.03.2019-17.03.2019.
2.	Validation studies for Ion Exchange Chromatography Principle-based 'Laboratory Reference Method for estimation of HbA1c' and 'International Guideline' based protocols for various quality control tests/ parameters for evaluating rapid HbA1c assay kits	Department of Endocrinology, AIIMS, New Delhi and Biochemical Kit Laboratory, National Institute of Biologicals, NOIDA	24 Months	i) Biochemical Kit Laboratory has signed a Memorandum of understanding (MoU) with Department of Endocrinology, AIIMS, New Delhi ii) Presently literature review and survey of available test protocols for validation of Ion Exchange HPLC based HbA1c assays is being done. iii) Information regarding the spectrum of Rapid HbA1C assays available in the Indian market is also being done.

b) CDL Notification:

- The laboratory is notified Central Drug Laboratory (C.D.L) for Glucose Test Strips and Fully automated analyzer based Glucose Reagents vide Gazette Notification G.S.R. 908 (E) dated December 22, 2014.
- The laboratory is notified Central Medical Device Testing Laboratory (C.M.D.T.L.) for Glucose Test Strips and Fully automated analyzer based Glucose Reagents vide Gazette Notification S. O. 2237 (E) dated 01.06.2018

c) Government Analyst:

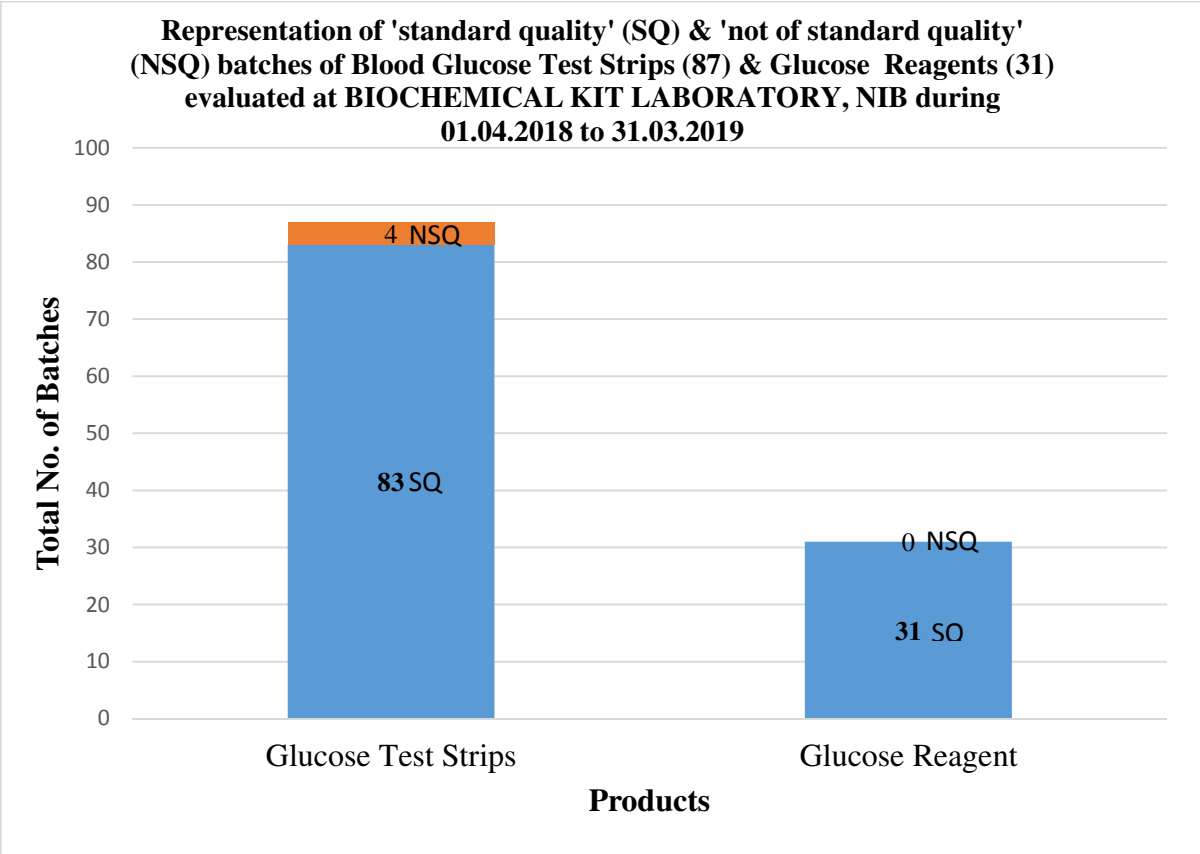
- Ms. Ajanta Sircar, Head, Biochemical

Kit Laboratory is Government Analyst by the Central Government for the whole of India in respect of the classes of drugs (i.e. Glucose test strips and fully automated analyzer based glucose reagents) vide Gazette Notification S.O. 2393 (E) dated September 02, 2015.

- Ms. Ajanta Sircar, Head, Biochemical Kit Laboratory is Medical Device Testing Officer by the Central Government in respect of Medical Device (i.e. Glucose test strips and fully automated analyser based glucose reagents) vide Gazette Notification S.O. 3400(E) dated July 11, 2018.

4. Testing of Biologicals:

Name of Biologicals Tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of Standard Quality	No. of batches found not to be of Standard Quality	No. of Inter-Laboratory sample tested
Biochemical kit	Glucose Test Strips	87	83	04	Nil
Biochemical kit	Fully automated analyser based glucose reagents (closed system chemistry and Open ended system chemistry)	31	31	Nil	Nil



5. Trend in volume of work as compared to the previous year:

In the financial year 2018-19, a total of 118 batches (87 batches of Blood Glucose Test Strips and 31 batches of Glucose Reagent) were received and evaluated. The testing capacity of the Biochemical Kit Laboratory, with the current staff strength, is 300 batches of the mandated products (i. e., Blood Glucose Test Strips and Fully Automated Analyzer based Glucose Reagents) annually.

6. Proposed target for testing of new Biologicals being undertaken:

New types of products:

The laboratory is evaluating newer technology-based products that entail the use of Smartphone/ Mobiles. Products such as 'Dnurse SP1' Blood Glucose Meter for Smart Phone have been tested and/or are under testing at the laboratory. These are small external devices that fit easily into a smartphone and function as a glucose meter together with a specific 'App' on the phone. These devices have a clinical decision supporting website and 3-4 blood glucose readings/day for any Type 1 diabetes patient can be downloaded for analysis of the glycaemic pattern/ trends which helps patients and clinicians for treatment decision. The App also provides an e-Log book where blood glucose data can be saved and printed later or can be emailed to health care providers. In addition, these apps have graphical displays to see and interpret blood glucose entries and thus motivate patients to regulate calorie intake/ blood glucose testing frequency; resulting in better glucose control. Integrated insulin calculators also help patients on multiple daily injections; review their bolus insulin dose and improve glycaemic control without increasing severe hypoglycaemia in insulin-requiring patients with diabetes.

7. Training/ Workshop/ Conference organized:

A. Workshop/ Conference organized:

i. The Biochemical Kit Laboratory, Technical team constituting Ms. Ajanta Sircar, Scientist Grade-III & Head and Mr. Tara Chand, Scientist Grade-III, organized an ICMR- NIB collaborative sensitization training/ workshop on requirements of ISO 15197 for the manufacturers of glucose sensing devices for eighteen member, technical staff team of M/s Biosense Technologies Pvt. Ltd., on 04.06.2018 at M/s Biosense Technologies Pvt. Ltd., Thane, Mumbai.

ii. The Biochemical Kit Laboratory has organised ICMR-NIB Collaborative training/workshop on 'Requirements of ISO 15197' and 'continuous validation of laboratory reference method for glucose' during 04.10.2018 to 05.10.2018. A total of 19 participants from Dept. of Endocrinology, All India Institute of Medical Sciences, New Delhi; Narayana Hridyalaya, Bengaluru; Dr. Mohan's Diabetes Center, Chennai; Dept. of Endocrinology, Pondicherry Institute of Medical Sciences, Puducherry and Biochemical Kit Laboratory, National Institute of Biologicals, Noida to acquire knowledge and skill on 'the requirements of ISO 15197 and tests related to the certain quality control parameters pertaining to the glucose test strips' and on the 'continuous validation of laboratory reference method'.

iii. Technical team of NIB comprising of Ms. Ajanta Sircar, Scientist Grade – III & Head, Biochemical Kit Laboratory and Mr. Tara Chand, Scientist Grade – III visited Pondicherry Institute of Medical Sciences, Pondicherry for carrying out ICMR-NIB Collaborative project work during the period 03.03.2019-17.03.2019 to provide their expertise for collecting data. The objective of the collaborative center was to independently evaluate the performance of indigenous glucose sensing devices, viz., Biosense Glucose Test Strips + Meters, Non-Invasive Glucometers, developed with the support of ICMR New Delhi. The NIB Scientists, reached PIMS Puducherry center to provide technical support, interacted with Prof. Ashok K. Das, Department of Medicine & Endocrinology, PIMS and Ms. R. Suganiya, Project Technician in collecting the data for different QC test parameters in the Diabetic Clinics of PIMS Puducherry. Shri Tara Chand has coordinated with Dr. Sunil Nanda, Dept. of Biochemistry, PIMS for availing the reference data from his NABL accredited laboratory and fantastic correlation were achieved between the data generated by PIMS Puducherry centre and data generated by the National Institute of Biologicals, Noida for the same study.

B. Participation in proficiency testing/ EQAS:

The laboratory is presently enrolled in the Association of Clinical Biochemists of India (ACBI)/ Christian Medical College (CMC) in External Quality Assessment Scheme (EQAS) – 2018 & 2019 for Chemistry II (Glucose, Cholesterol and Triglyceride), conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore.

8. Participation in Training/ Workshop/ Conference:

S. No.	Name of the Laboratory staff	Area of Training	Period	Venue	Trainer
1.	1. Sh. Tara Chand, Scientist Grade-III 2. Dr. Ashwini Kr. Dubey, Scientist Grade-III 3. Outsourced staff (01)	Equipment operation training for "Dnurse SP1 blood glucose meter used with compatible app installed smartphone" (M/s Suraksha Health Care, New Delhi)	23.04.18	Biochemical Kit Laboratory, NIB, Noida	Application specialist from M/s Suraksha Health Care, New Delhi
2.	1. Sh. Tara Chand, Scientist Grade-III 2. Dr. Ashwini Kr. Dubey, Scientist Grade-III 3. Ms. Girija L.V., Lab. Technician	High ended equipment operation training for 'Pentra C-400' for Glucose Chemistry by application specialist from M/s Horiba India Pvt. Ltd., for the	20.09.18 to 29.09.18	Biochemical Kit Laboratory, NIB, Noida	Application specialist from M/s Horiba India Pvt. Ltd.

S. No.	Name of the Laboratory staff	Area of Training	Period	Venue	Trainer
	4. Outsourced staff (02)	Quality control Evaluation of six batches of Glucose reagent samples (PAP & HK), simultaneously.			
3.	1. Sh. Tara Chand, Scientist Grade-III 2. Dr. Ashwini Kr. Dubey, Scientist Grade-III 3. Ms. Girija L.V., Lab. Technician 4. Outsourced staff (02)	High ended equipment operation training for 'ILab 650' for Glucose Chemistry by application specialist from M/s Instrumentation Laboratory India Pvt. Ltd.	13.12.18 to 18.12.18	Biochemical Kit Laboratory, NIB, Noida	Application specialist from M/s Instrument-ation Laboratory India Pvt. Ltd.
4.	1. Sh. Tara Chand, Scientist Grade-III 2. Dr. Ashwini Kr. Dubey, Scientist Grade-III 3. Outsourced staff (01)	High ended equipment operation training for 'AU480' for Glucose Chemistry by application specialist from M/s Beckman Coulter India Pvt. Ltd.	29.01.19 to 31.01.19	Biochemical Kit Laboratory, NIB, Noida	Application specialist from M/s Beckman Coulter India Pvt. Ltd.

9. Outstanding achievements of the Lab:

9.1 Collaboration with ICMR, New Delhi

With a view to develop low cost indigenous devices, ICMR has aided the development of glucose sensing devices since 2010, and now three prototypes have been developed. These products are now ready for the manufacturing process and so their performance needs to be independently validated following standard norms and regulation as an integral part of the process. The Biochemical Kit Laboratory is in a very prestigious collaboration with the Division of Innovation and Translational Research-Indian Council of Medical Research (ICMR), New Delhi for guiding the manufacturer with respect to product design, sensitizing them about the Device's Test parameters, and their specifications and limits of acceptance. Biochemical Kit Laboratory, NIB will also guide the different clinical data generation centers at Pondicherry, Mysore, Chennai and New Delhi for harmonizing their glucose estimation methodologies for ease of corroboration of test results through all the centers. Before these indigenously developed products are licensed to manufacture on a commercial scale, they will be required to be tested at NIB, NOIDA. This collaboration of the indigenous manufacturers with the Biochemical Kit Laboratory, during product development stage, will sensitize them regarding the Quality parameters and develop their preparedness for going to the next level.

The activities planned through this collaboration are-

- Biochemical Kit Laboratory, NIB, NOIDA to conduct ICMR- funded

Workshops for the Manufacturers and the Collaborating Centers for sensitizing them about the requirements of ISO 15197

- Biochemical Kit Laboratory to provide technical assistance to establish a uniform 'Internal Quality Control Program for Glucose estimation' in the four clinical data generating centers at Pondicherry, Mysore, Chennai and New Delhi with; with a view to harmonize the data generated by all the four centers.
- ICMR to fund recruitment of Technical Staff for this project and purchase of IQC materials and other laboratory consumables/ services for enabling the IQC Program in Biochemical Kit Laboratory and all the participating laboratories.
- Testing of the indigenous Glucose sensing devices/ test strips and other materials/ and execution of the test protocols, at Biochemical Kit Laboratory and all the four clinical data generating centers at Pondicherry, Mysore, Chennai and New Delhi.
- Collection, collation and analysis of the data generated by all the four participating centers for conclusively commenting on the quality of performance of the indigenously developed glucose sensing devices.

9.2 Collaboration with AIIMS, New Delhi

Department of Endocrinology, AIIMS, New Delhi has signed a Memorandum of understanding (MoU) with Biochemical Kit Laboratory, NIB- NOIDA to collaborate for establishing validation protocols for Ion Exchange Chromatography Principle-based 'Laboratory Reference Method for estimation of HbA1c.' The collaboration is also for imparting training for use and execution of 'International Guideline' based protocols for various quality control tests/ parameters for evaluating rapid HbA1c assay kits.

Fig. 1 (a). Two days ICMR-NIB collaborative training at NIB- Noida to 05 collaborative centers-(i) Department of Endocrinology, AIIMS- New Delhi; (ii) Narayana Hridayalaya, Bengaluru; (iii) Mohan's Diabetes Center, Chennai; (iv) Department of Endocrinology, Pondicherry Institute of Medical Sciences, Puducherry and (v) Biochemical Kit Laboratory, NIB- Noida during 04.10.2018- 05.10.2018 on 'Requirements of ISO 15197' and 'continuous validation of laboratory reference method for glucose'.

Fig. 1(b). Ms. Ajanta Sircar, Head & Scientist Grade–III and Sh. Tara Chand, Scientist Grade–III, Biochemical Kit Laboratory, with the technical team of M/s Biosense Technologies Pvt. Ltd. at M/s Biosense Technologies Pvt. Ltd., Mumbai during the ICMR- NIB sensitization training/ workshop on requirements of ISO 15197 for the manufacturers of glucose sensing devices (June 04, 2018).

Fig. 1(c). Visit of Ms. Ajanta Sircar, Head & Scientist Grade- III, and Sh. Tara Chand, Scientist Grade- III, Biochemical Kit Laboratory, to Pondicherry Institute of Medical Sciences (PIMS), Puducherry to coordinate the ICMR-NIB collaborative project work during March 03- 17, 2019.

Fig. 2(a). Equipment operation training to laboratory staff for high ended equipment 'Pentra C-400' for Glucose Chemistry by application specialist from M/s Horiba India Pvt. Ltd.

Fig. 2(b). Equipment operation training to laboratory staff for high ended equipment 'ILab 650 for Glucose Chemistry by application specialist from M/s Instrumentation Laboratory India Pvt. Ltd.

Fig. 2(c). Equipment operation training to laboratory staff for high ended equipment 'AU 480 Chemistry Analyzer' for Glucose Chemistry by application specialist from M/s Beckman Coulter India Pvt. Ltd.

VACCINE LABORATORY

1. Name of Head:

Mr. Jaipal Meena, Scientist grade-III

2. Manpower in the Lab/Division:

I. Name of Scientific staff:

Mr. Harit Kasana, Junior Scientist

Mr. Ajay Kumar Ade, Junior Scientist

Mrs. Archana Sayal, Junior Scientist

II. Name of Technical Staff

Mr. Sukhen Majhi, Lab. Technician

III. No(s). of Outsourced staff: 09

3. Scientific Activities Undertaken:

Collaboration with other organizations

a) Vaccine laboratory of NIB in collaboration with World Health Organisation (WHO) participated in the proficiency testing study on "Determination of the Polyribosyl-Ribitol-Phosphate (PRP) content of the Haemophilus influenzae type b (Hib) capsular polysaccharide in liquid vaccine presentations by High Performance Anion Exchange Chromatography Pulsed Amperometric Detection (HPAEC-PAD)"

b) CDL notification:

- Institute is notified CDL for the BCG Vaccine, Cell Culture Rabies Vaccine, Live attenuated Measles Vaccine, Live Attenuated Rubella Vaccine. (Ref. Gazette Notification No: G.S.R. 250 (E) - Part-II - Section 3 - Sub-Section (i) dated 15.03.2017).
- Oral Polio Vaccine (Ref. Gazette Notification No: G.S.R. 249 (E),dated 04.04.2002)

c) Development of monograph:

Second Stakeholder's Meeting regarding inclusion of WHO protocol for Determination of PRP content of Hib (Haemophilus Influenzae type b) in liquid vaccine presentations by HPAEC- PAD in Indian Pharmacopoeia was organized on 23.05.2018 at NIB. Meeting was attended by representatives of Indian Pharmacopoeia Commission and six Indian Vaccine Manufacturers. The purpose of this meeting was to optimize the protocol for final validation studies and bringing the stakeholders on common consensus for final inclusion of WHO protocol in Indian Pharmacopoeia.

The validation of WHO protocol will be done by Indian manufacturers at their end. NIB is the nodal point and it will co-ordinate the activities between Indian manufacturers and IPC.

d) Publication: Jaipal Meena, Shivani Sood, Neha Rani etal: Estimation of potency of Hepatitis B Immunoglobulin marketed in India to evaluate the manufactures production consistency: Role of National Control Laboratory. Biologicals, 2019, 59; 72-73.

e) Proficiency testing study:

Vaccine laboratory of NIB received a consignment of 3 batches of Hib vaccine samples along with the 2nd NIBSC international reference standard for the WHO Proficiency Testing Study on 27.12.2018. Samples have been tested for "Determination of the Polyribosyl- Ribitol- Phosphate (PRP) content of the Haemophilus influenzae type b (Hib) capsular polysaccharide in liquid vaccine presentations by High Performance Anion Exchange Chromatography Pulsed Amperometric Detection (HPAEC-PAD)" and reports have been submitted to Dr. Ute Rosskopf, World Health Organization, Geneva, Switzerland on 12.03.2019.

4. Testing of Biologicals:

Name of Biologicals Tested	Type of Biologicals	No. of Batches Evaluated	No. of Batches found to be of standard quality	No. of Batches found not to be of standard quality	No. of Inter-laboratory sample tested	Remarks
Rabies immunoglobulin	Viral vaccine	11	11	0	11	11 Batches tested
Cell Culture Rabies Vaccine	Viral vaccine	21	21	0	-	21 batches released

Name of Biologicals Tested	Type of Biologicals	No. of Batches Evaluated	No. of Batches found to be of standard quality	No. of Batches found not to be of standard quality	No. of Inter-laboratory sample tested	Remarks
Hepatitis B Vaccine	Viral vaccine	06	06	0	-	06 batches released
Measles Vaccine	Viral vaccine	01	01	0	-	Standardized
Rubella Vaccine	Viral vaccine	01	01	0	-	Standardized
MMR vaccine	Viral vaccine	02	02	0	-	Standardized
Rotavirus Vaccine	Viral vaccine	05	05	0	-	Standardized
Haemophilus influenza type b (Hib) TT conjugate vaccine	Bacterial vaccine	02	02	0	-	Standardized
Inactivated Single Serotype (Hikojima) Cholera Vaccine	Bacterial vaccine	01	01	0	-	Standardized
Bacillus Calmette Guerin (BCG) vaccine	Bacterial vaccine	05	05	0	-	Standardized
Hib Pentavalent vaccine (Determination of PRP content by HPAEC-PAD)	Bacterial Vaccine	03	03	0	-	Standardized only for PRP Content
Tetanus Toxoid Vaccine Adsorbed	Bacterial vaccine	02	02	0	-	Under Standard-ization
Varicella Vaccine	Viral vaccine	02	02	0	-	Under Standard-ization
Japanese Encephalitis Vaccine	Viral vaccine	02	02	0	-	Under Standard-ization

5. Preparation and supply of national Standards, Sera Panel etc.:

The lab will take up the feasibility study for the reference standard preparation for r-DNA Hepatitis-B vaccine in collaboration with manufacturers and IPC.

6. Trend in volume of work as compared to previous year:

S. No.	Name of the product	No. of batches evaluated for the period	
		2017-18	2018-19
1.	Human Rabies Immunoglobulin	11	14
2.	Live attenuated MMR vaccine	00	02
3.	Live attenuated Measles vaccine	02	01
4.	Live attenuated Rubella vaccine	01	01
5.	Cell Culture Rabies Vaccine	17	21
6.	Live attenuated Measles and Rubella Vaccine	05	00
7.	Japanese Encephalitis Vaccine	00	02
8.	Human Papilloma Virus vaccine	03	03
9.	Inactivated Polio Vaccine	03	00
10.	Rotavirus Vaccine	05	05
11.	Hepatitis A Vaccine	04	00
12	Hepatitis B Vaccine	09	06
13	Varicella Vaccine	010 (under standardization)	02 (under standardization)
14	Bacillus Calmette Guerin (BCG) vaccine	05	05
15	Tetanus Toxoid Vaccine	0	02
16	Cholera Vaccine	02	01
17	Hib Pentavalent vaccine (Determination of PRP content by HPAEC-PAD	10	03
18	Haemophilus influenza type b (Hib) TT conjugate vaccine	05	02
19	Samples for Moisture Content	276	303

Figure 1: Number of Vaccines & Sera samples evaluated in the period 2018-2019

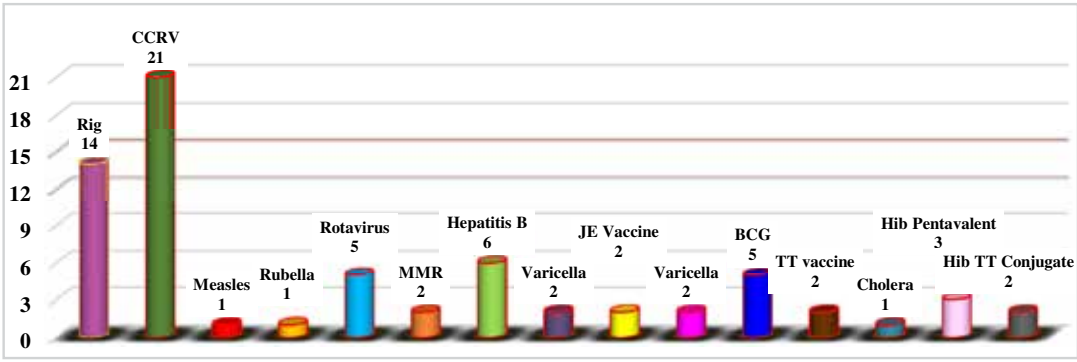
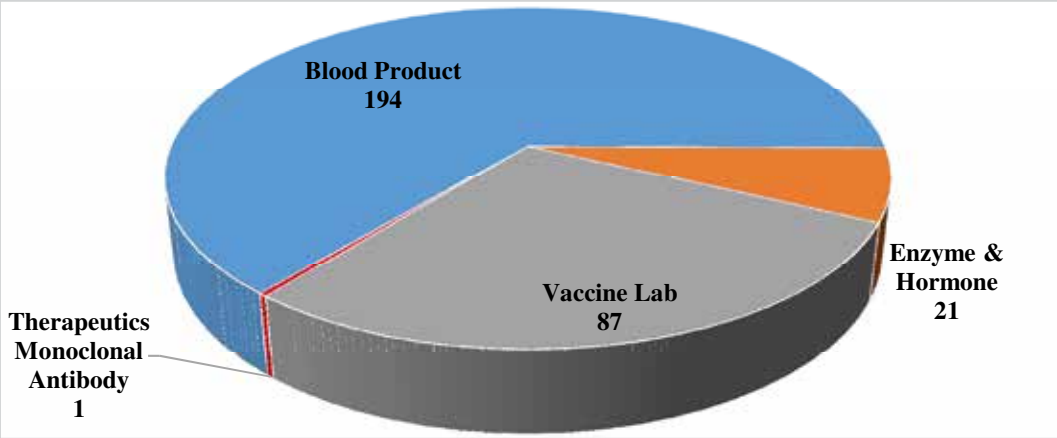


Figure 2: Number of Batches Evaluated for Moisture Content in 2018-19



7. Proposed targets for testing of new Biologicals being undertaken: Meningococcal Vaccine

8. Participations in training/workshop/conference:

S. No.	Name of the scientist	Name of Programme	Duration & place of training
1	Mr. Harit Kasana, Junior Scientist, Mr. Ajay Kumar Ade, Junior Scientist and Vaccine laboratory staff	Hands on training on "Potency assay of Meningococcal Polysaccharide Vaccine A, C, Y, W- 135" imparted by Scientists from Incepta Vaccine Ltd, Bangladesh **(Ms. Shamima Nasrin Shimu, Ms. Zebun Nahar)**	August, 29- 30, 2018 (Two Days), NIB- NOIDA
2	Mr. Harit Kasana, Junior Scientist	Training on Polio related WHO GAP III	February, 18-22, 2019 (Five Days), Bandung, Indonesia
3	Mr. Harit Kasana, Junior Scientist	Advanced Auditor's training	March, 25- 29, 2019 (Five Days), National Institute of Virology (NIV), Pune

9. Outstanding achievements of the Lab:

9.1 Mr. Jaipal Meena, Scientist Grade-III, Head Viral Vaccine Laboratory visited as Technical Expert of South African National Accreditation System, the accreditation body of South Africa. The visit on 26.02.2019 was for Desktop Surveillance Assessment of South African National Control Laboratory (SANCL) for ISO17025:2017 accreditation for Oral Polio Vaccine, Measles Vaccine and Yellow Fever Vaccine.

9.2 Mr. Harit Kasana, attended the WHO SEARO GAP III Implementation Training for poliovirus laboratory containment in Bandung, Indonesia from February 18-22, 2019. This training was provided by the WHO in association with Global Polio Eradication Initiative (GPEI) partners and in collaboration with Riskren Bio risk Management to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use was imparted.

9.3 Mr. Harit Kasana, Junior Scientist, Vaccine Laboratory visited National Institute of Virology (NIV), Pune from March 25-29, 2019 (Five Days) for Advanced Auditor's training.

BLOOD PRODUCTS LABORATORY

1. Name of Head:

Dr. J. P. Prasad, Scientist Grade-I (Till 15.11.2018)

Ms. Sudha. V. Gopinath, Scientist Grade-III (From 16.11.2018)

2. Manpower in the lab/division:

I. Name of Scientific Staff

Ms Madhu Y, Scientist Grade-III

Dr. Varun Singh, Junior Scientist

Mr. Mohd. Daud Ali, Junior Scientist

Mr. Anirban Mukherjee, Junior Scientist (from 14.08.2018)

II. No(s) of Outsourced Staff: 12

3. Scientific Activities Undertaken:

a) Collaboration with Other organizations

i. Proficiency Testing (PT) Programme: Successful results received for participation in PTS 164, an international PT study organized by European Directorate for Quality of Medicines (EDQM), France for Estimation of Clottable Protein in Fibrinogen and Assay for Thrombin in Fibrin Sealant Kit (31.07.2018 to 02.08.2019).

ii. Registered for Proficiency Testing (PT) Programme PTS 201, an international PT study organized by EDQM, France for Protein Composition test in Human Normal Immunoglobulin, for calendar year 2019.

b) CDL Notification

The laboratory is notified Central Drug Laboratory vide Gazette of India Extraordinary Part II Section 3-Subsection (i) No.684 published in December 2014 for the following products:

i. Human Albumin

ii. Human Normal Immunoglobulin (Intravenous & Intramuscular)

iii. Human Coagulation Factor VIII

iv. Human Coagulation Factor IX

v. Plasma Protein Fraction

vi. Fibrin Sealant Kit

vii. Anti- Inhibitor coagulant Complex

c) Government Analyst:

1. Dr. J. P. Prasad, Scientist Grade –I & Head, Blood Products Laboratory is notified Government Analyst vide Gazette No. S.O 2393(E) for testing of plasma derived products published on September 2, 2015

2. Dr. J. P. Prasad, Scientist Grade –I & Head, Blood Products Laboratory is notified Government Analyst vide Gazette Notification Extraordinary Part-II, Section (3), subsection ii, published on September 26, 2011.

3. As per the Gazette No.- S.O. 3400(E) dated 11.07.2018, Dr. J. P. Prasad is notified Medical Device Testing Officer under the sub rule (1) of rule 18 of the Medical Devices Rules, 2017 for Blood grouping reagents.

d) Development of monographs

The following are proposed for inclusion in I.P. -2018 Monograph

i) Proposal for inclusion of Haemolysis in the test for Anti-A & Anti-B

Haemagglutinins based on observations in few batches of indigenously manufactured Human normal Immunoglobulins for intravenous use in Monographs for Human Normal Immunoglobulin for Intravenous use and Dried Human Antihaemophilic Fraction has been communicated to Indian Pharmacopoeia Commission (IPC), Ghaziabad.

ii) With regard to Deletion of test for Abnormal Toxicity in relevant Monographs for Blood Products to harmonize with European and British Pharmacopoeia and also in consideration with 3Rs global concept proposed, IPC, Ghaziabad in the "Expert Working Group on Blood and Blood related products "held on 28.02.2018. In this regard Expert Working Group on Blood and Blood related products decided that NCL may have the authority to test batches at its own discretion and final decision will be taken in the 3rd meeting of Expert Group proposed to be held in August 2019.

iii) Proposal have been submitted to Indian Pharmacopoeia Commission (IPC), Ghaziabad for Revision in Reagents and Buffers (Page 888, Volume I, IP 2018) in composition of Imidazole Buffer mentioned in Assay for Thrombin in monograph for Fibrin sealant kit (Pg. No.3917; Volume III, IP 2018).

e. Publications:

1. A comparative study of various compendial biuret methods for estimation of protein in human biologicals; Charu Arora, J. P. Prasad, et. al; Indian Journal of Pharmaceutical Sciences 2018; 80(5); 946-949. (as a Short Communication).

2. Intravenous Immunoglobulin preparations: Quality Assurance Measures and proposed strategies for improving its safe and judicious use in India. Sudha V. Gopinath and J. P. Prasad; Applied Clinical Research, Clinical Trails and Regulatory Affairs; 2018 Vol.5, Issue.1.

4. Testing of Biologicals

Table 1:

Name of Biologicals tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of standard quality (SQ)	No. of batches found to be Not-of standard quality (NSQ)	No. of inter-laboratory sample tested
Blood Products	Human Albumin	259	258	01	-
	Plasma Protein Fraction	03	03	Nil	-
	Human Normal Immunoglobulin IV	77	77	Nil	-
	Human Normal Immunoglobulin IM	15	15	Nil	-
	Specific Immunoglobulin IM (Hepatitis B immunoglobulin)	14	14	Nil	

Name of Biologicals tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of standard quality (SQ)	No. of batches found to be Not-of standard quality (NSQ)	No. of inter-laboratory sample tested
	Specific Immunoglobulin IV (Anti-T Lymphocyte)	01	01	Nil	-
	Specific Immunoglobulin IM (Tetanus Immunoglobulin)	23	23	Nil	-
	Specific Immunoglobulin IM (Anti-D Immunoglobulin IM)	19	19	Nil	-
	Specific Immunoglobulin IM (Rabies Immunoglobulin)	14	14	Nil	-
	Human Coagulation Factor VIII (Plasma derived)	104	99	05	-
	Human Coagulation Factor VIII rDNA	11	11	Nil	-
	Human Coagulation Factor IX	16	16	Nil	-
	Human Coagulation Factor IX rDNA	04	04	Nil	-
	Human Prothrombin Complex	05	05	Nil	-
	Fibrin Sealant Kit	33	29	04	-
	FEIBA (Anti-inhibitor coagulant complex)	11	11	Nil	-
	Total	609	599	10 (1.6%)	-

4a Details of testing of Legal Samples:

S. No.	Type of Biologicals	No. of batches evaluated	No. of batches found to be of standard quality (SQ)	No. of batches found to be Not-of standard quality (NSQ)
1.	Human Albumin	01	01	Nil
2.	Human Normal Immunoglobulin IV	09	09	Nil
3.	Human Coagulation Factor VIII (Plasma derived)	03	01	02
	Total	**13**	**11**	**02**

5. Preparation and supply of National Reference Standards (NRS)

The indigenous biopharmaceutical companies are dependent upon the Primary Reference Standards which are, many a times of limited supply. Hence as a standard procedure the companies have to develop in-house standards calibrated against the primary standard. NIB being the nodal laboratory for quality control of biologicals aims to develop National Reference Standard through collaborative studies for supply to the indigenous manufacturers thereby facilitating easy availability of such traceable standards. The laboratory has proposed development of two national reference standards:

a. 1st National Reference standard for total protein estimation of Human Albumin and

b. 1st National reference Standard for Potency assay of Human Coagulation Factor VIII.

The laboratory has initiated dialogues with indigenous manufacturers in this regard for (i) donation of bulk material, (ii) establishing process for lyophilization of these plasma derived products and (iii) preparation of filled vials with defined units to be declared as candidate materials for the collaborative study.

6. Trend in volume of work as compared to previous years

The trend in quantum of batches of various plasma derived products received and tested in last six years at Blood Products Laboratory, NIB has been depicted in Fig.1 below.

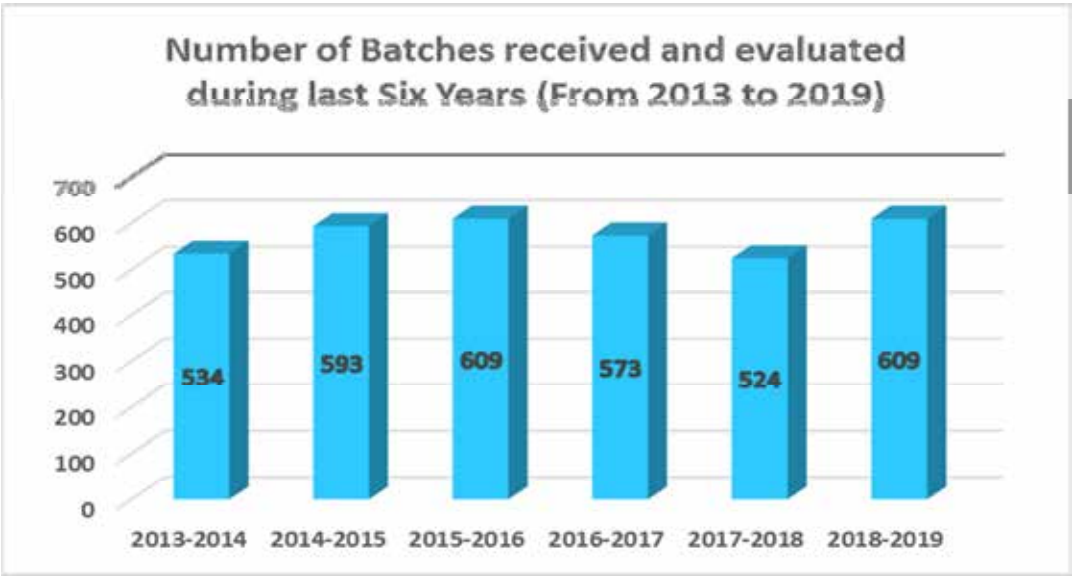


Fig.1 Quantum of batches received and tested in last five years (2013 – 2019)

The results of Quality Control testing and number of batches found not of standard quality in last nine years at NIB have been summarised and shown in Fig 2 below.

During the reporting period 2018 -2019, ten batches of various blood products are found Not of Standard Quality (NSQ), which amounts 1.6%. Out of which, one batch of

Human Albumin was found NSQ due to high value in assay for Pre-kallekrein activator (PKA), low potency in Human Coagulation Factor VIII batches and low pH observed in one batch of Fibrin Sealant kit.

Three batches of indigenously manufactured Fibrin Sealant kit were found giving out of specification results for various parameters like assay for Fibrinogen, assay for Thrombin, pH, solubility and stability. In one batch of Human Coagulation Factor VIII out of specification results was observed in test for Pyrogen.

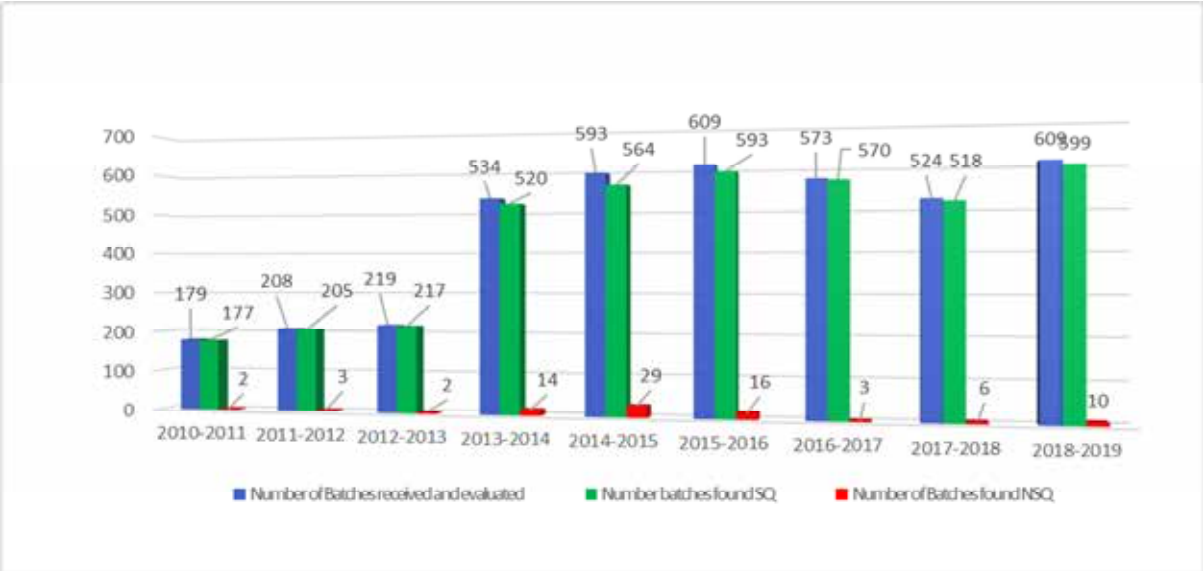


Fig 2. Quality Control testing of various Blood Products in last nine years (2010 to 2019)

7. Proposed target for testing of new biologicals

a) The laboratory has received and tested one batch of anti-thymocyte globulin (rabbit), which is imported in to the country for immunosuppressive therapy in kidney transplantation for treatment of patients with kidney failure. Anti-thymocyte globulin (rabbit) is indicated for the prophylaxis and treatment of acute rejection in patients receiving a kidney transplant. Thymoglobulin is to be used in conjunction with concomitant immunosuppression.

b) The laboratory has initiated establishing of Quality Control testing of Human Normal Immunoglobulin (Sub-cutaneous). The method verification and establishment for testing of this product is targeted to be completed by May 2019.

c) The laboratory has initiated establishing of Quality Control testing of Human Fibrinogen. The method verification and establishment for testing of this product is targeted to be completed by July 2019. Once the quality control testing is established, the Monograph will be written and proposed for publication in Indian Pharmacopoeia.

8. Participation in training/ workshop/ conference

8.1 Dr. J. P. Prasad, Scientist Grade-I & Head, Blood Product Laboratory (BPL) attended

MFDS Global Bio Conference 2018, Korea and delivered a lecture on "Current Consideration for Immunoglobulin in NIB, India" on June 26- 29, 2018, in Seoul, Korea, organized by Ministry of Food and Drug Safety (MFDS), Korea.

8.2 Dr. J. P. Prasad, Scientist Grade-I & Head, BPL was invited as a panel member for the session on "Biologics at India Pharma 2019" conference held at Bengaluru on February 19, 2019. Delivered lecture on "Challenges in Quality Control of Biosimilar in India: Role of National Institute of Biological".

8.3 Dr. J. P. Prasad, Scientist Grade-I & Head, BPL was invited as a speaker to deliver a talk in "two days national seminar on "Impact of Recent Policy Changes on Pharmaceutical Industry", held on March 1- 2, 2019, at JSS College of Pharmacy, Ooty.

8.4 Dr. J. P. Prasad, Scientist Grade-I & Head, BPL invited as Technical Expert for Scientific Advisory Group (Biotherapeutics) Sub Committee Meeting held on 27.09.2018, at Biotechnology Industry Research Assistance Council (BIRAC) (A Government of India Enterprise), 1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi.

8.5 Dr. J. P. Prasad, Scientist Grade-I & Head, BPL and Mrs. Sudha V Gopinath, Scientist Grade-III, Blood Products Laboratory attended Meeting on "Inclusion of Anti-D (Rho) Immunoglobulin (Monoclonal) Monograph in IP 2018", held on August 03, 2018 at IPC, Ghaziabad.

8.6 Mrs. Y. Madhu, Scientist Grade-III, BPL attended 6th WHO Inter-Region Bi-annual Quality Control Laboratory Prequalification Seminar held at New Delhi, India, from October 23– 25, 2018.

8.7 Dr. J. P. Prasad, Head, BPL invited for an event "University-Industry was Research Round Table (UIRRT) in the area of Biotechnology" organised by Gautam Buddha University, Greater Noida, U.P. on November 22, 2018.

8.8 Mr. Anirban Mukherjee, Junior Scientist attended an internal training on "ISO: IEC 4.3 & 4.13 – Document Control and Control of Records" organized by Quality Management Unit, NIB at NIB, NOIDA held on 20.11.2018.

8.9 Dr. Varun Singh, Junior Scientist attended a short course on "Occupational Medicine" February 18- 22, 2019, organized by Harvard T.H. Chan School of Public Health Foundation of India, at Gurgaon, India.

8.10 Dr. Varun Singh, Junior Scientist selected as a member of Editorial Board in Journal of Hematology & Hemotherapy, an open access, peer-reviewed international journal dedicated to disseminating the scientific knowledge globally.

9. Outstanding achievements of the laboratory

9.1 The laboratory has tested and reported 609 batches of 16 types of various plasma derived products forwarded by the office(s) of the Drugs Control General of India, out of which 10 (1.6%) have been found to be Not of Standard quality. The role of laboratory in assuring the quality of such lifesaving drug is reiterated thereby safeguarding public health.

9.2 During the reporting period the laboratory, had tested 13 legal samples of various plasma derived products, forwarded by the office(s) of the Drugs Control General of India. Out of which 2 samples have been found to be Not of Standard Quality (NSQ).

9.3 The laboratory imparted summer training to nine post graduate student to fulfill their post graduate degree. (requirement in various disciplines)

9.4 During this reporting period, the laboratory has established following Quality Control Test Parameters:

Table 9.4 a

S. No.	Name of the test	Name of the Product
1.	test for Identification by Immuno-electrophoresis	Human Albumin, Human Normal Immunoglobulin for intravenous use, Human Normal Immunoglobulin (IM), Human Normal Immunoglobulin (SC), Human Specific Immunoglobulin for intravenous use (Anti-d Immunoglobulin (IV) and Hepatitis B Immunoglobulin (IV)), Human Specific Immunoglobulin (IM) (Tetanus Immunoglobulin (IM), Rabies Immunoglobulin (IM), Anti-D Immunoglobulin (IM) and Hepatitis B Immunoglobulin (IM)).
2.	test for Anti-D antibodies	Human Normal Immunoglobulin for intravenous use and Human Normal Immunoglobulin (Sub-Cutaneous), Human Specific Immunoglobulin for intravenous use (Hepatitis B Immunoglobulin (IV)).
3.	test for Factor XIII in component 1 (Fibrinogen	Fibrin Sealant Kit
4.	test for Anti-complementary activity	Human Normal Immunoglobulin for intravenous use and Human Specific Immunoglobulin for intravenous use (Anti-D Immunoglobulin (IV) Hepatitis B Immunoglobulin (IV)).
5.	test for Activated Coagulation Factor	Human Coagulation Factor IX.
6.	test for Heparin	
7.	test for total protein by Kjeldahl and Specific Activity	Anti-inhibitory coagulation complex
8.	test for Thrombin Activity	
9.	test for Plasmin Activity	
10.	test for Prekallikrein Activity	
11.	test for Kallikrein Activity	
12.	test for Potency	
13.	test for Factor-X Activity	
14.	test for Heparin	Human Prothrombin Complex
15.	test for Factor-II	
16.	test for Factor-VII	
17.	test for Factor-X	
18.	test for Activated Coagulation Factor	
19.	Assay for von Willebrand factor (vWf)	Human Coagulation Factor VIII.

RECOMBINANT PRODUCT LABORATORY

1. Name of Head:

Dr. Charu Mehra Kamal, Scientist Grade-II

2. Manpower in the Laboratory/ Division

I. Name of the Scientific staff:

Ms. Gurminder Bindra, Scientist Grade-III

Dr. Meena Kumari, Scientist Grade-III

Dr. Richa Baranwal, Scientist Grade-III (From 10.07.18 to 18.09.18)

Dr. Manoj Kumar, Scientist Grade-III (w.e.f. 18.09.18)

Dr. Sanjay Mendiratta, Junior Scientist

Dr. Birendra Kumar, Junior Scientist (w.e.f. 17.05.18)

II. Name of the Technical Staff:

Ms. Poonam, Laboratory Technician

Mr. Mohit Lal, Laboratory Technician

Mr. Rajeev Srivastava, Laboratory Assistant (w.e.f. 17.05.18)

III. No(s) of outsourced staff: 03

3. Scientific activities undertaken

a) Collaboration with Other organizations

Interlaboratory collaborative study for develpment of National Reference Standard for Filgrastim has been initiated with 09 participants, including 08 indigenous Filgrastim stakeholders and United States Pharmacopoeia (USP) .

b. Central Drugs Lab Notification

The laboratory has been notified as Central Drugs laboratory (CDL) vide The Gazette of India, Extraordinary, notification No. GSR 908 (E)-Part II-Sec 3 (i) on December 22, 2014 for class of products mentioned in Table 1.

Table 1: CDL Notified recombinant products

S. No.	Name of Product	Type of Product
1	Recombinant Insulin	Anti-Diabetic
2	Recombinant Insulin Analogues	
3	r-Erythropoietin (EPO)	Growth factors
4	r-Granulocyte colony stimulating factors (G-CSF)	

c. Government Analyst: Nomination of two scientists is under consideration by Central Drugs Standard Control Organization (CDSCO) for declaration as Government Analyst.

d. Development of Monographs:

i. Laboratory has contributed towards development of four monographs as given in Figure 1

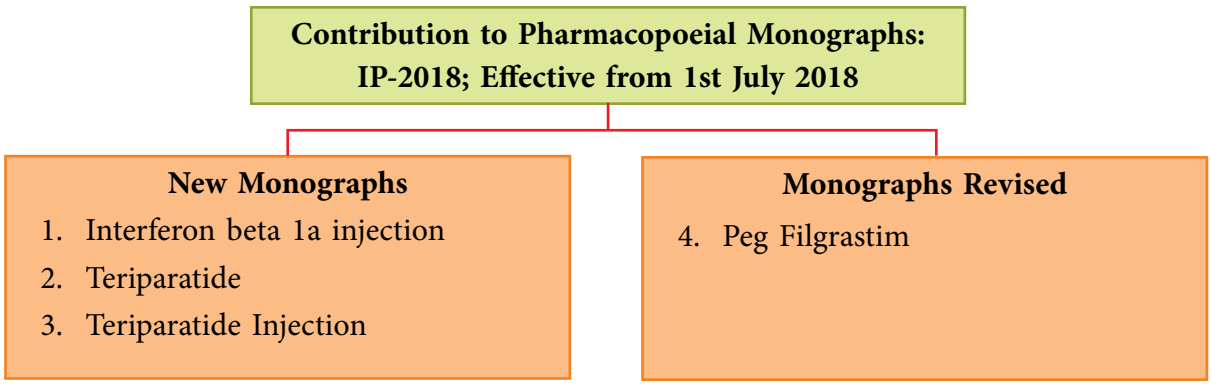


Figure 1: Contribution of NIB in Development of IP Monographs

e. Publication:

1. Establishment of the first National Reference Standard for Insulin Lispro: Report of a Collaborative Study". Biologicals. 2019 March; 58: 1-6 Gurminder Bindra, Gaurav Pratap Singh Jadaun, Shruti Dixit, Vandana Saklani, Zafar Abbas, Parveen Jain, Kim B. Dancheck, Matthew W. Borer, Meena Kumari, Charu Mehra Kamal, Renu Jain, Surinder Singh and Participants of the Study

4. Testing of Biologicals

Laboratory tested a total of 120 batches of antidiabetic viz Insulin and Insulin analogues, growth factors also. insulin, insulin analogues, growth factors etc. Out of which 05 batches have been found of Not of Standard Quality(NSQ) (Table 2).

Table 2: Summary of batches tested during 2018-19

Name of Biologicals tested	Type of Biologicals	No. of Batches Evaluated	No. of Batches Found to be of Standard Quality (SQ)	No. of Batches Found Not to be of Standard Quality (NSQ)	No. of Inter lab-oratory sample tested	Remarks
Insulin Regular	Anti Diabetic - Insulin	08	36	05	87	Medical supplies: 38
ii Insulin Biphasic		27				
iii Insulin NPH		06				
i. Degludec/ Aspart	Anti Diabetic-Insulin Analogues	0	23	Nil		
ii. Glargine		07				
iii. Aspart		06				
iv. Lispro		04				
v. Biphasic lispro		06				
i. Filgrastim	Growth Factors	11	49	Nil		Medical supplies: 23
ii. Peg Filgrastim		02				
iii. Erythropoietin		30				
iv. Interferon Alpha 2b		01				Survey: 06
v. Interferon beta 1a		03				
vi. Interferon beta 1a		01				
vii. Peg Erythropoietin		01				

Name of Biologicals tested	Type of Biologicals	No. of Batches Evaluated	No. of Batches Found to be of Standard Quality (SQ)	No. of Batches Found Not to be of Standard Quality (NSQ)	No. of Inter laboratory sample tested	Remarks
i. Teriparatide	Small Peptides	03	07	Nil	Nil	--
ii. GLP - Dulaglutide		04				
TOTAL		**120**	**115**	05	87	

5. Preparation and supply of National Standards, Sera Panel etc.

5.1 Reference Standard Program

The effective implementation of IP monographs on rDNA Biotherapeutic products requires suitable use of Reference Standards. In this regard laboratory developed reference standard for Insulin Lispro by collaborative study which was released on 14.09.2018. The development of reference standard for Filgrastim is under progress (Table 3).

Table 3. Development of Reference Standards

S. No.	National Reference Standard	Study Period	Details
1	Insulin Lispro	2016-2018	1) This is an outcome of Inter-laboratory Collaborative (ILC) Study of 6 Laboratories (NIB, Insulin Stakeholders and Pharmacopoeia Labs). 2) The aim of this study was to develop 1st National Reference Standard for Insulin Lispro for the purpose to benefit the Stakeholders viz., Manufacturers of Insulin Lispro, Drug Regulatory Authority, Central Drugs Laboratory (National Control Laboratory), Academia institutes to demonstrate the accuracy of results, to enable comparison of methods and to validate methods. 3) The information of this Insulin Lispro IPRS is available on NIB website as well as IPC website.
2	Filgrastim (Preparation under progress)	2017-2019	1) Collaborative study of 09 Laboratories (NIB, Filgrastim Stakeholders, & Pharmacopoeia Labs). 2) Candidate material has been received from one of the stakeholders and ILC study has been initiated with 09 participants.

5.2 Supply of Reference Standard for Human Insulin (IPRS)

During 2018-19, 10 vials of IPRS for Human Insulin have been supplied to one of the indigenous stakeholder M/s Torrent Pharmaceuticals Ltd, Gujarat. The details for supply of IP Reference Standard for Human Insulin (IPRS) are available on NIB website at: http://nib.gov.in/ordering%20info%20IPRS%20HI-2.htm

6. Trend in Volume of Work as Compared to the previous year

6.1 Trend in Test and Analysis of Recombinant Biotherapeutic products

The laboratory has capacity and infrastructure to test 500 batches on the basis of complete testing of recombinant products annually. As a consequence of directions issued from DCG (I) office on 07.02.2018 to various offices/ port/zonal to draw samples of r DNA derived drugs in future, as per the risk based criteria, the number of batches received has reduced from 491 to 120 batches in current year. The inflow of samples from various sources such as port offices, survey and medical supply of various state medical corporation is shown in Figure 2.

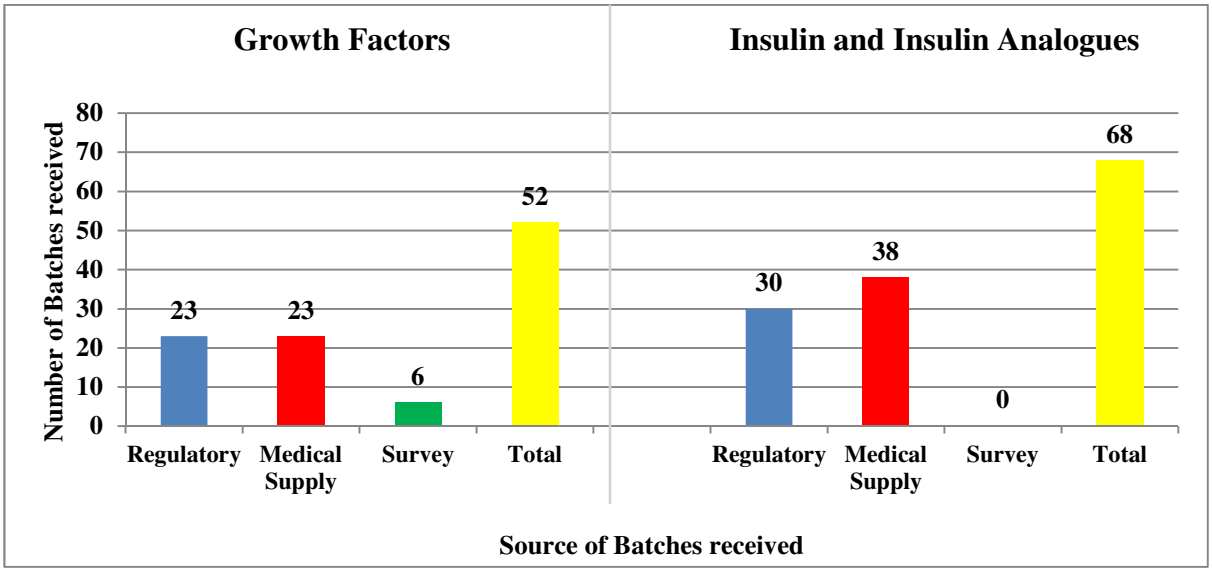


Fig 2: Batches received from various sources such as Regulatory, Medical supply and Survey

6.2 Out Of Specification (OOS) results

Lab has reported "Not of Standard Quality" results for 05 Biphasic Human insulin samples on the basis of Soluble content (03) and Zinc content (02) as indicated in the figure 3. All these batches were from one indigenous manufacturer for medical supply and this data has been communicated to DCG (I).

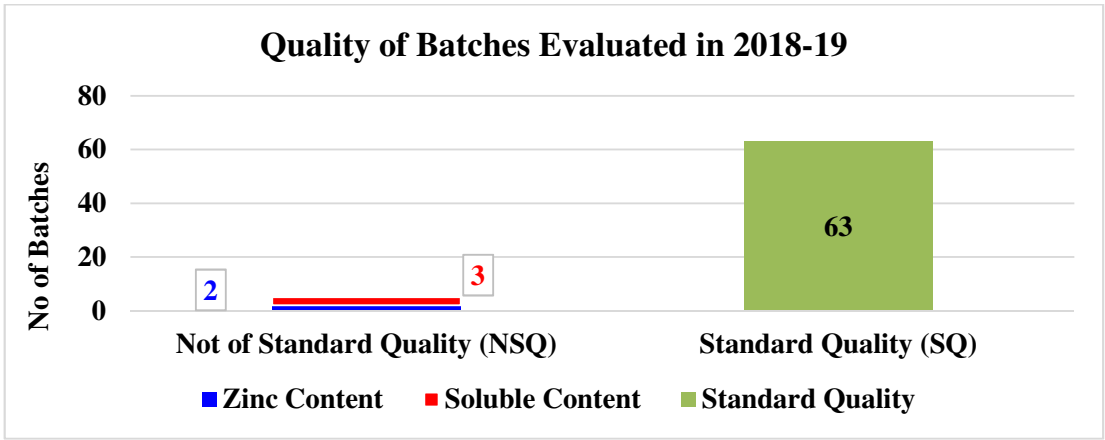


Fig 3: Results for Out Of Specification (OOS) batches of Insulin

6.3 Inter-laboratory testing of samples:

As a part of inter-laboratory testing, lab has evaluated 87 samples for various parameters such as Particulate matter by Light obscuration method, Osmolality and Bacterial Endotoxin Test (BET) using quantitative Kinetic Chromogenic Assay (KCA) from Blood Products lab (BPL), Therapeutic Monoclonal Antibody lab (TMAb), Allergen Testing Lab (ATL) and Enzymes and Hormones Lab (EHL) as shown in figure 4 and table 4.

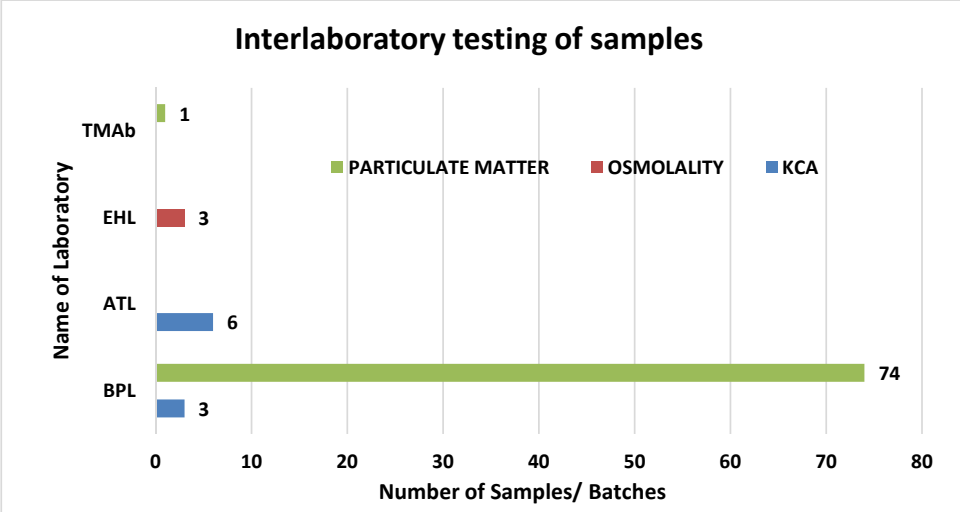


Fig 4: Inter-laboratory testing of samples from other labs of NIB

Table: 4 Inter-laboratory testing of samples from other labs of NIB

Laboratory	Parameter	No. of samples tested
Blood products	Particulate Matter	74
Therapeutic Monoclonal Antibody		01
Enzyme & Hormone	Osmolality	03
Allergen Testing	BET (KCA)	06
Blood products		03
Total		**87**

6.4 Out of total 120 batches of Recombinant Bio-therapeutic products tested 30 were imported products and 90 were indigenous products (Figure 5)

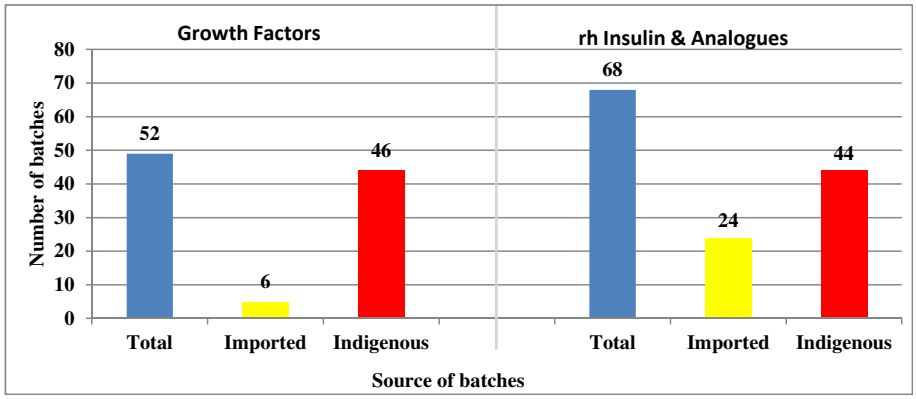


Figure 5: Source of Recombinant Biotherapeutic Products tested in 2018-2019

7. Proposed Target for Testing of New Biologicals and being undertaken

Laboratory has undertaken QC testing of following new products:

S. No.	Product	Pharmacopoeial/ Non-pharmacopoeial	Testing validated/ Established
1	Faster Acting Insulin Aspart (Fiasp) – Insulin analogue	Non-pharmacopoeial	Testing validated as per manufacturer's specifications
2	Pegylated Erythropoietin (Growth factor)	Non-pharmacopoeial	Under process as per manufacturer's specifications

8. Training/ Workshop/ Conference Organized

Laboratory organized/ participated in following meetings organized at NIB:

Meetings For

Monograph development

1. To address the queries in Monograph on Peg Filgrastim published in IP 2018. The meeting was attended on 15.05.2018 by the stake holders, Indian Pharmacopoeia and NIB team

2. Scientific interaction with team from HQ Korea of LG Chem Life Sciences on 25.07.2018 to discuss and clarify with respect to various test parameters on "IP monograph of Recombinant Human Erythropoietin injection"
3. Discussion of technical issues of IFN-b1a monograph as per IP 2018 with Indian Pharmacopoeia and industry stakeholders on 30.10.2018

Reference Standard Preparation

1. Official release of Reference Standard Preparation of Insulin Lispro (IPRS) on 14.09.2018 (IPRS is available for commercial sale)

2. Scientific Meeting with Manufacturer (M/s Cadila Healthcare Ltd) for discussion on Inter-Laboratory Collaborative (ILC) study for development of National Reference Standard for Filgrastim on 08.01.2019 (Preparation under progress)

QC Testing

1. Meeting with Manufacturer (M/s Eli Lilly) for discussion of modalities for testing Insulin Analogue: Dulaglutide on 11.01.2019

Presentation

1. **On "Quality Attributes of Recombinant Bio-therapeutics"**
   Dr. Charu Mehra Kamal, (Scientist Grade-II and Head Recombinant Product & Enzyme and Hormone Laboratory) presented at India Bio-Pharma Landscape Conference titled "Collaborate to Innovate Connecting end –to- end drug manufacturing with technology and innovation" at Bombay Exhibition Center, Mumbai on 25.04.2018

9. Participations in Training / Workshop/ Conference:

S. No.	Name of the Scientist (s)	Name of Programme	Duration	Venue
1.	Dr. Manoj Kumar Dr. Sanjay Mendiratta	Elucidating the guidelines on similar biologics for India.	Dec 12-14, 2018	IIT, New Delhi
2.	Dr. Charu M. Kamal Ms Gurminder Bindra	Proteomic characterization of biotherapeutics: concepts and case studies.	Dec 13, 2018	IIT, New Delhi
3.	Ms. Gurminder Bindra	5th Annual USP Biologics Workshop on Biologics and Peptides	Feb 05-06, 2019	USP, Hyderabad

10. Outstanding achievements of the Laboratory:

1. The first National Reference Standard for Insulin Lispro (IPRS) developed by laboratory was officially released on September 14, 2018 for commercial sale.
2. Ten vials of Human Insulin IPRS have been supplied to a stakeholder.
3. Preparation of National Reference Standard for Filgrastim is under progress. Candidate material has been received from one of the stakeholders and ILC study has been initiated with 09 participants.
4. Laboratory participated in Charles River's LAL Proficiency Testing Program for Bacterial Endotoxin Testing (BET) during 1st quarter of the year 2019. The results will be uploaded on PTP web interface of Charles River after analysis.
5. **Publication:** Gurminder Bindra, Gaurav Pratap Singh Jadaun, Shruti Dixit, Vandana Saklani, Zafar Abbas, Parveen Jain, Kim B. Dancheck, Matthew W. Borer, Meena Kumari, Charu Mehra Kamal, Renu Jain, Surinder Singh and Participants of the Study. Study of the first National Reference Standard for Insulin Lispro: Report of a Collaborative Study. *Biologicals 2019; 58: 1-6.*

ENZYME AND HORMONE LABORATORY

1. Name of Head

Dr. Charu Mehra Kamal, Scientist Grade-II (01.04.2018 to 17.05.2018)

Dr. Akanksha Bisht, Scientist Grade- III (17.05.2018 onwards)

2. Manpower in the Lab/ Division

I. Name of Scientific Staff

Dr. Birendra Kumar, Junior Scientist (01.04.2018 to 17.05.2018)

Mr. Paras Jain, Junior Scientist (17.05.2018 to till date)

II. Name of Technical Staff

Mr. Brij Bahadur, Lab Technician

Mr. Reetesh Kumar, Lab Technician (18.05.2018 to till date)

III. No (s). of Outsourced Staff: 04

3. Scientific Activities Undertaken :

a) Collaboration with other organization:

The laboratory participated in "Method Verification of Follicle Stimulating Hormone Injection Monograph IP 2018" with IPC and Stakeholders. The study was in response to the query raised by stakeholders for amendment in potency assay and Free subunits by SDS PAGE (non-reducing) in Monograph of rFSH, IP-2018.

b) CDL Notification:

The laboratory is notified Central Drugs Laboratory (CDL) vide the Gazette of India, Extraordinary, Notification No. : G.S.R. 250 (E)- Part-II - Section 3- Sub- Section (i) dated March 15, 2017 for class of products mentioned in Table - 1.

Table 1: CDL notified Enzyme and Hormone products.

S. No	Name of Products
(a)	Streptokinase (Natural and Recombinant)
(b)	Human Chorionic Gonadotropin (hCG)
(c)	Human Menopausal Gonadotropin (hMG)

c) Development of Monograph: The laboratory has initiated the monograph development of Urokinase Injection for incorporation in Indian Pharmacopoeia.

4. Testing of Biologicals:

The Details of Biologicals and number of batches received for Quality Control testing during the reporting year are summarized in Table 2. Total 24 batches of Enzymes and Hormones were received in the laboratory, for which CoA has been released. This comprises of 05 batches of new product namely Tenecteplase (TNK-t-PA) introduced by the laboratory. All the samples (23) received in laboratory were of Standard Quality except 01 batch of Urokinase Injection which was found to be 'Not of standard quality'.

Table 2: Testing of Biologicals during 2018-2019

Name of Biologicals Tested	Type of Biologicals	No. of Batches evaluated	No. of batches found to be of Standard Quality	No. of batches found not to be of Standard Quality	No. of Inter–Lab. Sample tested
Streptokinase Inj.	Enzyme	**03**	**03**	**Nil**	------

Name of Biologicals Tested	Type of Biologicals	No. of Batches evaluated	No. of batches found to be of Standard Quality	No. of batches found not to be of Standard Quality	No. of Inter–Lab. Sample tested
Heparin Inj.	Enzyme	**04**	**04**	**Nil**	------
Tenecteplase (TNK-t-PA)	Enzyme	**05**	**05**	**Nil**	------
Urokinase Injection	Enzyme	**01**	**Nil**	**01**	------
Human Chorionic Gonadotropin (HCG) Inj.	Hormone	**03**	**03**	**Nil**	------
Menotropin (HMG) Inj.	Hormone	**05**	**05**	**Nil**	------
Follitropin Inj.*	Hormone	**Nil**	**Nil**	**Nil**	------
Somatropin Inj. (recombinant)	Hormone	**03**	**03**	**Nil**	------
Coagulation Factor VIII & Antiheamophilic Factor VIII	Blood Product	----	----	**Nil**	**12**
Coagulation Factor IX	Blood Product	----	----	**Nil**	**02**
Anti-D Rho Immunoglobulin	Blood Product	---- ----	---- ----	**Nil**	**13**
Rituximab, Trastuzumab	Therapeutic Monoclonal Antibody Product	----	----	**Nil**	**02**
Rabies Vaccine	Viral Vaccine Lab	----	----	**Nil**	**26**

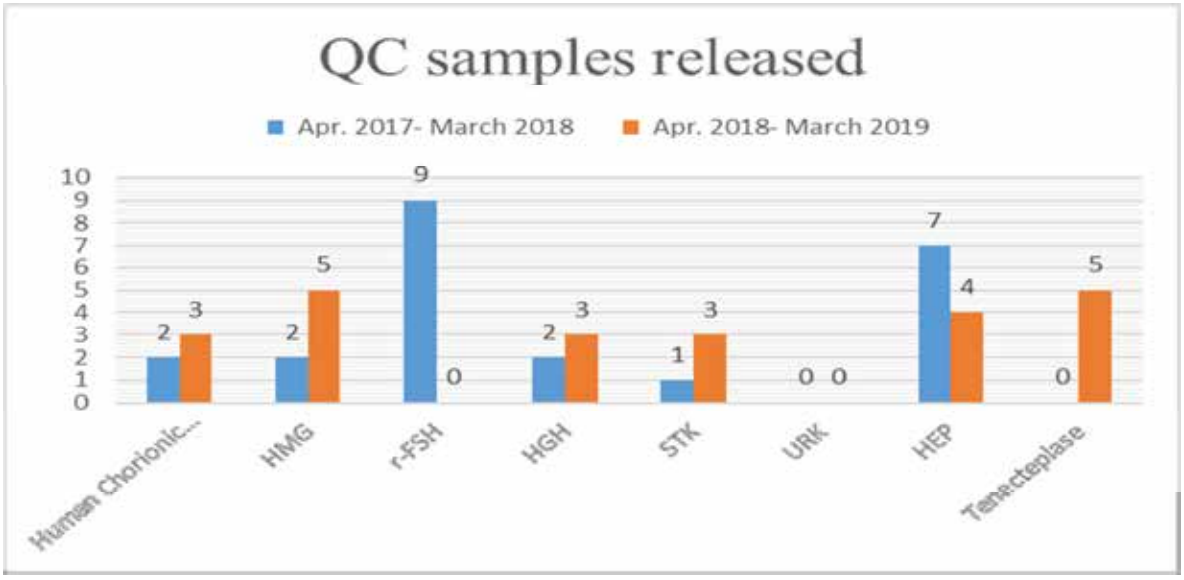
*No sample of Follitropin Inj. has been received for batch release since the Monograph of Follitropin Inj. (IP 2018) is under verification.

5. Preparation and supply of National Standard, Sera Panel:

The study protocol and characterization of candidate material for preparation of National Reference Standard (NRS) of rFSH has been initiated.

6. Trend in volume of work as compared to the previous year:

A. **Quality evaluation of Biologicals:** The laboratory received 24 batches of Enzymes and Hormones which were evaluated. The Trends of samples received for QC evaluation as compared to previous year: Product wise/ Total sample are shown in Figure- 1.



*No sample of Follitropin Inj. has been received for batch release since the Monograph of Follitropin Inj. (IP 2018) is under verification.

Figure 1: The Trends of samples received for QC evaluation as compared to previous year

B. Interlaboratory Sample testing: A total of 55 Interlaboratory samples have been received for safety test by *Bacterial Endotoxin–Gel Clot Method*. Out of 55 samples 27 samples were of Blood Product Laboratory, 02 samples of Therapeutic Monoclonal Antibody Laboratory and 26 samples of Viral Vaccine Laboratory.

C. Establishment of potency assay of Urokinase as per manufacturer's method: During this year, the laboratory has standardized the potency assays of Urokinase Injection using samples from Bharat Serum and Vaccines Ltd. Mumbai and Health Biotech, Baddi, Himachal Pradesh.

D. Method & Protocols presentation in IAEC: The methods and protocols for testing of different test parameter (such as Potency test of Hormone, Streptolysin Activity of Streptokinase, Pyrogen and Abnormal Toxicity test of enzyme and hormone samples) were presented by Dr. Akanksha Bisht, Scientist Grade-III and Head, Enzyme and Hormone Laboratory in IAEC meeting held on 19.11.2018, and 08.03.2019.

7. Proposed target for testing of new Biologicals being undertaken:

A. The laboratory has initiated the standardization of the Quality parameters of the following Rare Disease Products:

Table 3:

Product name	Timeline
Idursulfase (r-DNA origin)	June 2019
Velaglucerase (r-DNA origin)	July 2019
Agalsidase alfa (r-DNA origin)	August 2019

B. hCG Pregnancy test kit: The laboratory is planning to undertake the Quality evaluation of hCG Pregnancy test kit. In this regard, the two officials of laboratory were trained in the laboratories of HLL Lifecare Ltd. and AIIMS.

8. Training/ Workshop/ Conference organized:

Table 4: Teleconference /Meeting organised by laboratory:

S. No.	Title of Talk/ Meeting organised	Date
1.	Teleconferencing with the Edara Research Foundation, pertaining to Quality control testing of Streptokinase	13.07.2018
2.	Method Verification of Follicle Stimulating Hormone Injection Monograph, IP 2018 with IPC and Stakeholders	19.07.2018
3.	Meeting with Stakeholder (LG Life Sciences) and representative from IPC to discuss IP test of Content of Uniformity of Human Chorionic Gonadotropin and Menotropin Injection.	25.07.2018
4.	Meeting with Stakeholder (Baxalta Bioscience India Pvt. Ltd.,) to discuss about QC testing of New Enzyme Products	27.07.2018
5.	Meeting with Stakeholder (Baxalta Bioscience India Pvt. Ltd. Now Part of Shire) to discuss about QC testing of New Enzyme Products i:e Replagal, Elaprase and Vpriv	18.09.2018
6.	Meeting to finalize the Quality control testing fees of Tenecteplase (TNK-tPA), at 1st floor meeting room Laboratory building, National Institute of Biologicals, Noida.	15.10.2018

9. Participations in Training/ Workshop/ Conference

Table 5: Training attended by laboratory staff:

S. No.	Name of Scientists	Name of the Programme	Duration	Place
1.	Mr. Paras Jain and One outsourced staff	National workshop on GLP organised by Department of Science and Technology	24.08.2018	Translational Health Science and Technology Institute, Faridabad
2.	Mr. Paras Jain	CBT Course series 2018	12.12.2018-14.12.2018	IIT, Delhi
3.	Mr. Paras Jain and One outsourced staff	Meeting of Experts and Stakeholder for Heparin Sodium & Dalteparin Sodium Monograph related queries organized by IPC Ghaziabad	20.12.2018	IPC, Ghaziabad
4.	Mr. Paras Jain	Annual workshop on Biologics	05.02.2019-06.02.2019	USP, Hyderabad
5.	Mr. Brij Bahadur	Occupational health medicines	18.02.2019-22.02.2019	PHFI, Gurgaon
6.	Mr. Paras Jain	"Mass Detection for Everyone"	13.03.2019	Waters India Pvt Ltd, New Delhi

10. Outstanding achievements of the Lab/ Division:

A total of 14 quality control parameters for Tenecteplase (Tissue Plasminogen Activator) a new product, were standardized by the Laboratory in short span of 40 days and aslo CoA for 3 batches of Tenecteplase were released by the laboratory.

THERAPEUTIC MONOCLONAL ANTIBODY LABORATORY

1. Name of the Head:

Mr. Subhash Chand, Scientist Grade-III

2. Manpower in the lab/division:

I. Name of Scientific Staff:

Dr. Richi V. Mahajan, Junior Scientist
Ms. Apoorva Anand, Junior Scientist

II. Name of Technical Staff:

Dr. Mohammed Imran, Lab Technician

III. No(s). of Outsourced Staff: 09

3. Scientific Activities Undertaken

a) Collaboration with other organization:

(i) Director, CSIR-IMTECH along with team of Scientists visited NIB on 08.01.2019 to discuss the collaboration in the area of Bio-analytical characterization, and initiation of Skill Development Course aimed at creating industry ready National Talent Pool in cutting edge technologies for characterization of Biologicals for Biopharma Industry.

(ii) Dr. Deus Mubangizi, Group Leader, WHO Prequalification team visited TMA Lab on 15.02.2019 for exploring the testing capability of NIB for Rituximab and Trastuzumab for WHO-pre qualification of National Control Laboratory for said products.

(iii) Initiation and upgradation of Centralized Facility for Cell Culture Bioassays for Therapeutic Products: TMA laboratory has initiated Centralized Facility for Cell Culture Bioassays for Therapeutic Products which is functional currently at the bioassay laboratory of TMA Lab. In order to upgrade the same to the international standards, a team from TMA Lab, along with the DD(QC)i/c (Therapeutics, Allergens & AF) and Consultant (Regulatory) visited various biopharma facility across the country viz. M/s Mankind Biologics facilities, Gurugram on 03.07.2018, M/s Vimta Lab Ltd. and Dr. Reddy's Laboratory, Hyderabad on 10.08.2019 to explore and discuss various technicalities for designing of Clean Rooms for handling of all cell lines as per the cGMP/ Regulatory Norms for upgradation of Centralized Facility for cell culture bioassays (CFB) at NIB. Subsequent to the visits, a proposal along with blue print for upgradation of centralized facility for for Cell Culture Bioassays was taken up further necessary tendering process after due consultation with the Subject Expert Committee.

b) CDL Notification:

TMA laboratory has got NABL accreditation as per ISO17025:2005 for four products viz. Rituximab, Trastuzumab, Adalimumab and Bevacizumab vide certificate number 'TC7725' dated 16.08.2018. The CDL Notification of TMA Laboratory to be initiated since the NABL accreditation is prerequisite for CDL notification.

c) Government Analyst: The proposal for notification of one laboratory scientist as Government Analyst is under consideration by Ministry of Health and Family Welfare, Government of India.

d) Development of Monograph: Meeting on inclusion of Anti D (Rho) immunoglobulin (Monoclonal) Monograph in IP was held on August 3, 2018 at RS Iyer Hall, IPC-Ghaziabad. Meeting was attended by IPC Officials, NIB Scientists and other stakeholders.

e. Publication (s):

i) Research Articles:

Subhash Chand, Birendra Kumar, Vivek Morris Prathap, Surinder Singh, Richi V Mahajan (2018). Quality assurance of Rituximab (anti-CD 20) antibodies by potency testing: Determining the System Suitability Criteria and Sample Acceptance Criteria. Current Science. Current Science, 114 (12): 3513- 2518 (I.F=0.835)

ii) Book Chapter:

Richi V Mahajan, Subhash Chand, Mahendra Pal Singh, Apurwa Kestwal, Dr. Surinder Singh (2018). Advances in Production of Therapeutic Monoclonal Antibodies. A handbook on high value fermentation products published by Wiley-Scrivene Publishing, USA. 165-191

4. Testing of Biologicals

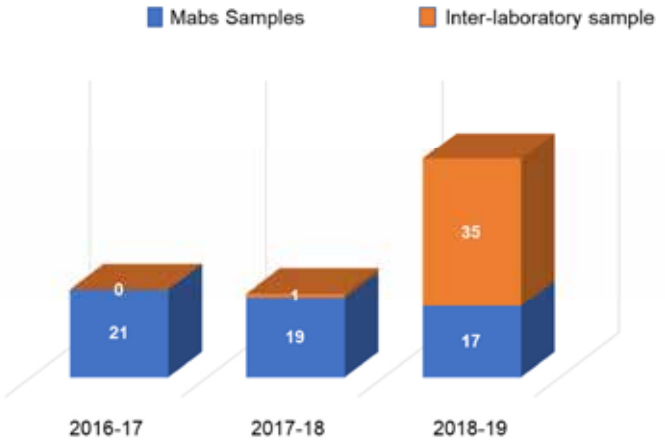
Name of Biologicals Tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of standard quality	No. of batches found not to be of standard quality	No. of Inter-laboratory sample tested	Remarks
Trastuzumab	Monoclonal Antibody	2	2	Nil	-	-
Bevacizumab	Monoclonal Antibody	2	2	Nil	-	-
Rituximab	Monoclonal Antibody	2	2	Nil	-	-
Pertuzumab	Monoclonal Antibody	2	2	Nil	-	New Biological Products undertaken for testing for complete testing
Ramucirumab	Monoclonal Antibody	2	2	Nil	-	
Anti-D (Rho)	Monoclonal Antibody	6	6	Nil	-	
Natalizumab	Monoclonal Antibody	1	1	Nil	-	
Trulicity (Dulaglutide)	Recombinant product	-	-	-	3	-
Aplevent	Recombinant product	-	-	-	2	New Biological Products undertaken for testing for CE testing

Name of Biologicals Tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of standard quality	No. of batches found not to be of standard quality	No. of Inter-laboratory sample tested	Remarks
Acaroid	Allergen	-	-	-	6	New Biological Products undertaken for testing for BET testing
Filgrastim	Recombinant product	-	-	-	12	New Biological Products undertaken for testing at Centralised Facility for Cell Culture Bioassay, TMA Lab
Peg-Filgrastim	Recombinant product	-	-	-	1	
Interferon β 1a	Recombinant product	-	-	-	3	
Interferon α 2b	Recombinant product	-	-	-	1	
Peg-Interferon	Recombinant product	-	-	-	3	
Teriperatide	Recombinant product	-	-	-	3	
Anti-T Lymphocyte	Blood Product	-	-	-	1	
Total		17	17	-	35	

5. Preparation and supply of National Standards, Sera panel etc:

Roadmap (2019-2024) for preparation of Reference Standard for TMA Laboratory prepared and incorporated into the Institutional Development Program (IDP) of NIB which has been presented in Governing Body meeting of NIB.

6. Trend in volume of work as compared to previous year:



7. Proposed targets for testing of new biologicals being undertaken:

i) Testing capability has been established for N=05 New mAb products (Pertuzumab, Ramucirumab, Ranibizumab and Eternacept, Natalizumab) in FY 2018-19.

ii) N=07 rDNA products taken up for testing at Centralized Facility for Cell Culture bioassays (CFB).

iii) Targets were undertaken for establishing the testing capability or following new products:

S. No.	Product/ test
1	Pembrolizumab
2	Obinituzumab
3	Omalizumab
4	Aflibercept

8. Participations in training/ workshop/ conference:

Name of the Scientist	Scientific Presentations given	Date	Venue
Mr. Subhash Chand, Scientist Grade-III & Head	Delivered an oral presentation on "Challenges in Quality Control Strategy of Biosimilars in India: Role of National Institute of Biologicals" in a session on "Opportunities and Challenges in development of Similar Biologics" at 70th Indian Pharmaceutical Congress (IPC)	22.12.2018	Amity University, Noida
Mr. Subhash Chand, Scientist Grade-III & Dr. Richi V. Mahajan, Ms. Apoorva Anand, Junior Scientist	Workshop on under-standing of applications on different techniques of HPLC and its supported applications in characterization of mAbs by M/s Thermo India	April 25-26, 2018	NIB, NOIDA
Mr. Subhash Chand, Scientist Grade-III & Dr. Richi V. Mahajan, Ms. Apoorva Anand, Junior Scientist	Glycan analysis of by Capillary electrophoresis of Therapeutic Monoclonal antibodies by M/s AB Sciex	September 14-18, 2018	NIB, NOIDA
Mr. Subhash Chand, Scientist Grade-III & Dr. Richi V. Mahajan, Junior Scientist	2nd World Conference on Access to Medical Products - Achieving the SDGs 2030 organised by WHO.	October 9-11, 2018	Pravasi Bhartiya Kendra, New Delhi
Ms. Apoorva Anand, Junior Scientist, one outsourced staff	Biosimilar Workshop 2018 on Glycan Analysis (USP Chapter <212>)	November 29- 30, 2018	Institute of Chemical Technology, Matunga, Mumbai
Dr. Richi V. Mahajan, Junior Scientist	Elucidating The Guidelines On Similar Biologics for India	December 08-10, 2018	IIM, Ahmadabad

Felicitation of Mr. Subhash Chand, Scientist Grade-III & Head Therapeutic Monoclonal Antibody (Panelist) by Dr. Surinder Singh, Director NIB (Session Chair) for presentation on "Challenges in Quality Control Strategy of Biosimilars in India and Role of National Institute of Biologicals at 70th Indian Pharmaceutical Congress (IPC), held at Amity University, Noida on 22.12.2018

9. Outstanding achievements of the Lab:

a TMA laboratory has got NABL Accreditation as per ISO 17025:2005 for four products viz. Rituximab, Trastuzumab, Adalimumab and Bevacizumab vide certificate number 'TC7725' dated 16.08.2018.

b Setting up of Centralized Facility for Cell Culture Bioassays (CFB) for Therapeutic Products.

c N=05 new mAb Products (Pertuzumab, Ramucirumab, Ranibizumab and Eternacept, Natalizumab). Testing capability had been established in FY 2018-19. N=07 rDNA products taken up for testing at Centralized Facility for Cell Culture bioassays.

d Publications: 01 Research article published in Journal 'Current Science' and 01 book chapter published.

ALLERGEN TESTING LABORATORY

1. Name of Head:

Dr. Achla Prasad, Scientist Grade-I (till 11.04.2018)

Ms. Shalini Tewari, Scientist Grade-III (from 11.04.2018)

2. Manpower in the lab/division:

I. Name of Scientific Staff:

Ms. Shalini Tewari, Scientist Grade-III (till 11.04.2018)

Mr. Brij Bhushan, Junior Scientist (From 08.05.2018)

II. No(s). of Outsourced Staff: 04

3. Scientific Activities Undertaken:

3.1 Collaboration with other organisations:

3.1.1 The work on developing Quality Control (QC) modalities for indigenous Allergens has been taken up for the first time at NIB. In view of rise in allergies, the QC of diagnostic and therapeutic allergen extracts is important.

Two subject expert committees viz. National Expert Committee and Core committee have been constituted to advise on developing QC modalities for Allergens in India. The members of these committees are eminent scientists of the field from different medical colleges/ hospital/ academia/ Govt. institutions/ CDSCO/ IPC etc. The National Expert Committee has been duly approved by Honourable Health Minister.

3.1.2 The work on project entitled "Development of Techniques and Reagents for Quality Control of Indigenous Cockroach (*P. americana*) Allergen Extracts- a Clinically Important Allergen" is being continued in collaboration with Metro Hospital, NOIDA

3.2 Development of Monographs: First Indian Monograph on Allergen Products was published in Indian Pharmacopoeia 2018. The Allergen extracts contain phenol which interferes with Modified Lowry Method given in IP 2018. For this purpose Bradford Method of protein estimation was standardized and validated at Allergen Testing Laboratory. Protocol for Bradford method along with supporting data has been submitted to Indian Pharmacopoeia Commission, Ghaziabad, for inclusion/ addition for protein estimation in phenol containing Allergen Extracts in Allergen Products Monograph in IP

4. Testing of Biologicals:

Name of the Biologicals tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of Standard Quality	No. of batches found Not to be of Standard Quality	No. of Inter-laboratory sample tested	Remarks
Acaroid Dermato-phagoides farinae 100% Strength A	Modified Allergen Product	01	01	00	--	

Name of the Biologicals tested	Type of Biologicals	No. of batches evaluated	No. of batches found to be of Standard Quality	No. of batches found Not to be of Standard Quality	No. of Inter-laboratory sample tested	Remarks
Acaroid Dermato-phagoides farinae 100% Strength B	Modified Allergen Product	01	01	00	--	Allergen Testing Laboratory, in consultation with CDSCO, undertook standardization and performed feasible testing as per manufacturer's specifications on 06 batches modified allergen product (Aluminium adsorbed) of House Dust Mite for test license on Form-11, Certificate of Analysis were submitted to the office of DCG (I) for taking further necessary action at their end
Acaroid Dermato-phagoides ptero-nyssinus 100% Strength A	Modified Allergen Product	01	01	00	--	
Acaroid Dermato-phagoides ptero-nyssinus 100% Strength B	Modified Allergen Product	01	01	00	--	
Acaroid Dermato-phagoides ptero-nyssinus 50%+ Dermato-phagoides farinae 50% Strength A	Modified mixed Allergen Product	01	01	00	--	
Acaroid Dermato-phagoides ptero-nyssinus 50%+ Dermato-phagoides farinae 50% Strength B	Modified mixed Allergen Product	01	01	00	--	
		06	**06**	**00**	--	

5. Trend in volume of work as compared to previous year:

5.1 Testing and release of Certificate of Analysis of Acaroid samples: For the first time Allergen Testing Laboratory received 06 batches of Acaroid- a modified House Dust Mite allergen product (Aluminium adsorbed) for the purpose of test license on Form- 11. The laboratory standardized all feasible tests and carried out testing of all 06 batches in coordination with CDSCO. The Certificate

of Analysis were submitted to the office of DCG (I) for taking further necessary action at their end.

5.2 Subsequent to deliberations in a meeting held on 21.03.2018 at FDA Bhawan, CDSCO requested NIB to standardize method of protein estimation in phenol containing bulk allergen extract samples by a suitable method as phenol interferes in Modified Lowry Method (IP-2018). Accordingly Bradford Method has been standardised and validated at Allergen Testing Laboratory. The method is to be included in monograph on Allergen Products for which necessary communication has been done with Indian Pharmacopoeia Commission, Ghaziabad.

5.3 Standardization and validation of tests on Cockroach & Moth allergen extracts: Allergen Testing Laboratory received total 10 samples, 5 samples each of Cockroach (*P. americana*) & Moth in the month of April, 2018 for validation and standardization of method for protein estimation considering phenol interference from four indigenous allergen manufacturers viz M/s Creative Diagnostics Medicare Pvt. Ltd., M/s Alcit India Pvt. Ltd, M/s Allcure Pharma, and M/s Bioproducts & Diagnostics Pvt. Ltd.

Protein Estimation:

Step 1: Standardization of Paul Ehrlich Institute (PEI) Protocol of Bradford Method for phenol interference in Commercial Allergen extracts:

As per protocols received for protein estimation with above samples from manufacturers, the claimed protein contents could not be reproduced at NIB. The values of protein content obtained at NIB were found to be much lower (0.68 – 10% of claimed values) for three out of four manufacturers, except Creative Diagnostics. Hence, for optimization of protein estimation in phenol containing allergen extracts, Bradford method (PEI Protocol) was performed using in- house chemicals as well as by Bradford Kit on above 10 samples. The results obtained for protein estimation by Bradford method for all four manufacturers were reproducible. (Table 1).

Table 1: Protein content of different indigenous manufacturers by Bradford Method (In-house & Kit Method)

S. No	Samples received	Protein content (mcg/ml)			80-120% of the claim Complies/ Not complies
		Manufacturer's Claim	NIB: mcg/ml (% of Claim)		
			In-house	Commercial Kit	
1	CDM	68.46	57.72 (84.31%)	66.37 (96.94%)	Complies
2	CDC	249.96	274.73 (109.90%)	235.76 (94.31%)	Complies
3	BPM	1900	12.69 (0.66 %)	24.62 (1.29%)	Low protein
4	BPC	2800	6.00 (0.21%)	19.17 (0.68%)	Low protein
5	ACPM	1570	181.50 (11.56%)	157.16 (10.01%)	Low protein
6	ACPC	1490	205.80 (13.81%)	194.51 (13.05%)	Low protein
7	AlcM1	3112	38.485 (1.23%)	44.27 (1.42%)	Low protein
8	AlcM2	3066.9	52.49 (1.71%)	60.23 (1.96%)	Low protein
9	AlcC1	2947.7	72.82 (2.47%)	87.93 (2.98%)	Low protein
10	AlcC2	2894.1	77.39 (2.67%)	94.20 (3.25%)	Low protein

Bradford Method (both Kit Method and In-house method) gives reproducible results for all phenol containing samples of allergen extracts.

Step 2: Verification of different methods of protein estimation in phenol containing Allergen Extracts:

To further verify and validate results obtained at NIB, all the manufacturers viz. M/s Creative Diagnostics Medicare Pvt. Ltd., M/s Alcit India Pvt. Ltd, M/s Allcure Pharma, and M/s Bioproducts & Diagnostics Pvt. Ltd. were requested to depute their technical personnel at NIB to demonstrate and verify the protein claim made by them in the submitted Cockroach and Moth Allergen extract samples (N=10) during May- July 2018. None of the representatives could reproduce their claim for protein content in their respective Cockroach and Moth Allergen extract samples at NIB. (Table 2). The technical personnel of each of the four manufacturers carried out protein estimation individually by Bradford Method also for the verification of results obtained at NIB with parallel testing performed by NIB scientist. The samples were coded and each manufacturer was given samples of other three manufacturers. The observations obtained at NIB, as mentioned above, were reproducible i.e. the protein content was much lower as compared to the claimed values and by using Bradford method the results were reproducible. (Table 3) Thus, Bradford method may be considered as validated for protein estimation in phenol containing allergen extracts.

Table 2: Observations made for protein content of Cockroach & Moth Bulk allergen extracts by Modified Lowry Method carried out by the technical personnel of manufacturer at NIB

Allergen	*Manufacturer's Analyst ➜	ALC	BP	ACP	CD
Moth	Protein Content (mcg/ml) ➜ claimed by Manufacturer	3112.0 3066.9	1900	1570	68.46
	Results observed at NIB ➜	No conclusion could be drawn since absorbance at different protein concentrations are almost equal.			
Cockroach	Protein Content (mcg/ml) ➜ claimed by Manufacturer	2947.7 2894.1	2800	1490	249.96
	Results observed at NIB ➜	No conclusion could be drawn since absorbance at different protein concentrations are almost equal due to Phenol interference.			

*CD, ALC, ACP, BP four indigenous manufacturers

Table 3: Protein content of Cockroach & Moth Bulk allergen extracts obtained by the technical personnel of manufacturer and NIB scientist using Bradford Method

Allergen	*Manufacturer's Analyst ➜		ALC	BP	ACP	CD
Moth	Protein Content (mcg/ml) ➜ claimed by Manufacturer		3112.0 3066.9	1900	1570	68.46
	Protein content (mcg/ml) obtained by	Technical personnel of the company at NIB ➜	37.55 59.77	19.46	331.4	75.1
		NIB scientist ➜	44.27 60.23	24.62	157.16	66.37

Allergen	*Manufacturer's Analyst ➜		ALC	BP	ACP	CD
Cockroach	Protein Content (mcg/ml) ➜ claimed by Manufacturer		2947.7 2894.1	2800	1490	249.96
	Protein content (mcg/ml) obtained by	Technical personnel of the company at NIB ➜	100.05 110.88	13.91	178.9	243.4
		NIB scientist ➜	87.93 94.20	19.17	194.51	235.76

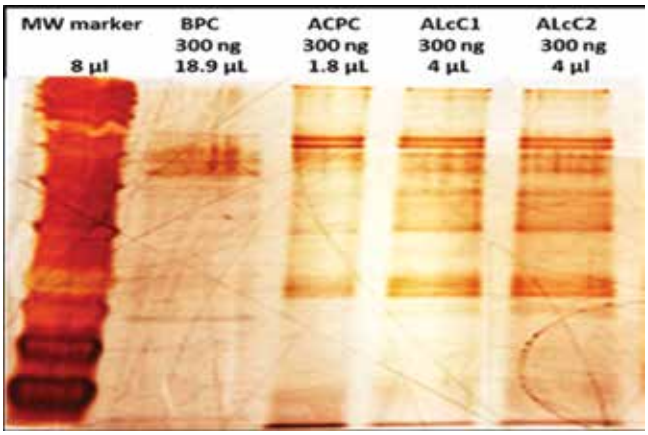
*CD, ALC, ACP, BP four indigenous manufacturers

The verification report with data was shared with individual manufacturer along with the protocol for Bradford Method.

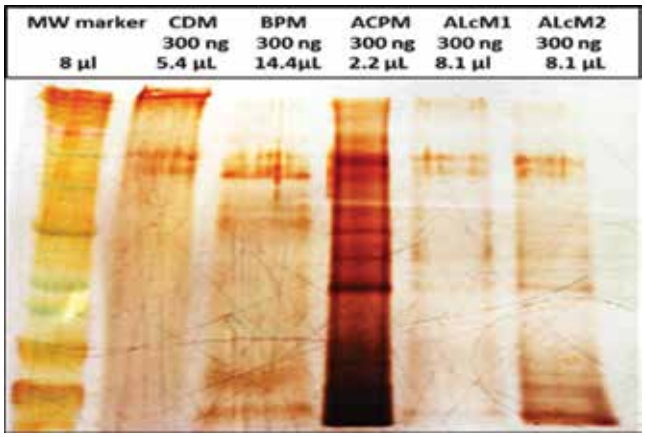
SDS-PAGE

Good resolution of protein bands is observed in SDS-PAGE run on 15% gels (in-house) and 4-20% (readymade gradient gels). Due to low protein content in commercial allergen extracts, the bands were not visible with staining of SDS-PAGE gels with Coomassie, hence, silver staining is required. Though band with silver staining could be seen at all protein concentrations >50 ng/well, best resolution was observed at 200-300 ng/well. (Figure 1)

Figure 1: SDS-PAGE of commercial Allergen extracts after silver staining



Cockroach allergen extracts



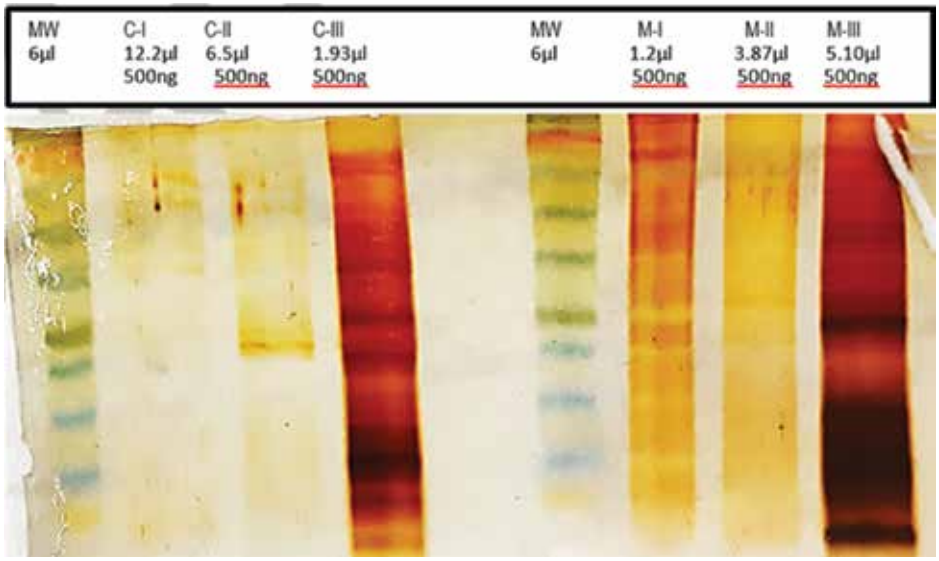
Moth allergen extracts

In February 2019, six more service samples (3 each of Cockroach and Moth allergen extracts) were received from one of the indigenous manufacturer along with results of protein content obtained by both Modified Lowry as well as Bradford Method. The protein content estimations by Bradford method were found to be reproducible except for three samples of Moth as shown in S. No. 4-6 in Table 4.

Table 4: Protein estimation of Cockroach and Moth allergen extracts by Bradford Method

S. No.	Samples received	Code	Protein content claimed by Manufacturer (mcg/ml)		Protein Content obtained at NIB (mcg/ml)
			Modified Lowry	Bradford	Bradford
1	Cockroach male (1:50)	C-I	1427	**35.4**	**34.88**
2	Cockroach male (1:50)	C-II	2095	**80.3**	**88.01**
3	Cockroach (1:10)	C-III	4684	**803.3**	**961.22**
4	Moth (1:50)	M-I	1143	**158.3**	**387.66**
5	Moth (1:50)	M-II	1489	**424.7**	**136.97**
6	Moth (1:10)	M-III	3843	**571.7**	**376.17**

Figure 2: SDS-PAGE of Cockroach and Moth Allergen extracts received from indigenous manufacturer after silver staining



5.4 Expert Meetings Held:

5.4.1 Allergen Product Monograph Modification: The meeting on Addendum/ modification proposed by one importer of allergen products, in Allergen product Monograph published in IP-2018 was convened at Indian Pharmacopeia Commission (IPC) on 27.06.2018. It was resolved that

5.4.1.1 the evaluation procedure mentioned for Bio potency given in the IP-2018 Monograph for Allergen products attracts clinical trials and hence the provision of

potency testing using human subjects may be exempted after receiving due approval from CDSCO.

5.4.1.2 Since the claims of protein contents submitted of Cockroach and Moth Allergen extracts by four Indigenous Allergen Manufacturers are not reproduced at NIB, standardization of protein estimation and SDS- PAGE to be done at NIB on priority.

5.4.2 To undertake Quality Control work of Allergen extracts at NIB: A meeting was convened on "issues related to Quality Control of Bulk Allergen products" at CDSCO-HQ on 07.03.19. The meeting was attended by the officials from CDSCO, IPC, NIB and experts of the field along with the representatives of four indigenous allergen manufacturers.

5.4.2.1 In view of variations observed in protein contents obtained by Modified Lowry method, it was proposed to consider Bradford method for testing of protein content apart from Modified Lowry method as prescribed under IP.

5.4.2.2 Deliberations were also made with indigenous manufacturers on the following issues:

1. stability data of the mother stock solution (1:20),
2. expression of antigenic content in metric system (i.e. mcg/ml or mg/ml) and label claim of the mother stock solution to be aligned based on protein content obtained after Bradford test,
3. to submit self-assessment report to CDSCO as per GMP checklist prepared by NIB,
4. potency testing and
5. consolidated list of 302 indigenously manufactured allergens prepared by NIB

5.5 Laboratory prepared 05 new SOPs for the various test procedures for testing of Acaroid samples, and reviewed 05 SOPs for Quality Control of Allergens.

6 Proposed targets for testing of new biologicals:

NIB is working further in coordination with CDSCO to take up quality evaluation of indigenously manufactured cockroach and moth allergen extracts.

7. Participations in Training/Workshop/Conference:

Name of Scientist	Name of programme	Duration	Place
Dr. Achla Prasad, Scientist Grade-I & I/c DD (QC)	Refresher Training Course for GLP Inspector organized by National GLP Compliance Monitoring Authority (NGCMA): DST	July 16-18, 2018	National Institute of Malaria Research, Dwarka, Delhi
Mr. Brij Bhushan, Junior Scientist	Short course on occupational medicine	February 18- 22, 2019	CCDC, Public Health Foundation of India, Gurugram

8. Outstanding achievements of the lab:

i) Testing and release of Certificate of Analysis of Acaroid samples: For the first time Allergen Testing Laboratory received 06 batches of Acaroid- a modified House Dust Mite allergen product (Aluminium adsorbed) for the purpose of test license on Form- 11. The laboratory standardized all feasible tests and carried out testing of all 06 batches in coordination with CDSCO. The Certificate of Analysis were submitted to the office of DCG (I) for taking further necessary action at their end.

ii) Laboratory has developed modalities for QC procedures for the first time in the country in coordination and guidance of experts of the field. Standardization and verification of Bradford method for protein estimation in phenol containing allergen extracts was done. Laboratory not only standardized and validated Bradford method for protein estimation in phenol containing allergen extracts but also sensitised and gave hands- on exposure to the technical personnel of all four indigenous allergen manufacturers.

iii) Updating monograph on Allergen product.

ANIMAL FACILITY

1. Name of Head:

Dr. Shikha Yadav, Scientist Grade- II, Vet. Pathologist

2. Manpower in the Lab/Division:

i. Name of Scientific Staff:

Dr. Suresh Kumar, Scientist Grade- III, Jr. Vet

ii. Name of Technical Staff

Mr. Parminder Kumar, Jr. Animal Care taker

Mrs. Rajendri Devi, Peon

iii. No(s). of Outsourced Staff : 16

Aim and Scope: Animal Facility is a central support unit for all laboratories of NIB which performs in-vivo tests for quality control evaluation of biologicals received in the institute. The facility also ensures timely availability of laboratory animals for various in-vivo tests by a planned breeding program. The staff of the facility ensure high quality animal husbandry and care that meets the requirements of animal welfare regulations and guidelines provided by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). Animal Facility also provides good quality laboratory animals to other research and education institutes as well as industry at reasonable rates.

3. Scientific Activities Undertaken:

a. Collaboration with other organisations:

Research Projects being continued from previous year:

i. Collaboration with Indian Institute of Technology (IIT), Delhi for project titled "Corneal delivery of antifungal-peptide conjugate encapsulated nanoparticle formulation in an experimental animal model of *Fusarium solani*"

ii. Collaboration with CSIR-Institute of Genomics and Integrative Biology (IGIB), Delhi for project titled "Evaluation of A1 and A2 variants of β casein in cow milk as factors causing allergic airway disease in murine model"

iii. Collaboration with Jaypee Institute of Information Technology (JIIT), Noida for project titled "Cardioprotective effect of Curcumin against drug induced toxicity"

iv. Collaboration with Jaypee Institute of Information Technology (JIIT), Noida for project titled "Identification and Characterization of miRNAs relevant to cardiac diseases"

New Research Project Undertaken w.e.f February 2019

v. Collaboration with IIT, Delhi for project titled "Nanoformulation-Cell penetrating peptide mediated delivery of Riboflavin to ocular cells".

b. Publication(s):

Research paper

Anita Kamra Verma, Ankita Leekha, Vijay Kumar, Imran Moin and **Suresh**

Kumar. Biodistribution and In-vivo Efficacy of Doxorubicin Loaded Chitosan Nanoparticles in Ehrlich Ascites Carcinoma (EAC) Bearing Balb/c Mice. Journal of Nanomedicine & Nanotechnology. 2018; 9:510

Published Chapter:

i. **Suresh Kumar (2018) 'Guidelines for designing experiments with laboratory animals for evaluation of biologicals and food products.'** Yadav A. S., Biswas A. K., Rokade J. J. and Gopi, M (Eds.) Technological advances in value addition as well as production of green and safe poultry products. ICAR sponsored summer school organized by ICAR-Central Avian Research Institute, Izatnagar-243122, Bareilly, (UP), INDIA during September 04 -24, 2018, pp 299-311. (ISBN No. 978-93-5311-841-9).

ii. Poster Presentation by Dr. Shikha Yadav

a) **Shikha Yadav**, Nakul Dev S Yadav, Mohammed Faruq, VP Singh, Pankaj Sharma (2018), **Evaluation of A1 and A2 variants of β casein in cow milk as factors exacerbating allergic airway disease in murine model.**

Presented in 8th Asian Federation of Laboratory Animal Science (AFLAS) Associations Congress 2018, held on November 29- December 01, 2018 at Hotel ITC Gardenia, Bangalore.

b) Rohira H, Shankar S, Shah S.G, **Yadav S**, Jain A, and Chugh A (2018). **Development of murine model of Fungal Keratitis to test the antifungal efficacy of CPP conjugated Natamycin.**

Presented by co-author in: **35th European Peptide Symposium, Dublin, Ireland** held on August 26-31, 2019.

c) Dr. Shah S G, Rohira H, Shankar S, Dr. Chugh A, **Dr. Yadav S**, Dr. Poojary A. **Mice model of *Fusarium* keratitis: lessons learnt.** Keracon 2018, Presented by co- author in national meeting of Cornea Society of India, November 30–December 2, 2018, New Delhi.

d) Dr. Shah S G, Rohira H, Shankar S, Dr. Chugh A, **Dr. Yadav S,** Dr. Poojary A. **Novel CPP conjugated Natamycin in experimental Fusarium keratitis: an in-vivo animal study.** Presented by co-author in annual meeting of Indian Eye Research group, Association for Research in Vision and Ophthalmology – India, July 27-29-2019, Hyderabad.

iii. Paper presented in Conference and abstracts published

a) Dr. Shah S G, Rohira H, Shankar S, Dr. Chugh A, **Dr Yadav S**, Dr. Poojary A (2018). Clinical efficacy of Novel antifungal in an animal model of Fusarium spp. keratitis. Annual Conference of the Maharashtra Ophthalmological Society, October 26-28, 2018, Aurangabad, Maharashtra, India- presented by co-author.

b) Awarded Best Paper Award

Kumkum Sharma, Aditi Jain, **Shikha Yadav**, Surinder Singh, Vibha Rani (2019); Curcumin as a Potential Molecule in Cardio-Oncology, in the "International conference on advancements in Bio-sciences and Biotechnology" held from January 31 to February 2, 2019 at Jaypee Institute of Information Technology, Noida.

Abstract published in Asian Journal of Pharmaceutical and Clinical Research, Vol. 12, Issue 2, 2019, pp- 176.

c) Sharad Saxena, Aditi Jain, **Shikha Yadav**, Surinder Singh, Vibha Rani (2019);Protective Effects of Curcumin Against Norepinephrine Induced Cardiac Stress", in the "International conference on advancements in Bio-sciences and Biotechnology" held from January 31 - February 2, 2019 at Jaypee Institute of Information Technology, Noida.

Abstract published in Asian Journal of Pharmaceutical and Clinical Research, Vol. 12, Issue 2, 2019, pp- 177.

4. Testing of Biologicals:

In-vivo QC evaluation tests i.e. Abnormal Toxicity Test, Pyrogen Test, Potency & Identity Assays & other miscellaneous tests have been performed on a total of 1211 samples of different biologicals forwarded by the laboratories of NIB. A total of 489 samples were tested for Abnormal Toxicity, 601 samples for Pyrogen, 83 samples for Identity and Potency Assay, 38 samples for miscellaneous tests. During the year 2018-19, a total of 13,800 animals were provided by the Animal facility of which 10031 animals were used to conduct the in-vivo QC tests, 208 were used for research and 3561 were sold to other institutes, details of which are provided in Table I.

Table I: Details of Animals used and supplied in 2018-19

S. No.	Species	Strain	Animal Provided in the Year 2018-19			
			QC Testing	Research	Sold to outside institutes	Total
1.	Mice	Swiss Mice	6803	-	1140	7943
		Balb/c/c	1820	154	386	2360
2.	Rats	SD Rats	308	24	962	1294
		Wistar Rats	-	-	1057	1057
3.	Guinea Pigs	Duncan Hartley	1022	-	16	1038
4.	Rabbits	New Zealand White	78	30	-	108
Total			10031	208	3561	
Grand Total			**13800**			

4.1 Approval of protocols by Institutional Animal Ethics Committee (IAEC): All the experiments involving animals have to be approved by the IAEC, constituted by CPCSEA. In the year 2018-19, two IAEC meetings were organized in which 43 ongoing protocols and 5 new protocols were reviewed and approved by the committee. The facility maintained all relevant records to ensure compliance to the approvals granted by the committee and progress under each approved protocol was put up for review by IAEC regularly in each meeting.

4.2. Abnormal Toxicity Test is conducted to determine the presence of any toxic substance in biological products intended for parenteral administration. The details of number of samples of various products and number of animals used are given in Table II.

Table II: Details of numbers of samples of various products & various animals used for Abnormal Toxicity Test

Laboratory	Name of Product	No. of Samples 2018-19	No. of Animals used	
			Mice	G. Pigs
Blood Products	Human Albumin	282*	1410	**564**
	Dried Human Antihemophilic Fraction (Factor VIII)	87*	435	**174**
	Human Specific Immunoglobulin (I/M) (SPIG-IM)	49	245	**98**
	Human Normal Immunoglobulin (I/M) (IGIM)	15	75	**30**
	Plasma Protein Fraction (PPF)	4*	20	**8**
	Human Rabies Immunoglobulin (RIg)	15	75	**30**
Enzymes & Hormones	Human Chorionic Gonadotropin (hCG)	1	5	-
	Streptokinase (STK)	3	15	-
	Urokinase	4	20	-
Vaccines	Haemophilus influenza type b conjugates	2	10	**4**
	Human Hepatitis B Immunoglobulin (HBIg)	16*	80	**32**
	Measles, Mumps and Rubella (MMR)	8	40	**16**
	Japanese Encephalitis Vaccine (JENVAC)	2	10	**4**
	Rubella Vaccine (R-VAC)	1	5	**2**
	Total	**489**	**2445**	**962**

*Including repeat testing

4.3 Pyrogen Test is conducted to detect the presence of any pyrogenic substance in the biologicals and vaccines intended for parenteral administration and are prescribed in the Indian and other Pharmacopoeia. The details of number of samples of various products tested for pyrogenicity are provided in Table III. A total of 78 rabbits were used in these tests.

Table III: Details of different products tested for Pyrogen Test (2018-19)

Laboratory	Name of Product	No. of samples 2018-19
Blood Products	Human Albumin	**274**
	Dried Human Antihemophilic Fraction (Factor VIII)	**102**
	Normal Immunoglobulin (I/V) (IGIV)	**73**
	Normal Immunoglobulin (I/M) (IGIM)	**12**
	Human Specific Immunoglobulin (I/M) (SPIG-IM)	**49**
	Human Specific Immunoglobulin (I/M) (SPIG-IV)	**03**
	Plasma Protein Fraction (PPF)	**03**
	Factor-IX	**19**
	Human Rabies Immunoglobulin (RIg)	**15**

Viral Vaccine	Human Hepatitis B Immunoglobulin (HBIg)	**14**
	Cell Culture Rabies Vaccine (CCRV)	**25**
	Human Hepatitis B Vaccine (HBV)	**08**
	Haemophilus influenzae type b conjugates	**2**
	Japanese Encephalitis Vaccine	**2**
	Total	**601**

4.4 Identity and Potency Assay is done to establish the identity and determine the strength and activity of the products before their use in humans. The details of different product tested for Potency assay are provided in Table IV.

Table IV: Details of different products tested for Potency Assay (2018-19)

Laboratory	Name of Product	No. of samples (2018-19)	No. of Animals used	
			Rats	Mice
Enzyme & Hormone	hCG	1	32	-
	r-FSH*	2	60	-
	HMG-LH*	3	108	-
	HMG-FSH	3	108	-
Blood Products	Human Rabies Immunoglobulin (RIg)	12	-	1682
Viral Vaccine	CCRV	23	-	2296
	Japanese Encephalitis Vaccine (JEV)	2	-	100
	Hepatitis B Vaccine (HBV)	2		220
Recombinant Product	Recombinant Erythropoietin (r EH)	35	-	1600
	Total	**83**	**308**	**5898**

*Including repeat testing

Table V: Miscellaneous tests performed in Animal Facility

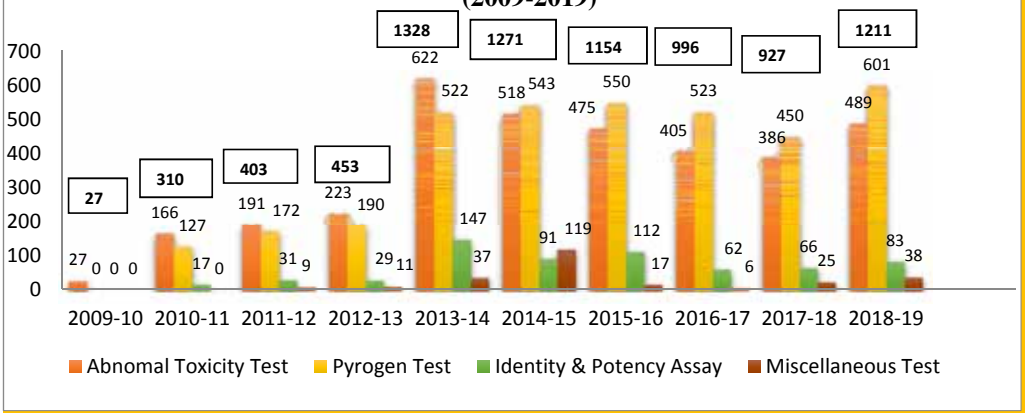
Name of test	No. of Samples	No. of Animals used	
		Mice	G. Pigs
Virulent Mycobacterium of BCG Vaccine	5	-	30
Skin Reactivity for BCG Vaccine	5	-	30
Virus Inactivation for CCRV Vaccine	28	280	
Total:	38	280	60

5. Trend in volume of work as compared to the previous years:

Quality Control Testing

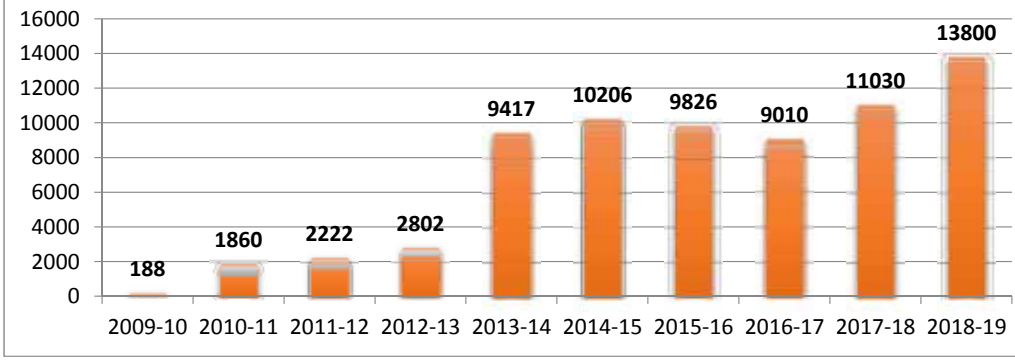
There has been an increase in number samples received and tested at Animal Facility as compared to previous years and the details are depicted in Figure 1 below:

Fig 1: Total Samples Received for *in-vivo* Quality Control Tests (2009-2019)



Further, the number of animals provided by Animal Facility has also increased compared to the previous years and the details of same are given in Figure 2.

Fig 2: Number of Animals Provided by Animal Facility (2009- 2019)



6. Proposed target for testing of new Biologicals being undertaken:

As a central facility, Animal Facility will take up mandatory in-vivo testing required for new products taken up by any laboratory of NIB.

7. Participations in Training/ Workshop/ Conference

7.1 Dr. Shikha Yadav, Scientist Grade-II & Head, Animal Facility

7.1.1 Delivered a talk on "Refinement in Animal Experimentation: Current Scenario and Future Prospective" on April 29, 2018 in the "National Symposium on New Paradigm in Veterinary Medical Research and Management of Laboratory and Farm Animals: Scientific, Ethical & Welfare Perspectives", organized at Department of Animal Husbandry, Govt. of Uttar Pradesh, Lucknow, UP.

7.1.2 Invited as a resource person in the "Workshop for Handling and Care of Laboratory Animals" at Jawaharlal Nehru University (JNU), Delhi from May 28- June 2, 2018 wherein lectures were delivered on critical topics like perioperative care, anaesthesia and analgesia in laboratory animals, refinement of experiments and severity assessment with case studies, protocol preparation for ethical approval, conduct hands on training and in the end assist in evaluation and assessment of participants of the workshop.

7.1.3 Invited as a Faculty at the Federation of European Laboratory Animal Science Associations (FELASA) an Accredited training program on "Certificate Course in Laboratory Animal Science" at Tamil Nadu University of Veterinary and Animal Sciences (TANUVAS), Chennai from September 27-29, 2018 and delivered lecture on "Severity Classification, humane end points and search for alternatives and final evaluation of participants. On case studies on ethical approval of Research Projects.

7.1.4 Invited as resource person by Dr. Uma Dhawan, Department Co-ordinator, DBT-Star College Scheme, Department of Biomedical Science, Bhaskaracharya College of Applied Sciences (BCAS), University of Delhi as faculty in the workshop on "Handling and Care of Laboratory Animals" to deliver talk on "A Practical & Effective Approach to Refine Animal Experiments for Good Animal Welfare and Good Science "on November 1, 2018.

7.1.5 Invited to deliver a talk on "Bio ethics in Animal Research: A need or Compulsion" in National Workshop on "Bioethics in Research" at Maharishi Dayanand University (MDU), Rohtak, Haryana on November 15, 2018.

7.1.6 Invited for guest lecture on "Importance of 3Rs and practical application in research experiments with emphasis on refinement" on March 13, 2019 in Carrier Enhancement Programme (CEP) Course titled "Alternative to Animal Research" for the benefit and awareness of DRDO Scientists/ Technical personnel involved in animal research, which was organized at Institute of Nuclear Medicine & Allied Science (INMAS), Ministry of Defence, Government of India.

7.1.7 Invited as resource person in "Workshop for Handling and Care of Laboratory Animals" at JNU, Delhi from February 4-7, 2019 to deliver lectures on reproductive biology of rodents, perioperative care, anesthesia and analgesia in laboratory animals and also assist in conducting hands on training in basic bio methodologies in mice.

7.1.8 **Meetings Attended as Expert or IAEC Member**

Nominated by Executive Director, Translational Health Science & Technology Institute (THSTI), Faridabad (DBT, Ministry of Science and Technology) in the High Power Purchase Committee to provide

recommendations for procurement of Automated Washer for Cage, rack and bottles for their Animal Facility for which meeting was held on April 12, 2018.

7.1.9 Nominated as External Expert by Institute of Liver and Biliary Sciences (ILBS), Delhi in committee comprising of Animal House Experts from esteemed academic institutes for facilitating the process of operationalizing its new Animal Facility in Phase II building in Vasant Kunj, Delhi for which meeting was held on December 21, 2018.

7.1.10 Nominated as member of the Assessment Committee for Assessment of Technical Staff of CSIR-IGIB, Delhi on March 15, 2019 at CSIR-IGIB, Mathura Road Campus, Delhi.

7.1.11 Nominated by Competent Authority of JNU, Delhi as External Expert in the committee for Development/ Fabrication of Laboratory to set up clean room facility for housing Athymic nude mice, Transgenic mice and Rabbits and its meeting was convened on March 29, 2019 at School of Life Sciences, JNU, Delhi.

7.2 Dr. Suresh Kumar, Scientist Grade-III

7.2.1 Delivered a lecture on "Guidelines for designing experiments with healthy laboratory animals for evaluation of biologicals" on February 27, 2019 in a workshop on "Ethical Contemplation of Animal Resources for Experimentation (WeCARE-2019)" organized at CSIR- Institute of Microbial Technology (IMTECH), Chandigarh, Haryana.

7.2.2 Delivered guest lecture on "Current practices & technologies for scientific management / experimentation of lab animals & resources for alternatives & use in drug development" on March 14, 2019 in Carrier Enhancement Programme course titled "Alternative to Animal Research" organized at Institute of Nuclear Medicine & Allied Science (INMAS), Ministry of Defence, Government of India, Delhi.

7.2.3 Delivered a guest lecture on "Experimental Design: Calculation of Animal Number' on March 28, 2019 in National Seminar on 'Laboratory Animal Experimentation", which is being organized at Centre for Medical Biotechnology,

Maharishi Dayanand University, Rohtak, Haryana.

7.2.4 **Meetings Attended as Expert or IAEC Member**

a) Invited as External Expert by CSIR-Recruitment & Assessment Board in the CSIR- Assessment Committee constituted in the area of Bioscience & Biotechnology at CSIR- National Botanical Research Institute, Lucknow, Uttar Pradesh from January 15-17, 2019 for the assessment of their Scientists from various CSIR Institutes.

b) Attended the Institutional Animal Ethics Committee (IAEC) meeting as a CPCSEA nominee on November 20, 2018 at PT. BD Sharma PGIMS, PT BD Sharma University of Health Science, Rohtak, Haryana.

c) Nominated by Committee for the Purpose of Control and Supervision of

Experiments on Animals (CPCSEA), Ministry of Environment, Forest and Climate Change, Government of India as member of Institutional Animal Ethics Committee (IAEC) in the Institutes mentioned in Table VI:

Table VI: Nomination as Member in IAEC committee of various institutes

S. No.	Name of the Institute	Address	Nominee Type
1.	National Research Centre on Equines	National Research Centre on Equines, Sirsa Road, Hisar – 125 001, Haryana	Scientist from outside of the Institute
2.	G.V.M. College of Pharmacy	G.V.M. College of Pharmacy, Murthal Road, Sonepat - 131 001, Haryana	
3.	Maharshi Dayanand University	Maharshi Dayanand University, Near Delhi Bypass, Rohtak – 124 001, Haryana	
4.	Department of Pathology PT. B.D.Sharma PGIMS, Rohtak	Department of Physiology PT.B.D. Sharma PGIMS, , Rohtak - 124 001, Haryana	Main nominee
5.	Advanced Institute of Pharmacy	Advanced Institute of Pharmacy, 70 K.M., Delhi Mathura Road, NH-2 Village Aurangabad, Palwal, Haryana - 121 105	Link Nominee
6.	Shaheed Hasan Khan Mewati Govt. Medical College	Director office SHKM Govt. Medical College. Nalhar Nuh Mewat, Haryana	

8. Outstanding achievements of the lab:

a) **Annual inspection** of the Animal Facility which is a regulatory requirement was done by IAEC on November 19, 2018. The inspection team in its report to CPCSEA strongly recommended the Animal Facility for further approval as it is an excellent facility meeting all CPCSEA requirements.

b) **In-vivo QC tests included in scope of NABL (ISO:17025:2005):** All in-vivo tests namely abnormal toxicity test, pyrogen test, identity and potency assays being performed in Animal Facility have been included in the scope of Animal Facility participated in the annual external audit by NABL on June 9-10, 2018. There was no nonconformity reported for Animal Facility thus reflecting the quality of testing procedures.

c) **Participation in Occupational Health and Safety Assessment Series (OHSAS) 18001 external audit** performed by *Bureau Veritas* on February 01, 2019. No Non Conformity raised for Animal Facility thus ensuring that a rigorous health and safety policy is in place which protects staff of Animal Facility against possible occupational risks and reduces the likelihood of accidents in the workplace.

d) **Commitment of NIB for implementation of 3R's**

As commitment towards the 3R's,

the scientists of Animal Facility and laboratories worked in close coordination to reduce the number of animals used in the quality control testing by testing more than one batch of same product at the same time with a common reference or control group. This enabled us to save 1000 laboratory animals in the year 2018-19, the details of which are provided Table VII;

Table VII: Summary of animals saved in various tests

S. No.	Details of QC Test	Number of Animals Saved
1.	Potency Assay for Rabies Immunoglobulin (RIg)	478 mice
2.	NIH Potency assay for Rabies Vaccine	372 Mice
3	Potency assay for Recombinant Erythropoietin (r EH)	150 Mice
Total		**1000 Mice**

STERILITY TESTING LABORATORY

1. Name of Head:

Dr. J. P. Prasad, Scientist, Grade-I

2. Manpower in the Lab/Division:

I. Name of Scientific Staff:

Sh. Kallol Saha, Junior Scientist

II. Name of Technical Staff:

Sh. Narender Kumar, Lab Assistant.

III. No(s) of Outsourced Staff- 03

3. Scientific Activities Undertaken:

Molecular characterization of environmental isolates:

Environment monitoring of classified area and isolation of microbes followed by biochemical and molecular characterization using DNA extraction, RT-PCR, Gel electrophoresis and DNA Sequencing. Till now the lab has isolated and identified *Bacillus megaterium and Bacillus aryabhattai* in the classified area.

Validation of antibiotics and antimicrobial products(having high chemical compatibility) with the help of red and green filter devices.

4. Testing of Biologicals:

Table 1: SUMMARY OF VARIOUS BIOLOGICALS TESTED FOR STERILITY

Name of Biological Tested	Type of Biologicals	No. of batch received and evaluated	No. of batches found to be of Standard Quality	No. of batches not found to be of Standard Quality
Recombinant Products	Insulin, Interferon, Erythropoietin, GSF	125	125	Nil
Blood Products	Albumin, Human Normal Immunoglobulin, Antithrombin, coagulation Factor	611	611	Nil
Enzymes & Hormones	Streptokinase, hCG, FSH, HMG, urokinase, Heparin	17	17	Nil
Viral Vaccines and Immunosera	Rabies Vaccine, MMR, Measles, Rubella, HPV, Hep. B Immunoglobulin & Rabies Immunoglobulin	49	49	Nil
Therapeutic Monoclonal Antibody	Trastuzumab, Bevatas, Bevacizumab & Rixubis	16	16	Nil
Allergen	Cockroach extract , Moth extract	18	18	Nil

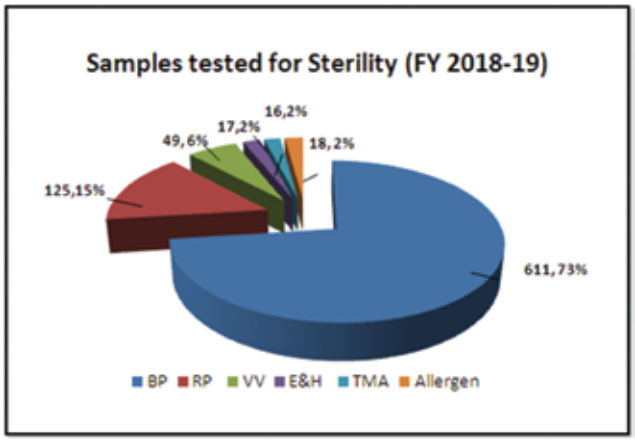


Fig 1: Different product types referred for Sterility test in Financial Year 2018-19.

5. Trend in volume of work as compared to previous year (2017-2018) including examination of technical dossiers: A summary of samples received and tested for sterility is depicted in Fig2 and Fig 3 respectively.

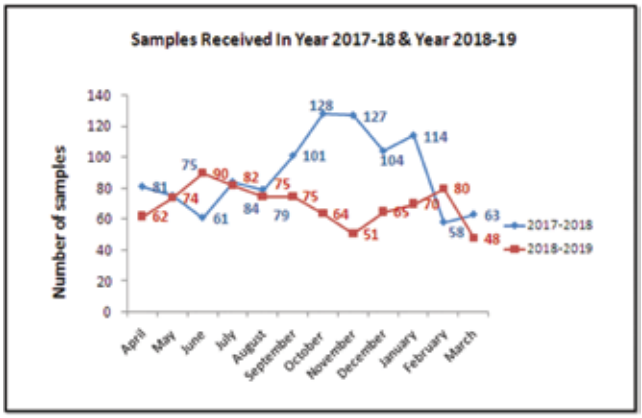


Fig 2 Samples received in year 2018 - 2019

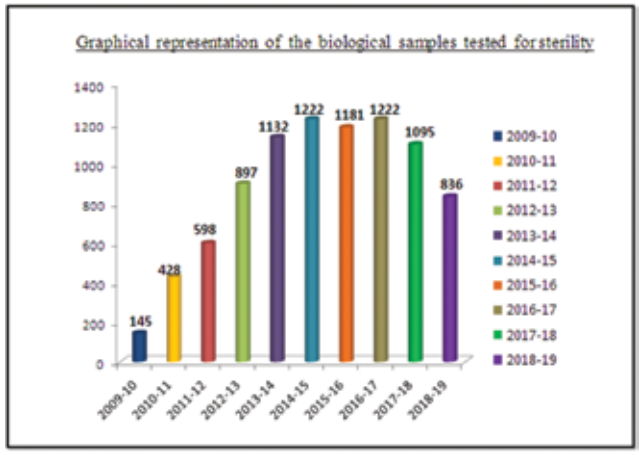


Fig 3 Samples tested for sterility during 2018-2019

6. Proposed targets for testing of new Biological and Biotherapeutics being undertaken:

This depends on different product referred through CDSCO and other regulatory bodies to NIB.

7. Participation in Training/ Workshop/ Conference:

Mr. Kallol Saha and one outsourced staff participated in One Day seminar on Next Generation DNA Sequencing organized by Thermo Fisher Scientific at Hotel Pullman, New Delhi on 07.10.2018.

8. Outstanding achievements of the Lab:

Coordination and establishment of Sterility Testing Laboratory area as per WHO & ISO guidelines.

RENDERING TECHNICAL EXPERTISE THROUGH JOINT INSPECTIONS

The Institute provides technical expertise for enforcement of implementing standards in India through joint inspections of (i) manufacturing premises in coordination with Central Drugs Standards and Control Organization (CDSCO), (ii) GLP- Laboratories conducted by National GLP Compliance Monitoring Authority (NGCMA) DST, and (iii) Animal Facilities conducted by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA).

cGMP inspections

1. Two Scientists from Blood Products Laboratory– Dr. J. P. Prasad, Scientist Grade-I & Head and Mrs. Y. Madhu, Scientist Grade-III, nominated as subject expert for inspection of M/s Hemarus Therapeutics Limited, Shameerpet, Hyderabad on September 10-11, 2018 for renewal of license in Form -28 E (Blood Products).

2. Two Scientists from Recombinant Products Laboratory– Dr. Charu M. Kamal, Scientist Grade-II and Dr. Meena Kumari, Scientist Grade-III, participated as experts with representatives of CDSCO and state FDA in joint cGMP inspection of M/s Virchow Biotech Pvt Ltd., Telangana on July 18-19, 2019 for Revalidation of Certificate of Pharmaceutical Product (COPP) as per WHO GMP scheme for r-DNA based products.

GLP inspections

3. Dr. Achla Prasad, Scientist Grade-I & I/c DD (QC) participated as a member of Good Laboratory Practice (GLP) inspections team constituted by National GLP Compliance Monitoring Authority (NGCMA); DST as under:

S. No.	Name of facility	Type and duration of inspection	
1	Dabur Research Foundation, Ghaziabad	Surveillance- cum- extension in scope	Nov 29-30, 2018
2	Accupres Res. Lab Pvt. Ltd., Ahmedabad	Pre-inspection	Dec 7-8, 2018
3	Diligence Bio Pvt. Ltd., Pondicherry	Final Inspection	Feb 5-6, 2019

CPCSEA inspections

4. Dr. Shikha Yadav, Scientist Grade-II and Head Animal Facility was Nominated by CPCSEA (Ministry of Environment, Forests and Climate Change) as Member (Scientist from outside the Institute) of Institutional Animal Ethics Committee (IAEC) of

a) Ram-Eesh Institute of Vocational and Technical Education, Greater Noida- attended IAEC meeting for ethical review of research protocols and performed Annual Inspection of their Animal Facility on May 19 2018 and on October 26, 2018.

b) Noida Institute of Engineering & Technology (NIET) Pharmacy Institute, Greater Noida- attended IAEC Meeting for ethical review of research protocols

and performed Annual Inspection of their Animal Facility on May 26, 2018.

c) IEC College of Pharmacy, Greater Noida- attended their Institutional Animal Ethics Committee (IAEC) meeting as a CPCSEA main nominee and also performed Inspection of their Animal facility along with other members on January 24, 2019.

5. Dr. Shikha Yadav, was selected by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) as an Adhoc Specialist (Site Visitor). The required permission for accepting the said offer from AAALAC International, USA was granted to her by Secretary (HFW) on May 4, 2018. She was invited by Dr. Gary Borkowski, Global Director, AAALAC International, USA as an Adhoc Specialist to assist AAALAC International in conducting site visits (audits) of 2 Animal Facilities (units) in Hyderabad on 01.03.2019 and 05.03.2019 to assess their institutional animal care and use programs for AAALAC accreditation purposes.

6. Dr. Suresh Kumar, Scientist Grade-III attended the IAEC meeting and performed annual inspection on

a) December 5, 2018 as CPCSEA- Link Nominee at Kirori Mal College, University of Delhi.

b) March 9, 2019 as CPCSEA- Scientist from Outside Institute at GVM College of Pharmacy Murthal Road, Sonipat, Haryana.

QUALITY MANAGEMENT UNIT

1. Name of Head :

Dr. J. P. Prasad, Scientist Grade-I & Quality Manager

2. Manpower in the Lab/ Division:

I. Name of Scientific staff

Mr. Neeraj Malik, Scientist Grade-II (Since 29.11.2018 - till date)

Mr. Subhash Chand, Scientist Grade-III & Deputy Quality Manager

Md. Daud Ali - Junior Scientist & Deputy Quality Manager

Dr. Anoop Kumar, Junior Scientist & Deputy Quality Manager (01.08.2018-till date)

Ms. Archana Sayal, Junior Scientist & Deputy Quality Manager (01.08.2018-till date)

Mr. Brij Bhushan, Junior Scientist

II No(s). of Outsourced Staff: 03

3. Aims and scope of the Unit:

3.1 Quality Management Unit (QMU) of NIB ensures the best global practices for quality evaluation of various biologicals being tested at NIB. QMU serves as a laboratory quality management tool with the following objectives to ensure:

3.1.1 Appropriate infrastructure, encompassing the organizational structure, procedures, processes, personnel and resources;

3.1.2 Taking systematic actions necessary to ensure adequate confidence that quality evaluation at NIB will satisfy given requirements for quality as per the various pharmacopoeial monographs/manufacturer's protocol.

3.2 The unit ensures inter-relationship between the laboratories and other technical & administrative departments for compliance of technical and management requirements. In addition, it ensures the vertical relationship between pharmacopoeial body and the regulatory system. The objective of Quality Management Unit is continuous improvement in the following areas:

3.2.1 Maintenance, Sustenance & Enhancement of Scope for NABL accreditation in accordance to ISO/IEC 17025: 2005 requirements & BS OHSAS 18001:2007.

3.2.2 Periodic Assessment by Accreditation/ Certification body.

3.2.3 Preparation and upgradation of Quality System Documentation.

3.2.4 Conducting periodical Internal Quality Audits as when required.

3.2.5 Conducting and facilitating the Management Review Meetings with technical managers and top management.

3.2.6 Harmonizing the quality control systems and testing among various product testing labs at NIB and assuring the quality of test results.

4. Accreditation and Certification Activities

4.1 Certification as per BS OHSAS 18001:2007

BS OHSAS 18001:2007 is the internationally recognized standard for Occupational Health and Safety Management Systems

(OHSAS). NIB acquired the BS OHSAS 18001:2007 certification (Certificate No. IND 18.8672U/HS) on 24.05.2018 valid up to 11.03.2021.

The first annual surveillance audit for management system of NIB in accordance to BS OHSAS 18001:2007 was successfully completed on 01.02.2019.

4.2 Accreditation as per ISO/IEC 17025: 2005

4.2.1 ISO/IEC: 17025:2005 (General requirements for the competence of testing and calibration laboratories) is the standard used by testing and calibration laboratories that enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work.

4.2.2 Enhancement of Scope for ISO/IEC 17025: 2005 Requirements

The scope of Accreditation has been enhanced in discipline of Chemical & Biological tests in seven different categories namely.

i) Biotechnology Derived Products

ii) Enzymes

iii) Hormones

iv) Biophrarmaceuticals

v) Immunological products

vi) Vaccines

vii) Other Specified Tests which include Biochemical Kit

4.2.3 Re-Assessment by NABL

Re-assessment by NABL Team of Assessors was held on 09.06.2018-10.06.2018 for renewal and accreditation of scope for various chemical and biological test parameters. The Institute obtained the Accreditation on 16.08.2018 for the following 10 product testing laboratories. The trend of three cycles is shown in Table 1 and the authorised signatories in the approved scope in Table 2:

Diagnostics

i. Biochemical Kit Laboratory

ii. Blood Reagent Laboratory

iii. Immunodiagnostic Kit & Molecular Diagnostic Laboratory

Therapeutics

iv. Blood Products Laboratory

v. Enzyme & Hormone Laboratory

vi. Recombinant Product Laboratory

vii. Therapeutic Monoclonal Antibody Laboratory

viii. Vaccine Division

Facilitating Units

ix. Sterility Testing Laboratory

x. Animal Facility

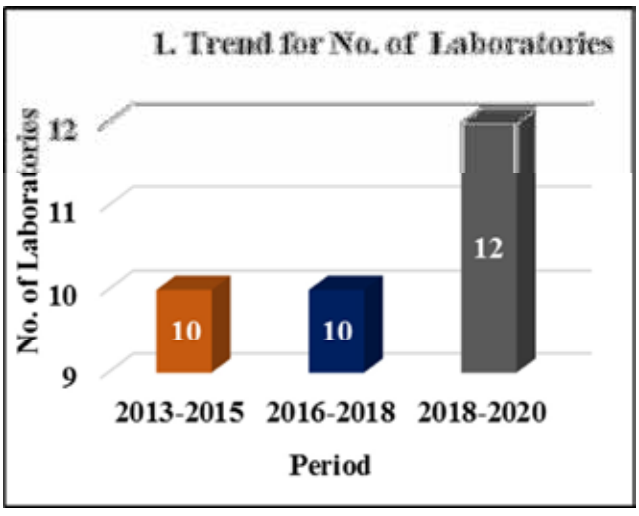
Table 1: Trend in Accreditation of Biological & Chemical tests for ISO/IEC 17025: 2005 (2013-2020)

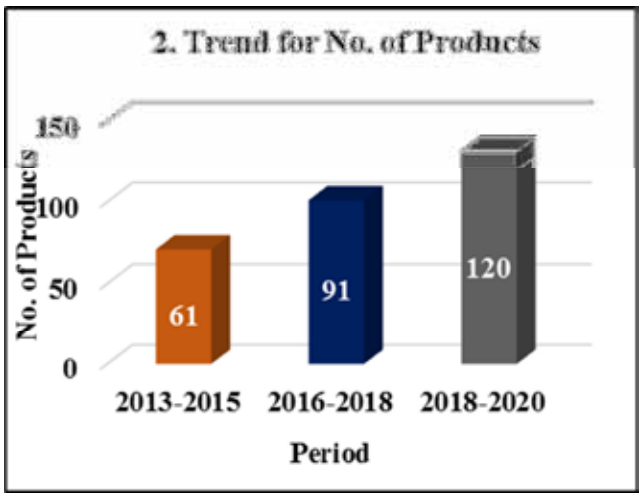
Areas	Period		
	2013-2015	2016-2018	2018-2020
Laboratories	10	10	12
Products	61	91	120
Tests (Biological and Chemical)	70 (34+36)	226 (86+140)	285 (125+160)

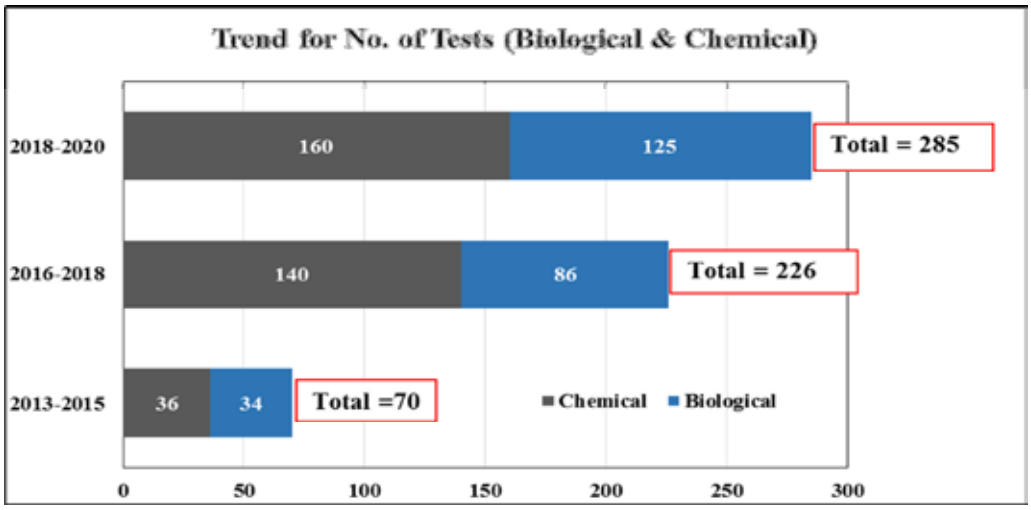
Table 2: Authorized signatories approved (N = 37) during the onsite audit in disciplines of Biological and Chemical Tests

S. No.	Area	Laboratory	Discipline of Testing	Authorized Signatories 2018-2020
1.	Diagnostics	Biochemical Kit	Biological	04
		Blood Reagent	Chemical & Biological	04
		Immunodiagnostic Kit & Molecular Diagnostic	Biological	06
2.	Therapeutics	Blood Products	Chemical & Biological	06
		Enzymes & Hormones	Chemical & Biological	02
		Recombinant Products	Chemical & Biological	05
		Therapeutic Monoclonal Antibody	Chemical & Biological	02
3.	Vaccines	Bacterial Vaccine	Chemical & Biological	02
		Viral Vaccine	Chemical & Biological	03
4.	Facilitating Units	Sterility	Biological	01
		Animal Facility	Biological	02

Graphs depicting enhancement of NABL Scope







5 Quality System Documentation

5.1 Review & Revision of Standard Operating Procedures (SOPs) and Manuals

Alert Calendar (Apr 2019- Mar 2020) for timely revision/ review of SOPs was issued to all areas of Diagnostic, Therapeutic, Vaccine Laboratories and Support/ Facilitating Units.

5.2 Presently the Quality Management System of NIB is strengthened with quality documentation procedures as summarized below (Table 3):

Table 3: Quality Documentation Procedures

S. No.	Laboratory / Unit Name	Number of Manual/ SOPs
	Manual	**N = 5**
1.	Quality Manual-Apex Quality document	01
2.	Biosafety Manual	01
3.	Purchase Manual	01
4.	BS OHSAS 18001:2007 Manual • Level I Document • Level II Document	02
	Management & Technical System Procedures	
5.	Standard Operating Procedures (SOPs) of various Product Testing Laboratories	**N = 746**
6.	QMU Approved Formats	1074

5.3 Equipment Maintenance

Authorized list of equipment usage is being updated timely with the details of preventive maintenance e.g. AMC / Calibration done with due date. An Alert Calendar for Fixed and Moveable Equipment for Apr 2019- Mar 2020 has been released to all users of the laboratory and the Stores & Purchase Unit which includes activity for: a) AMC, b) Validation and c) calibration. These services are rendered by OEMs of the equipment and NABL accredited agencies under seven

categories viz., Temperature Controlled, Mass/ Volume, UV – Vis Absorbance, Potentiometer Measurements, Centrifuge, Tele-thermometers, and Mercury Based Thermometers etc.

6 Annual Internal Quality Audit :

The annual internal quality audits were conducted as per the requirements of ISO/ IEC 17025:2005 & BS OHSAS 18001:2007 by the Quality Management Unit.

6.1 The Internal Audit as per ISO/IEC 17025:2005 was conducted in two phases to cover all the areas and laboratories

6.1.1 Phase 1 internal audit (Id: *Internal Audit- P-I/ 2018*) was conducted during 29.08.2018-31.08.2018 for the following areas:

6.1.1.1 Therapeutic Product Testing laboratories (N=04) namely Blood Products Lab, Enzyme & Hormone Lab, Recombinant Product Lab, Therapeutic Monoclonal Antibody Lab

6.1.1.2 Support Units (N=2) namely Sterility, and Animal Facility

6.1.1.3 Technical Units (N=3) Quality Management Unit, Sample Receipt & Report Dispatch Unit, Stores & Purchase Unit.

6.1.2 Phase 2 internal audit (Id: *Internal Audit- P-II 2018*) was conducted during 24.09.2018 – 26.09.2018 for the following areas:

6.1.2.1 Diagnostic Product Testing laboratories (N=03) namely Biochemical Kit Lab, Blood Reagent Lab, Immunodiagnostic kit & Molecular Diagnostic Laboratory.

6.1.2.2 Vaccine Division (Viral Vaccine & Bacterial Vaccine)

6.2 The internal audit as per the requirements of BS OHSAS 18001:2007 was held on 31.12.2018. The internal audit for OHSAS Standard ensures that OH&S management system is conducted at planned interval for the section Administration, Guest House, Hostel, Canteen, IBSC, QMU & Engineering Section.

7 Management Review Meeting

A review of the management system was conducted on 30.01.2019 (ISO/IEC 17025:2005 & BS OHSAS 18001:2007) using a formal agenda whose action were to be taken in time bound manner.

8 Trainings/ workshop/ conferences Organized

8.1 Trainings

A Training Calendar has been prepared in coordination with the Training Unit, NIB, for identifying training needs and providing training to the personnel. The training programme is relevant to the present and anticipated tasks of the laboratory with respect to the requirements of ISO /IEC 17025:2015 and On-Job-Specific activities. Scientific and technical persons working in the areas of product testing laboratories, Engineering unit, Stores & Purchase and Quality Management Unit, have been trained in the areas, as enlisted below in Table 4 (Total No. of Internal training=12)

Table 4: Management Systems– LQMS, Occupational Health & Safety: Internal Trainings Organized at NIB

S. No.	Name of Programme	Programme Attended By	Duration	Organizer
1.	Training on Loading and Unloading of the material in the Autoclave for sterilization & decontamination	Lab Attendants (N=28)	1 day (02.04.2018)	Quality Management Unit & IBSC
2.	Training on Handling & Restraining of the Animals	Animal Attendants (N=14)	1 day (02.04.2018)	Quality Management Unit & IBSC
3.	Training on Specific Guidelines for chemical testing laboratories as per NABL 103	Scientific Staff (N=30)	1 day (29.06.2018)	Quality Management Unit
4.	Emergency Evacuation Drill	All Staff (N=362)	2 day (06.09.2018 & 07.09.2018)	Quality Management Unit & Engineering Unit
5.	Training on Internal quality checks for assuring the quality of test results	Scientific Staff (N=28)	1 day (08.10.2018)	Quality Management Unit
6.	Training on Writing of Amendment & Review of standard operating procedures	Scientific Staff (N=31)	1 day (16.10.2018)	Quality Management Unit
7.	Training on Disposal of empty glassware and plastic ware generated during lab activity	Lab Attendants (N=21)	1 day (17.10.2018)	Quality Management Unit & IBSC
8.	Training on Biosafety Practices	Scientific Staff (N=28)	1 day (02.11.2018)	Quality Management Unit & IBSC
9.	Training on Control ISO/IEC 17025:2005 clause 4.3 & 4.13: Document control & Control of records	Scientific Staff (N=30)	1 day (20.11.2018)	Quality Management Unit
10.	In-house seminar on technicalities of Laboratory Glassware	All Scientific Staff	1 day (18.12.2018)	Quality Management Unit
11.	Medical Emergency Mock Drill	Scientific Staff (N=7)	1 day (04.01.2019)	Quality Management Unit & IBSC
12.	Fire Safety Mock Drill & Evacuation Plan	All Staff (N=171)	1 day (28.01.2019)	Quality Management Unit & Engineering Unit

8.2 Visit of Dignitaries:

S. No.	Date of Visit	Name	Designation
1.	04.04.2018	Dr. P.V. Vijayaraghavan	Vice Chancellor, Sri Ramchandra Medical College & Research Institute Chennai, Tamil Nadu
2.	05.04.218	Dr. Rakesh Kumar Mahajan	Professor & Consultant Dr. RML Hospital, PGIMER
3.	05.04.2018	Dr. K.S. Anand	Professor & Head, Senior Consultant Neurologist, Department of Neurology, Postgraduate Institute of Medical education & Research (PGIMER) & Dr. RML Hospital
4.	17.04.2018	Justice V K Gupta	Former Chief justice H.P. High Court
5.	12.06.2018	Dr. Ram Vishwakarma	Director- IIIM, Jammu
6.	19.06.2018	Dr. Aparna Singh Shah	Regional Adviser Blood Safety and Laboratory Technology, WHO
7.	22.06.2018	Prof Raies A. Qadri	Professor, Dept. of Biotechnology, University of Kashmir
8.	22.06.2018	Dr. Jyotdeep Kaur	Professor, Dept. Of Biochemistry, PGIMER Chandigarh
9.	22.06.2018	Dr. M.K. Saha	Scientist-ICMR NICED
10.	09.07.2018	Prof. C. K. Kokate	Former VC Kakatiya & KLE universities Former President Pharmacy Council of India
11.	09.07.2018	Dr. Pradeep Das	Director, Rajendra Memorial Research Institute of Medical Sciences, Patna
12.	09.07.2018	Dr. K.V Leela	Professor(Microbiology), Govt. Kilpauk Medical College, Chennai
13.	09.07.2018	Dr. J.A.S. Giri	Advisor, Pharmexcil Ex-President Indian Pharma Association (IPA), Hyderabad
14.	13.07.2018	Dr. Shanta Dutta	Director, National Institute of Cholera & Enteric Diseases, Kolkata ICHR Institute
15.	13.07.2018	Dr. Kavita Singh	Mission Director, National Biopharma Mission-BIRAC, DBT

S. No.	Date of Visit	Name	Designation
16.	13.07.2018	Dr. P. K. Sarma	Head Technical, Biotechnology Industry Research Assistance Council (BIRAC)
17.	23.07.2018	Dr. Shashi Bala Singh	Director, NIPER, Hyderabad
18.	17.08.2018	Kamal Gaur	Assistant Manager SD biosensor, New Delhi
19.	17.08.2018	Mr. Punit	Assistant Manager Regulatory Affairs SD biosensor, New Delhi
20.	17.08.2018	Mr. Prateek Mittal	Director - Marketing at Medsource ozone Biomedicals Pvt. Ltd. New Delhi
21.	17.08.2018	Ms. Ankita Patel	Assistant Manager Regulatory Affairs Meril Diagnostics Pvt. Ltd. Vapi, Gujarat
22.	21.08.2018	Bioassay Laboratory Team	Translational Health Science and Technology Institute (THSTI) Faridabad, Haryana
23.	18.09.2018	Dr. Debashish Gupta	Professor & HOD Transfusion Medicine, SCTIMST, Trivandrum
24.	18.09.2018	Dr. Ravneet Kaur	Professor & Head Transfusion Medicine, GMCH Chandigarh
25.	18.09.2018	Dr. Prasun Bhattacharya	Associate Prof & Head, MCH, Kolkata
26.	18.09.2018	Dr. T.R. Raina	Former Prof Head Dept. of Transfusion Medicine, Govt. Medical College, Jammu
27.	18.09.2018	Mr. Sella Senthil	Asst. Drug Controller, CDSCO, Delhi
28.	12.10.2018	Dr. Sheikh Daud Adnan	Associate Professor, NICVD, BANGLADESH
29.	12.10.2018	Dr. Supriya Sarkar	Deputy Program Manager, Hospital Services, DGHS, BANGLADESH
30.	12.10.2018	Dr. Aparna Singh Shah	Regional Advisor at WHO
31.	26.10.2018	Dr. Senda Bahri	General Director, Laboratoire National de Cintrole des Medicaments, TUNISIA
32.	26.10.2018	Dr. Yameogo Josias	Pharmacien spécialiste en Technologies pharmaceutiques et Biopharmacie, BURKINA FASO
33.	26.10.2018	Dr. Xiaowei Wang	Deputy Director, Quality Manager, Shenzhen Institute for Drug Control (SZIDC), CHINA

S. No.	Date of Visit	Name	Designation
34.	26.10.2018	Ms. Yongli Gao	Director of Quality Management, Shenzhen Institute for Drug Control (SZIDC), CHINA
35	26.10.2018	Mr. Zhiyuam Liang	Director Assistant, Shenzhen Institute for Drug Control (SZIDC), CHINA
36.	26.10.2018	Dr. Marini Roland	Dept. of Pharmacy, CIRM, University of Liege, BELGIUM
37.	27.11.2018	Swami Ritanandaji Maharaj	Secretary, Ramkrishna Mission Institute Of Home Services, Varanasi
38.	27.11.2018	Smt. Vinita Srivastava	National Senior Consultant, NHM
39.	27.11.2018	Mr. Jolly J Lazarus	Programme Officer Voluntary Blood Donation, NACO (Govt. of India)
40.	27.11.2018	Dr. Naresh Kumar Bhatia	President FBDOI
41.	27.11.2018	Sri Apurba Ghosh	Secretary General FBDOI
42.	27.11.2018	Dr. Tomcha Khuman	State Program Officer, State Blood Cell, NHM-Manipur.
43.	27.11.2018	Mr. Venoy Shetty	Member TRG, VBD / NBTC THINK FOUNDATION, Mumbai
44.	27.11.2018	Mr. R. Rajkumar	Member , TRG, VBD/NBTC , Chennai
45.	27.11.2018	Dr. Shyamal Baran Mukherjee	Secretary, Indian Red Cross Society
46.	05.12.2018	Dr. U.S.N Murty	Director, NIPER Guwahati
47.	05.12.2018	Mr. Srinivas Lanka	Senior Advisor, Pharma
48.	06.12.2018	Dr. Rajmohan	Assistant Professor, Govt. Medical College, Kottayam, Kerala
49.	06.12.2018	Vinaya D.V	Assistant Professor, Govt. Medical College, Kottayam, Kerala
50.	06.12.2018	Valsalakumari P.K	Associate Professor, Govt. Medical College, Kottayam, Kerala
51.	20.12.2018	Dr. K Kamraj	Honourable Member of Parliament, Tamil Nadu
52.	08.01.2019	Dr. Anil Koul	Director, Institute of Microbial Technology, Ministry of Science and Technology, Chandigarh
53	21.01.2019	Dr. Ashraf Ganie	Professor, All India Institute of Medical Sciences, New Delhi
54.	15.02.2019	Dr. Deus Mubangizi	Group Lead, WHO, Prequalification Team, Geneva
55.	27.03.2019	Dr. Ahmed Hamdy	Executive Director, African union, STRC

S. No.	Date of Visit	Name	Designation
56.	27.03.2019	Mme Marie Johnson	Technical Assistant to Executive Director, African Union, STRC
57.	27.03.2019	Gloriose Kankino	African union, STRC
58.	27.03.2019	Reema Roshan	Scientist, Indian Council of Medical Research

9 Outstanding Achievements

9.1 During NABL re-assessment, the Scope of Accreditation was enhanced w.r.t the no. of products from 91 products to 120 products.

9.2 The Scope of tests (Biological and Chemical) for Accreditation was enhanced from 226 tests to 285 tests.

9.3 W.r.t the continued satisfactory compliance to the requirements of ISO/IEC 17025:2005, the NABL accreditation of NIB laboratories was successfully renewed for the period 2018-2020 (Certificate No. TC-7725 in the field of testing valid from 16.08.2018 till 15.08.2020).

9.4 BS OHSAS 18001:2007 is the internationally recognized standard for Occupational Health and Safety Management Systems. OHSAS stands for Occupational Health and Safety Assessment Series. National Institute of Biologicals has successfully acquired the BS OHSAS 18001:2007 certification (Certificate No. IND 18.8672U/ HS) on 24.05.2018 valid up to 11.03.2021.

9.5 The first annual surveillance audit for management system of NIB in accordance to BS OHSAS 18001:2007 was successfully completed on 01.02.2019.

TRAINING UNIT

1. Name of Head

Dr. Achla Prasad, Scientist Grade-I, DD (QC) i/c. Therapeutics, Animal facility & Training, (from 01.05.2018 to 16.08.2018)

Ms. Sudha V. Gopinath, Scientist Grade-III, Overall I/c Training & Academics (from 16.8.2018)

Ms. Shalini Tewari, Scientist Grade-III, Head Training Unit, (from 08.05.2018 to 04.01.2019)

Sh. Subhash Chand Scientist Grade–III Head Training Unit (from 04.01.2019)

2. Manpower in the Lab/ Division:

I. Name of Scientific Staff:

Sh. Ajay Kumar Ade, Junior Scientist (from 04.01.2019)

Sh. Brij Bhushan, Junior Scientist (from 18.05.2018 to 04.01.2019)

Ms. Apoorva Anand, Junior Scientist (from 16.08.2018 to 04.01.2019)

II. No(s). of Outsourced Staff: 03

3. Aim and Scope:

The training unit of National Institute of Biologicals (NIB) comprises of the scientific staff of the institute who, along with their scientific duties are given additional responsibilities to function for synchronizing and implementing the training related activities of the institute.

The training unit functions with the objective, which is in line with NIB mandate 3.1.3 as laid down in Memorandum of Association. Besides regulatory officials, manufacturers, academicians, government analysts, blood bank officials, NIB also imparts training to graduate and post graduate students. This helps in building up the 'National Talent Pool of skilled and trained manpower' for indigenous manufacturing units for domestic consumption as well as export of biologicals which is expected to increase significantly over the years.

The training will help to bridge the gap of trained manpower for Quality Control of Biologicals in Government and Private sector as there is an acute shortage of skilled and hands-on trained manpower in the field of Biologicals.

4. Training Activities Undertaken:

4.1 Training of Blood Bank Officials in collaboration with Blood Cell, National Health Mission (NHM):

Blood Services are a crucial component of curative healthcare amenities. Adequate and safe supply of blood and blood components is essential to enable care of critical patients in the hospitals. The mission of the Blood Cell, NHM is to develop a coordinated long-term action plan for the development and integration of diverse activities in the area of blood banking with a careful consideration of priorities and optimal use of resources and funds to ensure effective blood services in the country.

NIB in collaboration with Blood Cell, National Health Mission (NHM), has conducted a series of eight training programmes on "Six Days Residential Training of Blood Bank Officials" with total 257 participants Table 1

for Govt. Blood Bank Officials at NIB, NOIDA for technical support in Strengthening Blood Services in India at IDKL, BRL and Hemovigilance Cell in the following areas:

i. EQAS for Transfusion Transmitted Diseases and Blood Group Serology.

ii. Training for Use of Cell counters and Its Quality Assurance.

iii. Haemovigilance training (BBO/ Clinicians/ Donors)

iv. Analysis of gaps in Blood Bank Management

v. Total Quality Management Systems

The objective of the training is to improve the standards of Blood Banks and the Blood services in our country.

This initiative will facilitate in building up a "National Talent Pool of skilled and trained manpower" to improve quality, safety and efficacy of blood and blood products, well-equipped blood centers with adequate infrastructure, meeting the requirements of current good Laboratory practices (cGLP) and Strengthen Total Quality Management System. The training programmes help Blood Banks of our country in improving their standards and thereby providing excellent and high quality services for safeguarding Public Health in our country.

Table 1: Training to Blood Bank officials who participated from seven states viz., Bihar, Chhattisgarh, Meghalaya, Uttar Pradesh, Jammu& Kashmir, Punjab and Kerala.

S. No.	Trainings	Duration		No. of Participants
		From	To	
1.	Training of Trainers for Strengthening of blood services and e- RaktKosh for the state Bihar	02-04-2018	07-04-2018	40
2.	Training of Trainers for Strengthening of blood services and e- RaktKosh for the state Chhattisgarh	16-04-2018	21-04-2018	33
3.	Training of Trainers for Strengthening of blood services and e- RaktKosh for the state Meghalaya	28-05-2018	02-06-2018	21
4.	Training of Trainers for Strengthening of blood services and e- RaktKosh for the state Uttar Pradesh	23-07-2018	28-07-2018	25
5.	Training of Trainers for Strengthening of blood services and e- RaktKosh for the state J&K	27-08-2018	01-09-2018	39
6.	Training of Trainers for Strengthening of blood services and e- RaktKosh for the state Chhattisgarh	08-10-2018	13-10-2018	45
7.	Training of Trainers for Strengthening of blood services and e- RaktKosh for the state Punjab	10-12-2018	15-12-2018	27
8.	Training of Trainers for Strengthening of blood services and e- RaktKosh for the state Kerala	11-03-2019	16-03-2019	27
			Total	**257**

4.2 Training of Graduate & Post Graduate Students from various Universities at NIB under "National Skill Development & Hands on- Training on Quality Control of Biologicals" programme:

NIB in line with National Skill Development programme under "Pradhan Mantri Kaushal Vikas Yojana (PMKVY)" provides training on "National Skill development and Hands-on Training in Quality Control of Biologicals". The training is imparted to for M.Sc. Biotechnology, Biochemistry and Microbiology students of University of Jammu &Kashmir, University of Himachal Pradesh, CRI-Kasauli and M. Pharm students of NIPER Kolkata, NIPER Mohali, NIPER Hyderabad, NIPER Rae Bareli, NIPER Guwahati and J.S.S Ooty (Table 2).

The objective of this training Programme is to develop and enhance analytical skills and technical knowledge of these students through Hands-on Training in Quality Control of Biologicals including Bio therapeutics, Diagnostics and Vaccines in NABL accredited and CDL notified laboratories.

The training covers techniques used in quality evaluation like HPLC, Electrophoresis, ELISA, Bacterial Endotoxin testing, Transfusion Transmitted Infection testing, Blood Serology, Cell culture aseptic handling, sub culturing and maintenance, cell line based potency assays, animal handling, use of Laboratory animals etc in QC testing of Biologicals performed in various labs of NIB and to create awareness about Global scenario of biological testing.

Table 2: Trainings under National Skill Development and Hands on Training in Quality Control of Biologicals

S. No.	Trainings	Duration		No. of Participants
		From	To	
1.	National Skill Development and Hands on Training in Quality Control of Biologicals for Post Graduate students of NIPER, Kolkata	23-04-2018	04-05-2018	33
2.	National Skill Development and Hands on Training in Quality Control of Biologicals for Post Graduate students of NIPER Kolkata, NIPER Mohali, NIPER Hyderabad & NIPER, Rae Bareli, NIPER Guwahati	05-09-2018	26-09-2018	26
3.	National Skill Development and Hands on Training in Quality Control of Biologicals for Post Graduate students of J.S.S Ooty, Mysore	03-12-2018	31-12-2018	4
4.	National Skill Development and Hands on Training in Quality Control of Biologicals for Post Graduate students of University of Jammu & CRI-Kasauli (DBT)	03-01-2019	17-01-2019	43
5.	National Skill Development and Hands on Training in Quality Control of Biologicals for Post Graduate students of Himachal Pradesh University (DBT)	11-02-2019	22-02-2019	18
			Total	**124**

The following lectures as mentioned in Table 3 were delivered by NIB faculties during the above mentioned training programmes:

Table 3: Lectures delivered by NIB faculties for National skill Development training programmes for MSc Biotechnology/ Biochemistry/ Microbiology/ M. Pharm students

S. No.	Topic	Name of the speaker
1.	NIB Overview	**Dr. Reba Chhabra,** DD (QC) Diag., Vaccines & Trg.
2.	GLP Regulations: Good Laboratory Practices-pre clinical research & drug development	**Dr. Achla Prasad,** DD (QC)-T & AF
3.	Biosafety practices in Biomedical laboratories and disposal of Biomedical waste	**Dr. Suresh,** Scientist Grade-III, AF
4.	Clean Room Procedure Applicable For Biologicals Products	**Dr. D. Roy**, Consultant (Regulatory) & Former DDC (I), CDSCO
5.	Challenges in QC of Biosimilar	**Mr. Subhash Chand**, Scientist Grade-III, TMA & DQM
6.	Haemovigilance Program of India, software introduction and Case Studies	**Dr. Akanksha Bisht** Scientist Grade-II & Head- HvPI
7.	Laboratory Quality Management of Systems (LQMS)	**Dr. J. P. Prasad**, Scientist Grade-I & Quality Manager
8.	Preparation of National Reference Standards	**Dr. Richi V Mahajan** Junior Scientist
9.	Artificial Intelligence in Bioinformatics: Case Studies	**Mr. P. S. Chandranand**, Junior Scientist- Bioinformatics

Specific lectures related to laboratories are given by the respective Laboratory Head

4.3 Training of Graduate/Post Graduate Students from various Universities.

The institute provides 4 to 8 weeks training programme and 3 to 6 months project work in Quality Control of Biologicals in various NIB laboratories to Graduate/ Post Graduate Students of various Universities and Institutes. The training on various analytical platform makes them proficient, and also helps in their future research endeavours and enable them to get good job opportunities.

Table 4: List of summer training/ project work conducted at NIB, NOIDA.

Trainings	Duration		No. of Participants
	From	To	
Summer Training / Project work of Post Graduate/ Under Graduate students from Life Sciences, Biotechnology, Biochemistry, Microbiology, Pharmacy etc.	April, 2018	February, 2019	82

Details are given in Table 5:

Table 5: Details of summer training/ project work conducted at NIB, NOIDA.

S. No	Title of Training	Date		Participant details	Laboratory
		From	To		
1	Evaluation of Purity and Bioactivity of Adalimumab like anti TNF alpha Monoclonal Antibody	15.02.2018	09.04.2018	Amity University	Therapeutic Monoclonal Antibody Laboratory
2	Evaluation of Human Papilloma Virus (HPV) infection in Cervical Scraps samples	01.02.2018	03.05.2018	Awadhesh Pratap Singh University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
3	Aspects of Laboratory Quality Management System in a Quality Control Laboratory"	15.01.2018	04.05.2018	Awadhesh Pratap Singh University	Biochemical Kit Laboratory
4	Physio-chemical characterization of Etanercept	15.01.2018	15.05.2018	UIBT Chandigarh	Therapeutic Monoclonal Antibody Laboratory
5	Comparative study of ELISA and CLIA used for the detection of HCV Antibody	01.01.2018	15.05.2018	IPIIT Noida	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
6	Estimation of total protein in Albumin and Immunoglobulin samples using direct UV method in comparison with Kjeldahl and Biuret method.	15.01.2018	15.05.2018	Chandigarh University	Blood Product Laboratory
7	Study to detect Hepatitis C Antibody on different Immunological Assays	08.01.2018	22.05.2018	Manglayatan University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
8	Detection of Anti-Hepatitis B core by ELISA, ELFA & CLIA techniques	08.01.2018	22.05.2018	Mangalayatan University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
9	Detection of Anti-HBc IgM/ Total in Human plasma sample	01.02.2018	25.05.2018	Mangalayatan University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory

S. No	Title of Training	Date		Participant details	Laboratory
		From	To		
10	Aspects of Laboratory Quality Management System in a Quality Control Laboratory	01.02.2018	30.05.2018	Jiwaji University	Biochemical Kit Laboratory
11	Rare Blood Typing through Gel Cards and Tube Method	01.02.2018	31.05.2018	Banasthali University	Blood Group Reagent Laboratory
12	Basic Cell Culture Techniques involved in Quality Control testing of Viral Vaccines	10.05.2018	30.05.2018	Banasthali University	Vaccine Laboratory
13	Minimum Detection Limit of Rapid & ELISA for HBsAg	04.02.2018	04.06.2018	Jiwaji University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
14	Basic Cell Culture Techniques involved in Quality Control testing of Vaccines	10.05.2018	08.06.2018	Banasthali University	Vaccine Laboratory
15	Determination of charged variants in Therapeutic Monoclonal Antibody by Cation Exchange Chromatography	10.05.2018	08.06.2018	Banasthali University	Therapeutic Monoclonal Antibody Laboratory
16	Physio-Chemical Characterization of Bevacizumab by Size exclusion Chromatography (SEC-HPLC)	10.05.2018	08.06.2018	Banasthali University	Therapeutic Monoclonal Antibody Laboratory
17	Validation of Protein Content in Plasma Derived Human Coagulation Factor VIII by Biuret method and UV method	12.02.2018	09.06.2018	CCS University	Blood Product Laboratory
18	Effect of pH on aggregate formation and Haemolysis due to Haemagglutinins in Human Normal Immunoglobulin preparation	12.02.2018	09.06.2018	CCS University	Blood Product Laboratory
19	Basic Cell Culture Techniques involved in Quality Control Testing of Viral Vaccines	14.05.2018	12.06.2018	Banasthali University	Vaccine Laboratory

S. No	Title of Training	Date		Participant details	Laboratory
		From	To		
20	Determination of Total PRP (Polyribosyl Ribitol Phosphate) Content in Haemophilus Influenzae Type-B (Hib) TT Conjugate Vaccine	14.05.2018	12.06.2018	Banasthali University	Vaccine Laboratory
21	Determination of free PRP (Polyribosyl Ribitol Phosphate) Content in Haemophilus Influenzae Type-B (Hib) TT Conjugate Vaccine	14.05.2018	12.06.2018	Banasthali University	Vaccine Laboratory
22	Identification of Filgrastim (GCSF) using Analytical Technique: HPLC & Gel Electrophoresis	01.02.2018	14.06.2018	Jiwaji University	Recombinant Product Laboratory
23	Basic Cell Culture Techniques involved in Quality Control Testing of Viral Vaccine	25.05.2018	19.06.2018	Chandigarh University	Vaccine Laboratory
24	Determination of Charge Variants in Monoclonal Antibody sample by Cation Exchange Chromatography (CEX-HPLC)	21.05.2018	19.06.2018	Chandigarh University	Therapeutic Monoclonal Antibody Laboratory
25	Determination of Molecular Size Distribution in Monoclonal Antibody by Size Exclusion Chromatography (SEC-HPLC)	21.05.2018	19.06.2018	Chandigarh University	Therapeutic Monoclonal Antibody Laboratory
26	Comparison for Quality Control Evaluation of Blood Grouping Reagents from Various Manufacturers Using Different Diluents	24.05.2018	22.06.2018	Banasthali University	Blood Reagent Laboratory
27	Establishment of Cell Culture and Evaluating Bioactivity of Anti-TNFα Monoclonal Antibody, Adalimumab	24.05.2018	22.06.2018	Amity University, Noida	Therapeutic Monoclonal Antibody Laboratory
28	Estimation of Impurity Content in Filgrastim Injection by Size Exclusion Chromatography (SEC)	01.06.2018	30.06.2018	Chandigarh University	Recombinant Product Laboratory

S. No	Title of Training	Date		Participant details	Laboratory
		From	To		
29	Quality Evaluation of Bacillus Calmette Guerin (BCG) Vaccine by ZN Staining Method	28.05.2018	29.06.2018	Chandigarh University	Vaccine Laboratory
30	Quality Evaluation of Bacillus Calmette Guerin (BCG) Vaccine by ZN Staining Method	28.05.2018	29.06.2018	Chandigarh University	Vaccine Laboratory
31	Diagnostic Tools used for Detection of HIV-Ab, HCV-Ab, HBsAg and Syphilis	01.06.2018	29.06.2018	Chandigarh University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
32	Basic Cell Culture Techniques Involved in Quality Control Testing of Vaccine Laboratory	01.06.2018	29.06.2018	Chandigarh University	Vaccine Laboratory
33	Basic Cell Culture Techniques Involved in Quality Control Testing of Vaccine	01.06.2018	29.06.2018	Amity University, Noida	Vaccine Laboratory
34	Basic Cell Culture Techniques Involved in Quality Control Testing of Vaccines	01.06.2018	30.06.2018	Chandigarh University	Vaccine Laboratory
35	Internal Quality Control Program for Laboratory Reference Method for Glucose	01.06.2018	30.06.2018	Chandigarh University	Biochemical Kit Laboratory
36	Estimation of Impurity Content in PEG-Filgrastim (Peg-GCSF) Injection by Size Exclusion Chromatography (SEC)	01.06.2018	30.06.2018	Banasthali University	Recombinant Product Laboratory
37	Identification and Assay of Somatropin by Size Exclusion Chromatography	01.06.2018	29.06.2018	Chandigarh University	Enzyme & Hormones Laboratory
38	Dimer and Related Substances of High Molecular Mass for Human Growth Hormone by Size Exclusion Chromatography	01.06.2018	29.06.2018	Chandigarh University	Enzyme & Hormones Laboratory
39	Study on Interference of (1-3)-β-D-Glucan in Gel Clot Limit method for Detection of Bacterial Endotoxin in Plasma derived Products	15.03.2018	30.06.2018	HNBG University Srinagar	Blood Product Laboratory

S. No	Title of Training	Date		Participant details	Laboratory
		From	To		
40	Evaluation of Biological Activity (Potency) of Anti TNF Alpha Monoclonal Antibody Sample by Cell Based Bioassay	15.05.2018	01.07.2018	Amity University, Noida	Therapeutic Monoclonal Antibody Laboratory
41	HPV Sample Processing and Screening	02.07.2018	06.07.2018	IGNT University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
42	Identification of Filgrastim (Granulocyte Colony Stimulating Factor) by using High Performance Liquid Chromatography (HPLC)"	15.05.2018	06.07.2018	Amity University, Noida	Recombinant Product Laboratory
43	Estimation of Impurity Content in PEG-Filgrastim (PEG-GCSF) Injection by Reverse Phase High Performance Liquid Chromatography (RP-HPLC)	01.06.2018	10.07.2018	Gargi College, Delhi University	Recombinant Product Laboratory
44	Identification, Assay, Dimer and Related Molecules of High Molecular Mass For Somatropin by SEC	11.06.2018	11.07.2018	GB University, Noida	Enzyme & Hormones Laboratory
45	Sequence Alignment and Phylogenetic Analysis of Therapeutic Monoclonal Antibody (RITUXIMAB)	11.06.2018	13.07.2018	HCST, APJAKT University	Bio-Informatics Division
46	Serological Assays Used for Detection of HIV-Ab, HCV-Ab, HBsAg & Syphilis	11.06.2018	13.07.2018	HCST, APJAKT University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
47	Screening Assays Used for Detection of HIV-Ab, HCV-Ab, HBs Ag and Syphilis	11.06.2018	13.07.2018	HCST, APJAKT University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
48	Assuring the Safety of Human Coagulation Factor VIII by Using In-vivo Rabbit Pyrogen Test and Abnormal Toxicity Test	11.06.2018	13.07.2018	HCST, APJAKT University	Animal Facility

S. No	Title of Training	Date		Participant details	Laboratory
		From	To		
49	Determination of Identity and Potency of Insulin Lispro	15.06.2018	15.07.2018	IMSEC, GZB, AKTU	Recombinant Product Laboratory
50	Protein Structure Analysis and Identification of Binding Motif on the Epitope Peptide in Rituximab Protein	15.06.2018	16.07.2018	IMSEC, GZB, AKTU	Bio-Informatics Division
51	Metastatic Cancer of Breast: An In silico Approach	15.06.2018	16.07.2018	IMSEC, GZB, AKTU	Bio-Informatics Division
52	Quality Control Testing of Plasma Derived Products	22.05.2018	21.07.2018	BHU Varanasi	Blood Product Laboratory
53	Quality Control Testing of Plasma Derived Products	22.05.2018	21.07.2018	BHU Varanasi	Blood Product Laboratory
54	Quality Control Testing of Plasma Derived Products	22.05.2018	21.07.2018	BHU Varanasi	Blood Product Laboratory
55	Basic Cell Culture Techniques Involved in Quality Control Testing of Vaccines	13.06.2018	22.07.2018	C. University Gujarat	Vaccine Laboratory
56	Observation of different Assays for detection of HIV, HCV, HBsAg & Syphilis	02.07.2018	23.07.2018	KMC, Delhi University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
57	Assuring the Safety of Human Tetanus Immunoglobulin EU (Tetanus Gamma 250 IU) by Using In-vivo Rabbit Pyrogen Test and Abnormal Toxicity Test	29.06.2018	28.07.2018	GB University, Noida	Animal Facility
58	A Hands-On Exposure to Quality Control Testing of Viral Vaccine	02.07.2018	27.07.2018	JPIIT, Noida	Vaccine Laboratory
59	Identification of Interferon Beta-1 Injection Using Gel Electrophoresis Technique	03.07.2018	30.07.2018	BHU Varanasi	Recombinant Product Laboratory
60	Determination of Potency in Anti-D (Rho-D) (Monoclonal) Human Immunoglobulin for Intramuscular Administration	03.07.2018	30.07.2018	BHU Varanasi	Blood Product Laboratory

S. No	Title of Training	Date		Participant details	Laboratory
		From	To		
61	Serological Assays used for Diagnosis of Transfusion Transmitted Infections (TTIs) Markers	11.06.2018	30.07.2018	HCST, APJAKT University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
62	Assuring the Safety of Biological Products by using In-Vivo Regulatory Tests, Humane Handling and Restraining Techniques of Laboratory Animals, Injection and Bleeding Procedures on Laboratory Animals as per the CPCSEA Guidelines	01.06.2018	10.07.2018	BITS Pilani	Animal Facility
63	Blood Grouping Techniques and Quality Control of Blood Grouping Reagents	03.07.2018	31.07.2018	BHU Varanasi	Blood Reagent Laboratory
64	In-vitro Diagnostic Assays for detection of Transfusion Transmitted Infectious (TTI) Markers viz HIV, HCV, HBsAg and Syphilis	01.06.2018	31.07.2018	Delhi Technological University	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
65	General Techniques for Quality Control of Allergens	03.07.2018	31.07.2018	BHU Varanasi	Allergen
66	Internal Quality Control Program and Method Validation Parameters of Laboratory Reference Method for Glucose	01.06.2018	31.07.2018	GGSI University	Biochemical Kit Laboratory
67	Basics of Animal Cell Culture Handling and Environmental Monitoring in Bioassay	03.07.2018	03.08.2018	IAMR Ghaziabad	Therapeutic Monoclonal Antibody Laboratory
68	General Techniques for Quality Control of Allergens	29.06.2018	10.08.2018	IILM College, Gr. Noida	Allergen
69	Relative Estimation of Potency of Heparin Sodium Injection Against International Reference Standard (IRS) of Unfractioned Heparin by Anti Factor-IIa Activity	21.06.2018	20.08.2018	CCS University	Enzyme & Hormones Laboratory

S. No	Title of Training	Date		Participant details	Laboratory
		From	To		
70	Internal Quality Control Program and Laboratory Reference Method for Glucose	02.07.20185	30.08.2018	IMS University	Biochemical Kit Laboratory
71	In-vitro Potency Determination of Anti TNF Alpha Antibody and Microbiological Environmental Monitoring of Bioassay Laboratory	11.06.2018	30.08.2018	HIMT AKTU	Therapeutic Monoclonal Antibody Laboratory
72	Diagnostic Tools for Detecting HIV, HCV, HBsAg, Syphilis	10.08.2018	10.09.2018	HIMT AKTU	Immuno Diagnostic Kit & Molecular Diagnostic Laboratory
73	Determination of Molecular Size Distribution in Monoclonal Antibody Sample by Size Exclusion Chromatography (SEC-HPLC) & Estimation of Extinction Coefficient by UV Spectroscopy	04.07.2018	04.09.2018	IAMR Ghaziabad	Therapeutic Monoclonal Antibody Laboratory
74	Determination of Charge Variants in Monoclonal Antibody Sample by Cation Exchange Chromatography (CEX-HPLC) & Estimation of Extinction Coefficient by UV Spectroscopy	04.07.2018	04.09.2018	IAMR Ghaziabad	Therapeutic Monoclonal Antibody Laboratory
75	Comparative Study for Viability of Cryopreserved Red Blood Cells When Thawed and Resuspended in Alsever's Solution for a Period of Four Weeks	09.08.2018	30.10.2018	BHU Varanasi	Blood Reagent Laboratory
76	Analysis of Charge Heterogenity in Monoclonal Antibodies by Capillary Zone Electrophoresis	10.06.2018	09.12.2018	J.S. University	Therapeutic Monoclonal Antibody Laboratory
77	Basic Cell Culture Techniques Involved in Quality Control Testing of Vaccines	15.10.2018	14.12.2018	GGS Indraprastha University, Delhi	Vaccine Laboratory

S. No	Title of Training	Date		Participant details	Laboratory
		From	To		
78	Physiochemical Characterization of Monoclonal Antibodies by Capillary Electrophoresis-Sodium Dodecyl Sulphate (CE-SDS)	03.12.2018	31.12.2018	IIT Delhi	Therapeutic Monoclonal Antibody Laboratory
79	Assuring the safety of blood products by rabbit pyrogen test and evaluating the rabbits for development of endotoxin tolerance due to their repeated use in pyrogen test	11.06.2018	10.12.2018	Deen Bandhu Chhotu Ram University	Animal Facility
80	Comparative Study of Environmental Isolates of Classified Area and Non Classified Area	13.08.2018	08.02.2018	AKTU, Lucknow	Sterility
81	Determination of Charge Variants in Monoclonal Antibody by Cation Exchange Chromatography (CEX-HPLC)	04.09.2018	28.02.2019	AKTU, Lucknow	Therapeutic Monoclonal Antibody Laboratory
82	Comparison Between Indian Pharmacopoeia & British Pharmacopoeia Method for Clottable Protein(Fibrinogen) Estimation of Fibrinogen component in fibrin sealant kit	04.09.2018	28.02.2019	AKTU, Lucknow	Blood Product Laboratory

4.4 Training to Manufactures/ Stakeholders: Training is also imparted at Animal facility as summarized below-

Scope and duration	No. of trainees
One-week training (2- 6 July 2018) in "Ethics, Regulation, Anaesthesia, Analgesia & Basic Bio methodologies in laboratory animals" to PhD scholars and M. Sc. Students from various universities and internal staff of NIB, Noida.	9
One week training (27- 31 August 2018) on "Basic Biomethodology in Laboratory Animals for M. Pharma students from Noida Institute of Engineering and Technology (NIET), Greater Noida, UP.	10

4.5 Expert Committee meeting on Training activities:

The first meeting of the newly constituted Expert committee to advise on training programmes for Skill Development for Life Sciences and Pharmacy students from various Universities/Institutions across the country in the area of Quality Control and Quality Management System of Biologicals including

the Haemovigilance Programme of India was held under the Chairmanship of Prof (Dr.) C. K. Kokate, Advisor to Pharmexcil, on 09th July 2018 at NIB. The expert committee members who attended the meeting are as given at Table 5:

Table 5:

A.	Expert Committee	
1.	Prof. (Dr.) C. K. Kokate Chairman	Advisor to PHARMEXCIL, Former, Vice Chancellor of Kakatiya and KLE Universities and Former President, Pharmacy Council of India
2.	Dr. J.A.S. Giri Member	Former President Indian Pharmaceutical Association, Hyderabad
3.	Dr. K. V. Leela Member	Professor, Deptt. of Microbiology, Government Medical College and Member-Governing Council, The Tamil Nadu Dr. MGR Medical University, Chennai
4.	Dr. A. Ramkishan Member	Dy. Drugs Controller (India), CDSCO, Eastern Zone, Kolkata
5.	Mr. Suresh Khanna	Honorary Secretary, Indian Pharmaceutical association and past President Karnataka Drugs and Pharmaceutical Manufacturer's Association, Bengaluru
6.	Dr Pradeep Das	Scientist G and Director, Rajendra Memorial Research Institute of Medical sciences, Patna
7.	Dr. USN Murty Member	Director, NIPER, Guwahati
8.	Dr. Achla Prasad Member	Scientist Grade-I & I/c- DD (QC)- TAF & Trg, National Institute of Biologicals (NIB)- NOIDA
9.	Ms. Shalini Tewari Member Secretary	Scientist Grade-III & Head Allergen Testing Laboratory, IT & Bioinformatics, Training, National Institute of Biologicals (NIB)- NOIDA

The training programme for Quality Control of Biologicals with special emphasis to practical sessions for Biotechnology and Pharmacy Post Graduate students from Northeastern States and also students from seven NIPERS was conceptualized during this meeting. Training being one of the mandate of NIB, the committee also recommended that all expense of travel and hospitality etc of trainees (100 pharmacy & 100 Biotechnology) should be borne by NIB. The committee felt that, this pilot programme will help in identifying lacunae and gaps for designing and updating the future training curriculum as per regulatory needs.

The Second Meeting of the Expert Committee was held under the Chairmanship of Prof (Dr.) C. K. Kokate, Advisor to Pharmexcil, on 09th August 2018 at Committee Room, CSIR-Indian Institute of Chemical Technology, at Hyderabad. The objective of the meeting was to design the course curriculum involving

academia, regulators and industry for the training programme conceptualized during the first meeting. The meeting was attended by the Expert Committee members, NIPER Directors, Special invitees and representatives from Biopharmaceutical industry as given in Table 6:

Table 6:

A. Expert Committee		
1.	Prof. (Dr.) C. K. Kokate Chairman	Advisor to PHARMEXCIL, Former, Vice Chancellor of Kakatiya and KLE Universities and Former President, Pharmacy Council of India
2.	Dr. J.A.S. Giri Member	Former President Indian Pharmaceutical Association, Hyderabad
3.	Dr. Saranjit Singh Member	Head Pharmaceutical analysis, NIPER- Mohali
4.	Dr. K. V. Leela Member	Professor, Deptt. of Microbiology, Government Medical College and Member-Governing Council, The Tamil Nadu Dr. MGR Medical University, Chennai
5.	Dr. A. Ramkishan Member	Dy. Drugs Controller (India), CDSCO, Eastern Zone, Kolkata
6.	Mohd. Yunis, Member	Asst. Drugs Controller (Kashmir division), Drugs & Food Control Organization, Kashmir
7.	Dr. Achla Prasad Member	Scientist Grade-I & I/c- DD (QC)- TAF & Trg, National Institute of Biologicals (NIB)- NOIDA
8.	Dr. USN Murty Member	Director, NIPER, Guwahati
9.	Ms. Shalini Tewari Member Secretary	Scientist Grade-III & Head Allergen Testing Laboratory, IT & Bioinformatics, Training, National Institute of Biologicals (NIB)- NOIDA
10.	Shri Brij Bhushan	Junior Scientist- Allergen Testing Laboratory, National Institute of Biologicals (NIB)- NOIDA
B. NIPER Directors		
11.	Dr. A. R. Rao	Director, NIPER- Mohali
12.	Dr. V. Ravichandiran	Director, NIPER-Kolkata
13.	Dr. USN Murty	Director, NIPER, Guwahati
C. Special invitee		
14.	Dr. S. Chandrasekhar	Director- CSIR-Indian Institute of Chemical Technology
15.	Dr. Surinder Singh	Director- National Institute of Biologicals (NIB)- NOIDA
16.	Dr. B. Prabhashankar	President- Indian Pharmaceutical Association- Telangana State Branch
17.	Shri Ravi Uday Bhaskar	Director General, PHARMEXCIL

18.	Dr. D. Roy	Former Dy. Drugs Controller (India)- CDSCO, Regulatory Consultant, National Institute of Biologicals (NIB)-NOIDA
D. Biopharmaceutical Industry		
	Dr. Sai D. Prasad	President Quality Operations Bharat Biotech, Hyderabad
	Dr. V. K. Srinivas	Vice President QA Bharat Biotech, Hyderabad
	Dr. K. Anand Kumar	Managing Director Indian Immunologicals Ltd, Hyderabad
	Dr. Sanjeev Kumar	Senior Vice president -Biologics, Zydus Cadila Ltd. Ahmedabad
	Dr. Sriram A.V	Senior Vice President Regulatory Biocon Ltd. Bangalore
	Dr. Arnab Kapat	Director Reliance Life Sciences- Mumbai
	Dr. Samir Kumar Mandal	Director- Product Analytics Dr. Reddy's Laboratories- Biologics, Hyderabad
	Dr. Vikas Kumar	Director- Bioanalytics Dr. Reddy's Laboratories- Biologics, Hyderabad

Prof (Dr.) C. K. Kokate, Chairman appreciated Director- NIB for his vision to train Pharmacy and Biotechnology Students of the country to ensure availability of readymade-trained manpower to industry. He apprised the gathering about the NIB's initiative under the National Skill Development Programme under Pradhan Mantri Kaushal Vikas Yojana (PMKVY) contributing to capacity building in the area of Biologicals.

The committee unanimously agreed to roll out the 2- week pilot training programme from 5th September 2018 at NIB for 21 students (14 from the 7 NIPERs and 07 from other North-Eastern states). As the training programme is proposed to be of dynamic nature, it was recommended that changes will be made in the curriculum as when as required after review by the committee as per industry need. Revised training programme may be Prepared with amendments. Chairman apprised the industry that training programme will be about 20% Theory and 80% Hands-on and overnight stay of faculty at NIB campus for Interaction with the students.

The institute successfully launched this programme on 5th September 2018 wherein 26 M. Pharm students from five NIPERs were trained. Further three more training programmes were conducted for Biotechnology/ Microbiology/ Biochemistry Postgraduate students from various universities viz Jammu University, Himachal Pradesh University & Central Research Institute Kasauli, Himachal Pradesh and JSS Ooty Mysore as given in the Table 2.

Expert Committee meeting held at IICT Hyderabad

4.6 Rise in Jammu & Kashmir- 2018

NIB, participated in the exhibition 'Rise in Jammu & Kashmir 2018', at Yatri Niwas, Bhagwati Nagar, Jammu from November 1-3, 2018. A total of 45 national institutions/ organisations exhibited their respective areas of services to the nation and interacted with the students, general masses and made them aware about the skill development programmes and job opportunities in the different field which motivated and encouraged the youth and masses.

Under leadership of Dr. Reba Chhabra, In-charge Deputy Director, Quality Control, the team comprising three NIB Scientists Shalini Tewari, Subhash Chand, P.S Chandranand and two outsourced staff showcased NIB's multidimensional activities

viz career and training opportunities in the field of biologicals. They also highlighted its contribution to the academia and health care professionals in the State of Jammu and Kashmir pertaining to Quality Control testing of Biologicals and Haemovigilance Program of India (HvPI).

The main focus of NIB in the event was to promote national skill development, create awareness and to provide training facilities in Quality Control testing of Biologicals and also to disseminate knowledge on various activities related to quality of biological drugs in the treatment of life threatening diseases like cancer, Haemophilia, diabetes, heart disease, kidney disorders, and diagnosis of transfusion transmitted infections like Hepatitis B & C, Syphilis, HIV and other seasonal diseases like Dengue, Chikungunya etc.

food at optimum temperature. State. The support of the and Aman Slathia. ufacturers and vendors who

NIB showcases its multidimensional activities

■ STATE TIMES NEWS

JAMMU: National Institute of Biologicals (NIB), an autonomous institution under the aegis of Ministry of Health and Family Welfare, Government of India, participated in the event 'Rise in Jammu & Kashmir 2018', a mega event represented by various national institutions/ organisations exhibiting their respective areas of services to the nation from the November 1 to 3, 2018, at Yatri Niwas, Bhagwati Nagar, Jammu.

Led by Dr Reba Chhabra, In-charge Deputy Director, Quality Control, the team comprising three NIB Scientists Shalini Tewari, Subhash Chand, P.S Chandranand and two Biologists Ashrath Elahi and Faraz Sheikh showcased NIB's multidimensional activities viz career and training opportunities in the field of biologicals.

MP Shamsher Singh and MLA Sat Sharma during visit to NIB's workshop at Jammu on Friday.

They also highlighted its contribution to the academia and health care professionals in the State of Jammu and Kashmir pertaining to Quality Control testing of Biologicals and Haemovigilance Program of India (HvPI).

The main focus of NIB in the event is to promote national skill development, create awareness and to provide training facilities in Quality Control testing of Biologicals and also to disseminate knowledge on various activities related to quality of biological drugs in the treatment of life threatening diseases like cancer, Haemophilia, diabetes, heart disease, kidney disorders, and diagnosis of transfusion transmitted infections like Hepatitis B&C, Syphilis, HIV and other seasonal diseases like Dengue, Chikungunya etc.

Visitors were briefed that

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Visitors were briefed that (i) under Pradhan Mantri Kaushal Vikas Yojna (PMKVY), NIB has been imparting hands-on training to the Post Graduate Students of Biotechnology, Microbiology and Biochemistry from Universities of Jammu, Kashmir and various other universities in the area of Quality Control of Biologicals and (ii) NIB also provides hands-on training to blood bank officials in collaboration with Blood Cell, National Health Mission, Ministry of Health & Family Welfare, Govt. of India.

NIB's stall, was the center of attraction as they demonstrated mobile app based Point of Care Blood Glucose monitoring devices to all those who visited NIB stall under Pradhan Mantri Kaushal Vikas Yojna (PMKVY), NIB has been imparting hands-on training to the Post Graduate Students of Biotechnology, Microbiology and Biochemistry from Universities of Jammu, Kashmir and various other universities in the area of Quality Control of Biologicals.

The team also provided hands-on training to blood bank officials in collaboration with Blood Cell, National Health Mission, Ministry of Health & Family Welfare, Government of India.

They demonstrated mobile app based Point of Care Blood Glucose monitoring devices to all those who visited NIB stall.

Also the visitors were explained about the latest applications of artificial intelligence in the diagnosis of cervical cancer.

and it was highly impressive with the latest innovations and techniques. Also the visitors were explained about the latest applications of artificial intelligence in the diagnosis of cervical cancer. About 20000 people approx. visited the exhibition including 60 schools and colleges participated and made this event huge success.

HAEMOVIGILANCE DIVISION

1. Name of Head:

Dr. Akanksha Bisht, Scientist Grade-II

2. Manpower in the Lab/ Division:

I. Name of Scientific staff:

Mr. Paras Jain, Junior Scientist

II. Name of Scientific staff:

Mr. Reetesh Kumar, Lab Technician

III. No (s). of Outsourced Staff: 04

3. Scientific Activities Undertaken

a. Implementation and coordination of activities of Haemovigilance Programme of India (HvPI) is one of the mandates of NIB as per its bye-laws 3.4.1 as approved in the 24th Governing Body meeting of NIB held under the Chairmanship of Secretary (Health & F.W.)/ Chairman, Governing Body of NIB on 12.12.2014.

b. A total of 170 Blood Banks are enrolled under this programme. National Institute of Biologicals has a web based reporting system for adverse transfusion reactions and donor reactions via indigenously developed software(s) Haemo-Vigil and Donor-Vigil. A total number of 8,571 Adverse Reaction Reports have been reported via Haemovigilance Software(s) out of which 3,488 reports pertains to adverse blood transfusion reactions and 5,083 reports are attributed to reactions during blood donation. Further, India being the member country of the International Haemovigilance Network has uplinked transfusion reaction data of year 2016 to ISTARE (International Surveillance of Transfusion- Associated Reactions and Events) on June 4, 2018.

c. **Publication(s)**

An Article published as "International haemovigilance: what have we learned and what do we need to do next?" Wood E.M., Ang, A.L., Bisht, A., Bolton-Maggs, P.H., Bokhorst, A.G., Flesland, O. Land, K., Wiersum-Osselton, J.C, Schipperus, M.R., Tiberghein, P. and Whitaker, B.I. (2019) in Official Journal of The British Blood Transfusion Society, 12.01.2019. Besides bringing out biannual release of HvPI newsletter to disseminate information about HvPI to health care professionals & other stakeholders.

4. Training/ Workshop/ Conference Organized:

NIB under Haemovigilance Programme of India (HvPI) has organized 10 CMEs/ Workshops across the country & trained about 1538 participants which includes Blood bank officials, clinicians, nurses & blood bank technical staff so as to create awareness about the programme.

5. Participation in Training/ Workshop/ Conference:

Dr. Akanksha Bisht, Head- HvPI was invited by International Society of Blood Transfusion (ISBT) as a speaker to deliver a lecture on "Indian Experience of Introducing a Haemovigilance Scheme" in the 35th International Congress of the ISBT, held at Toronto, Canada from June 02-06, 2018.

6. Outstanding achievements of the Lab/ Division:

Bangladesh Delegates through WHO, SEARO visited National Institute of Biologicals to study Capacity Building on Haemovigilance System for Quality and Safety of Blood Donation and Transfusion from October 08-12, 2018.

The visit was undertaken by Dr. Sheikh Daud Adnan, Associate Professor and Head Department Transfusion Medicine, NICVD and Dr. Supriya Sarkar, Deputy Programme Manager HSM, DGSH from the Directorate General of Health Services, Government of the People's Republic of Bangladesh.

Objective of the visit

- To know the protocol of Haemovigilance for blood donors and patients and see the implementation of protocol at NIB.
- To learn how data of blood donors and patients are compiled for reporting purpose on Haemovigilance.
- To know how data/reports are being used at the facilities for preventing adverse events and challenges.

Inauguration and Lamp lighting

Opening remarks by Dr. Reba Chhabra Scientist Grade-I, NIB, NOIDA

Opening Remarks by Dr. Aparna Singh Shah, Regional Advisor, Health Laboratory Services and Blood Safety, WHO Regional Office for South-East Asia, New Delhi

Group Photograph

Scientific Session

INFORMATION TECHNOLOGY DIVISION

1. Name of Head:

Ms. Rashmi Srivastava, Scientist Grade-III (26.05.2017 to 08.05.2018)

Ms. Shalini Tewari, Scientist Grade-III (08.05.2018 to 04.01.2019)

Sh. Subhash Chand, Scientist Grade-III (Since 04.01.2019)

2. Manpower in the Lab/ Division:

I. Name of Scientific staff:

Sh. Deepak Mahajan, Computer Officer & i/c IT Division

Sh. P.S. Chandranand, Junior Scientist

II. No(s). of Outsourced Staff: 03

3. Activities Undertaken:

IT Division has initiated the following activities:

3.1 The Institute has implemented the e-Procurement System of NIC through its website i.e., https:// eprocure.gov.in/ eprocure/app, to make transparency in the tendering process as per Govt. guidelines.

3.2 As per the directions of NIC, the Institute has raised the requirements of NIC Cloud Servers for migration of Institute's website and other web based applications. The required Cloud Servers have been allocated to the Institute on 08.09.2018 at National Data Centre, NIC, Shastri Park, Delhi.

3.3 Security Audit – The IT Division has also participated in Security Audit of Institute's website, Haemo-vigil and Donor-vigil web based applications. The security audit were conducted as per Govt. of India guidelines from CERT-IN empanelled auditors and submitted its compliance audit report and certificate to National Informatics Centre (NIC). The Cyber Security Division of NIC has also conducted the compliance audit and notified that the Institute's website and Donor-vigil web based application of the Institute have under gone a third-party audit for web application security vulnerabilities and has been declared safe for hosting.

Further, as directed by NIC, IT Division migrated the Institute's website and Drug Survey– AKS Software web based application on NIC Cloud Server for compliance audit. In this matter, Cyber Security Division, NIC notified that the web based application of the Institute have under gone a third-party audit for web application security vulnerabilities and has been declared safe for hosting.

3.4 The IT Division has drafted the "Website Quality Manual" to obtain the Website Quality Certification through STQC as per the directives of Ministry of Health & Family Welfare, Govt. of India. In this matter, 4th & 5th cycles of STQC audit on current website of the Institute have been conducted.

3.5 IT enabled services undertaken during the year 2018-2019 are given below:

3.5.1 Laboratory Information Management System (LIMS) Software: The IT Division is developing in-house LIMS software in which generation of online Certificate of Analysis (CoA) part for all Laboratories of the Institute has been completed.

3.5.2 Sample Tracking Invoice Generation Software: The IT division is maintaining the in-house developed software for Invoice Generation against testing fees received for Quality Control evaluation of all indigenously produced and imported biological products submitted at NIB.

3.5.3 Other Invoice Generation Software: The IT division is maintaining the in-house developed software for generation of Other Invoice against payment received other than testing fees of samples such as Sale of Laboratory Animals to CPCSEA Registered Institutes and Reference Standards – Biotech Products etc.

BIOINFORMATICS DIVISION

1. Name of Head

Ms. Rashmi Srivastava, Scientist Grade-III (till 08.05.18)

Ms. Shalini Tewari, Scientist Grade-III (from 08.05.18)

Dr. Reba Chhabra, Scientist Grade–I & I/c DD (QC) (09.05.2018 to 29.05.2019)

Dr. Reba Chhabra, DD (QC) from 30.05.2019 to till date.

2. Manpower in the Lab/ Division:

Name of Scientific Staff

Mr. P. S. Chandranand, Junior Scientist

3. Scientific Activities Undertaken:

3.1 Conducted a review study on "Algorithms for screening of Cervical Cancer: A chronological review" using Artificial Intelligence (Machine Learning). The study has been successfully published in Cornell University (https://arxiv.org/abs/1811.00849).

3.2 Initiated a project titled LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS). This project is engaged towards development of an in-house software application that is intended to digitize all actions related to Quality Control testing of Biologicals received thus enabling an audit trail and transparency into the processes carried out within the institute. The module is under testing phase within the Institute. Upon successful testing, the same shall be subjected to necessary security audits and subsequent launch as a web application thus facilitating online access of LIMS application to all stakeholders 24×7 for viewing real time status of QC testing processes.

3.3 **Publications:** Algorithms for screening of Cervical Cancer: A chronological review. Yasha Singh, Dhruv Srivastava, P.S. Chandranand, Dr. Surinder Singh. Cornell University (https://arxiv.org/abs/1811.00849)


Cornell University

We gratefully acknowledge support from the Simons Foundation and member institutions.

arXiv.org > cs > arXiv:1811.00849

Search...

Computer Science > Machine Learning

Algorithms for screening of Cervical Cancer: A chronological review

Yasha Singh, Dhruv Srivastava, P.S. Chandranand, Dr. Surinder Singh

(Submitted on 2 Nov 2018)

There are various algorithms and methodologies used for automated screening of cervical cancer by segmenting and classifying cervical cancer cells into different categories. This study presents a critical review of different research papers published that integrated AI methods in screening cervical cancer via different approaches analyzed in terms of typical metrics like dataset size, drawbacks, accuracy etc. An attempt has been made to furnish the reader with an insight of Machine Learning algorithms like SVM (Support Vector Machines), GLCM (Gray Level Co-occurrence Matrix), k-NN (k-Nearest Neighbours), MARS (Multivariate Adaptive Regression Splines), CNNs (Convolutional Neural Networks), spatial fuzzy clustering algorithms, PNNs (Probabilistic Neural Networks), Genetic Algorithm, RFT (Random Forest Trees), C5.0, CART (Classification and Regression Trees) and Hierarchical clustering algorithm for feature extraction, cell segmentation and classification. This paper also covers the publicly available datasets related to cervical cancer. It presents a holistic review on the computational methods that have evolved over the period of time, in chronological order in detection of malignant cells.

Comments: This critical review of various machine learning algorithms for Cervical Cancer Screening was completed at National Institute of Biologicals(NIB), India by B.Tech final year Computer Science students at JSSATE, Noida, India under the supervision of Director at NIB Dr. Surinder Singh and Jr. Scientist Sh. P.S. Chandranand

Subjects: Machine Learning (cs.LG); Machine Learning (stat.ML)

Cite as: arXiv:1811.00849 [cs.LG]

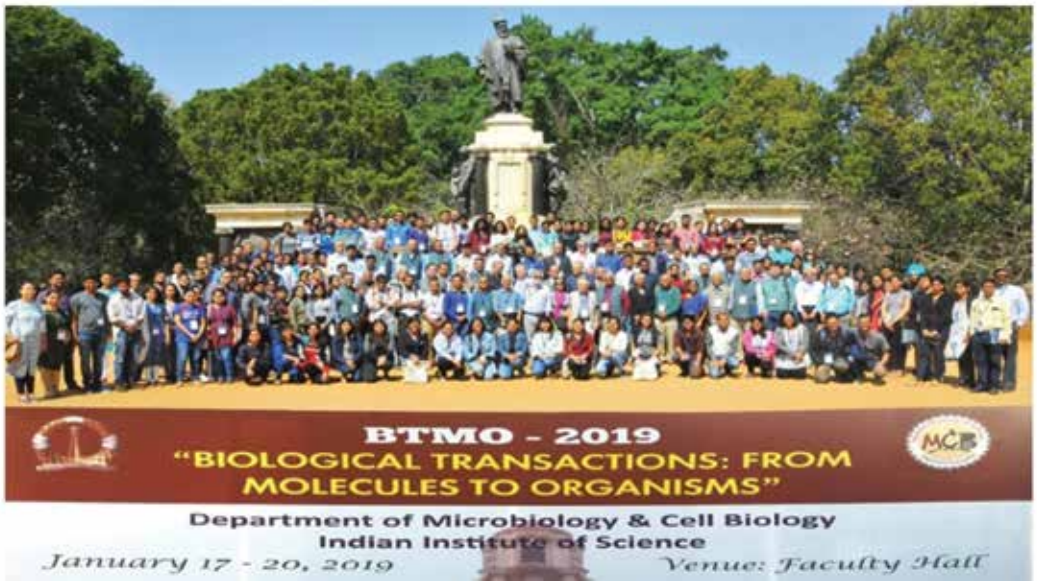
(or arXiv:1811.00849v1 [cs.LG] for this version)

4. Outstanding achievements of the lab:

Bioinformatics division presented following two posters at

4.1 Vigyan Bhawan, New Delhi on "Nanotechnology in Healthcare Applications – A Quality Control Perspective" in "6th world congress on Nanomedical Sciences-ISNSCON-2018", "Chemistry-Biology Interface 2019" and "Conference on "Science and Technology for the Future of Mankind" from 7 to January 7-10,2019. This international event was held for the first time in India with a very large number of participation from distinguished scientists from India as well as overseas including Nobel Laureates. The abstract has been published in the book of abstracts, a supplement to the journal of International Journal of Artificial Cells Nanomedicine and Biotechnology.

4.2 Indian Institute of Science, Bengaluru on "Machine Learning and Computer Vision in Diagnostics" in the event "From Biological Transactions: Molecules to organisms 2019 (BTMO 2019)" organized on January 17-20, 2019.



ENGINEERING DIVISION

Electro- Mechanical Engineering Works Undertaken:

The NIB campus specifically Laboratory & Animal House Building is complemented by various engineering services/ facilities/ installation to facilitate the day to day scientific activities. The detailed information about the various engineering works/ services/ facilities and installation undertaken during the Financial Year 2018-19 is as under:

a) Renovation of IT Cell and Training Unit in Library at NIB Campus Noida.

b) Furnishing of Room No. L-0147 for WHO-PQ support activities at ground floor at Laboratory building in NIB.

c) Supply, installation & commissioning of new dedicated walk in cold room for SRRDU (-20° C & 2-8° C) by M/s. HLL, Noida at NIB, Noida.

d) Repair works of Centrifugal chiller, 750 Tr, M/s Carrier, USA make for HVAC system installed for Laboratory & Animal House Building.

e) Obtained the License for storage of HSD from M/s Petroleum and Explosive for Safety Organization (PESO), Agra (formerly Department of Explosives, Government of India)

f) Administration of various electro-mechanical engineering services/ facilities installation of day to day operation and maintenance & repairing, which are provided/ installed in the various buildings/ areas of NIB Campus.

Apart from the above the Institute has finalized the services/contracts for annual operation and maintenance contract, and AMCs/ CMCs of the following Engineering Services/ facilities and fixed scientific equipment during the financial year 2018-19:

i) Operation and Non Maintenance contract for External & Internal services (Electrical) installed at NIB, Noida

ii) Operation and comprehensive maintenance contract for fire-fighting system, water supply system, water softening plant system, neutralization system including centralized water softening plant of the Institute.

iii) Operation and maintenance contract for CCTV Surveillance system and Access Control system installed in various building/ locations/ areas of the Institute.

iv) Operation and maintenance contract for HVAC plant System including Window/ Split Cassette and package type AC units installed in various buildings of the Institute.

v) Operation & maintenance of 3x2.8T/Hr at 10.5kg/Sq.cm Steam Generating Boiler including Economizers and allied accessories etc. installed at NIB, Noida.

vi) Operation and maintenance of 20 Nos. Walk-in-cold Rooms, Constant Humidity Chambers and Environment Rooms, installed in the Laboratory & Animal House Building at NIB, Noida.

vii) Operation and maintenance contract for Sterilizers, Glass Washers, Glassware Dryers, Tunnel Washers and Cage & Rack Washers including other equipment of Steris, USA make installed in the Laboratory & Animal

facility of the Institute.

viii) Operation and maintenance contract for centralized R. O. Plant system installed in the Laboratory & Animal House.

ix) Repair and maintenance of the following engineering installation/ facilities/ fixed scientific equipment under AMC/ CMC contract with OEM or their authorized service agency in India, which are installed in various buildings/ areas of the Institute namely are: Elevators/ Lifts, Centralized UPS system, Electrical appliances, LED Signage, Telecommunication/ EPABX system/ PRI lines services, Bio-Safety Cabinets & Laminar Air Flow Stations, Chemical Fume Hoods, Air Compressor (Atlas Copco make), Refrigerators and Bio-waste Disposal including follow up with external agencies/departments like BSNL, PVVNL, U.P. Pollution Control Board and NPC & PESO (formerly Department of Explosives, Government of India), respectively for environmental & safety consent orders.

x) Annual Contract for Housekeeping/ cleaning Services at NIB, Noida.

xi) Award CMC of 20 Nos. data Logger System installed on all 20 Nos. walk-in-Cold Rooms, Incubators etc. at NIB, Noida.

xii) Assign the work for Inspection & rectification of underground firefighting piping network to CPWD.

Major Civil works undertaken:

1. Complete support & management of repairs, maintenance and trouble shooting in buildings (area of buildings more than 35000 Sq.m.), services and Institute campus measuring 18 Acre approx.
2. Monitoring & maintaining of controls, checks, systems and documentation for ISO/ IEC 17025: 2005 and OHSAS 18001-2007
3. Award of fresh Annual Contract for Maintenance of Lawns and Gardens in NIB Campus, Noida.
4. Designing, supply and installation of Vertical Garden Panels and increasing green cover inside the buildings under Swachhata Action Plan (SAP).
5. Construction of cement concrete access path from road to Transformer yard, DG set, Cooling Tower, Monkey Ladders in various buildings, outdoor electrical panels etc.
6. Award of fresh contract for General Pest Control, Rodent Control and Anti-Termite Treatment in NIB Campus Noida.
7. Construction of Ramps in NIB Campus under Accessible India plan.
8. Signage installation in buildings & service areas. Demarcation of assembly area for emergency evacuation etc.
9. Furnishing for setting up new WHO-PQ Support Cell activities.
10. Furnishing for Expansion of Sterility Laboratory.
11. Furnishing for setting up new WHO-CC Laboratory.

REPORT OF THE ADMINISTRATIVE WORK

Head of the Administration:

Dr. Reba Chhabra, Deputy Director (Admin)

During the year 2018-19, the following promotions/ appointments have been made by the Institute:-

S. No.	Name of Employee	Designation
1.	Sh. Kallol Saha	Junior Scientist
2.	Sh. Brij Bhushan	Junior Scientist
3.	Sh. Subhash Kumar	Junior Scientist
4.	Sh. Pradeep Kumar	Junior Accountant
5.	Sh. Dhirender Singh	Junior Accountant
6.	Sh. Praveen Kumar Pant	Computer Operator

Meetings of the General / Governing Body

A. The 12th Meeting of the General Body was held on 11.03.2019

Composition of the General Body:

Secretary Health & Family Welfare — Chairman
Ministry of Health & Family Welfare,
Nirman Bhawan, New Delhi.

Secretary — Member
Department of Biotechnology,
New Delhi

Secretary, DHR & DG, ICMR — Member
Ansari Nagar, New Delhi – 110029

Director General of Health Services, — Member
Ministry of Health & Family Welfare,
Nirman Bhawan, New Delhi – 110011.

Additional Secretary (Health) Member
Ministry of Health & Family Welfare,
Nirman Bhawan, New Delhi – 110011.

Additional Secretary & F.A. Member
Ministry of Health & Family Welfare,
Nirman Bhawan, New Delhi – 110011.

Joint Secretary Member
Ministry of Health & Family Welfare,
Nirman Bhawan, New Delhi – 110011.

Drugs Controller General (India), Member
Directorate General of Health Services,
F.D.A. Bhawan, Kotla Road
New Delhi - 110002.

Secretary Member
Health & Family Welfare, H. Block Secretariat,
Govt. of Andhra Pradesh,
Hyderabad, Andhra Pradesh

Secretary Member
Health & Family Welfare Department,
Government of West Bengal,
Writers Building, Kolkata.

Chairman Member
Serum Institute of India Ltd.,
212/2 Hadapsar,
Pune - 411 028

Director Pasteur Institute of India, Coonoor – 643 103 (The Neelgiris)	Member
The Chairman-cum-Managing Director National Dairy Development Board, Anand, Gujrat.	Member
Managing Director Haffkine Bio-Pharmaceutical Corpn. Ltd., Acharya Donde Marg, Parel, Mumbai.	Member
Director, NIB, NOIDA	Member Secretary

B. The 28th Meeting of the Governing Body was held on 11.03.2019

Composition of the Governing Body:

Secretary (Health & Family Welfare) Ministry of Health & Family Welfare Nirman Bhawan, New Delhi-110011	Chairperson
Secretary (DBT), Govt. of India Block No.2, C.G.O. Complex Lodhi Road, New Delhi – 110003.	Member

Secretary, DHR & DG, ICMR Ansari Nagar, New Delhi – 110029	Member
Director General of Health Services Directorate General of Health Services, Nirman Bhawan, New Delhi- 110011.	Member
Additional Secretary (Health) Ministry of Health & Family Welfare Nirman Bhawan, New Delhi – 110011.	Member
Additional Secretary & F.A. Ministry of Health & Family Welfare Nirman Bhawan, New Delhi – 110011	Member
Joint Secretary Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi - 110011.	Member
Drugs Controller General of India Directorate General of Health Services, Nirman Bhawan, New Delhi- 110011.	Member
Director, NIB, NOIDA	Member Secretary

C. Meetings of Standing Finance Committee.

i. The 29th Meeting of the Standing Finance Committee was held on 26.11.2018

Composition of the Standing Finance Committee:

Additional Secretary Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi	Chairman
Additional DG, ICMR or his nominee Indian Council of Medical Research, Ansari Nagar, New Delhi - 110029.	Member
Joint Secretary Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi - 110011	Member
Drugs Controller General (I) or his nominee (Not below the rank of Asstt. Drugs Controller (I)) FDA Bhawan, New Delhi - 110002	Member
Director (IFD) Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi - 110011.	Member
Director, NIB, NOIDA	Member Secretary

PERSONNEL

A. Scientific & Technical

S. No.	Name	Designation
1.	Dr. Surinder Singh	Director
2.	Dr. Reba Chhabra	Scientist Grade-I
3.	Dr. Achla Prasad	Scientist Grade-I
4.	Dr. J. P. Prasad	Scientist Grade-I
5.	Dr. Shikha Yadav	Scientist Grade-II (Sr. Vet.[Path.])
6.	Sh. Neeraj Malik	Scientist Grade-II
7.	Dr. Charu Mehra Kamal	Scientist Grade-II
8.	Ms.Ajanta Sircar	Scientist Grade-III
9.	Ms Sudha V Gopinath	Scientist Grade-III
10.	Ms Kanchan Ahuja	Scientist Grade-III
11.	Dr. R. K.Sharma	Scientist Grade-III
12.	Ms. Gurminder Bindra	Scientist Grade-III
13.	Ms. Shalini Tewari	Scientist Grade-III
14.	Ms. Rashmi Srivastava	Scientist Grade-III
15.	Dr. Richa Baranwal	Scientist Grade-III
16.	Dr. Suresh Kumar	Scientist Grade-III (Jr. Vet.)
17.	Ms. Madhu Y	Scientist Grade-III
18.	Dr. Meena Kumari	Scientist Grade-III
19.	Dr. Akanksha Bisht	Scientist Grade-III
20.	Sh. Tara Chand	Scientist Grade-III
21.	Dr. Manoj Kumar	Scientist Grade-III
22.	Sh. Pankaj Kumar Sharma	Scientist Grade-III
23.	Sh. N. Nanda Gopal	Scientist Grade-III
24.	Sh. Subhash Chand	Scientist Grade-III
25.	Sh. Jaipal Meena	Scientist Grade-III
26.	Sh. Ashwini Kumar Dubey	Scientist Grade-III
27.	Dr. Sanjay Mendiratta	Junior Scientist
28.	Sh. Harit Kasana	Junior Scientist

S. No.	Name	Designation
29.	Ms. Vandana Tandasi	Junior Scientist
30.	Dr. Manjula Kiran	Junior Scientist
31.	Dr. Birendra Kumar	Junior Scientist
32.	Dr. Varun Singh	Junior Scientist
33.	Sh. Rajeev Kumar	Junior Scientist
34.	Sh. P.S.Chandranand	Junior Scientist
35.	Md. Daud Ali	Junior Scientist
36.	Dr. Richi V. Mahajan	Junior Scientist
37.	Dr. Anoop Kumar	Junior Scientist
38.	Dr. Anirban Mukherjee	Junior Scientist
39.	Ms. Archana Sayal	Junior Scientist
40.	Sh. Ajay Kumar Ade	Junior Scientist
41.	Ms. Apoorva Anand	Junior Scientist
42.	Ms. Swati Shalini	Junior Scientist
43.	Sh. Paras Jain	Junior Scientist
44.	Sh. Kallol Saha	Junior Scientist
45.	Sh. Subhash Kumar	Junior Scientist
46.	Sh. Brij Bhushan	Junior Scientist
47.	Ms. Girija L. V	Laboratory Technician
48.	Sh. Brij Bahadur	Laboratory Technician
49.	Ms. Poonam	Laboratory Technician
50.	Sh. Sukhen Majhi	Laboratory Technician
51.	Dr. Mohammed Imran	Laboratory Technician
52.	Sh. Reetesh Kumar Prajapati	Laboratory Technician
53.	Sh. Mohit Lal	Laboratory Technician
54.	Sh. Mohit Sharma	Laboratory Assistant
55.	Sh. Rajeev Kumar Srivastava	Laboratory Assistant
56.	Sh. Prdeep Kumar	Laboratory Assistant
57.	Ms. Priya Bhatt	Laboratory Assistant
58.	Sh. Narender Kumar	Laboratory Assistant
59.	Sh. Parminder Kumar	Junior Animal Care Taker

B. Administration, Procurement & Accounts

S. No.	Name	Designation
60.	Sh. S. K. Sharma	Budget & Finance Officer
61.	Sh. J.P. Pant	Section Officer
62.	Sh. W. Z. Quazi	Procurement Officer
63.	Sh. P.K. Mohapatra	Section Officer (Admn.)
64.	Sh. Sushil Kumar Dixit	Junior Hindi Translator
65.	Sh. Deepak Mahajan	Computer Officer
66.	Sh. Praveen Kumar Pant	Computer Operator
67.	Sh. Pawan Kumar Sharma	Data Entry Operator
68.	Sh. Manmeet Singh	Private Secretary
69.	Sh. R.K. Arora	Steno Grade-III
70.	Sh. Pradeep Kumar	Junior Accountant
71.	Sh. Upender Nath Sharma	Cashier
72.	Sh. Dhirender Singh	Junior Accountant
73.	Sh. Sanjeev	Stores Assistant
74.	Sh. Partho Pratim Mondal	Stores Clerk
75.	Sh. Prem Chand Gupta	Stores Clerk
76.	Sh. Pardeep Kumar Mehta	UDC
77.	Ms. Savita Rani	Receptionist
78.	Sh. Govind Singh Rawat	Staff Car Driver Grade-II
79.	Sh. Ravi Dutt	Staff Car Driver Grade-II
80.	Sh. Harinder Singh Chauhan	Staff Car Driver Grade-II
81.	Sh. Leela Kishan	Staff Car Driver Grade-II
82.	Sh. Bijender Singh	MTS
83	Sh. Suraj Pal	MTS
84.	Sh. Subhash Chand	MTS
85.	Sh. Rakesh	MTS
86.	Sh. P. C. Diwan	MTS
87.	Ms. Shobha	MTS
88.	Ms. Rajendri Devi	MTS

C. Engineering

S. No.	NAME	DESIGNATION
89.	Sh. Mukesh Kumar	Assistant Engineer (Electrical)
90.	Sh. R. P. Joshi	Assistant Engineer (Civil)
91.	Sh. Subhash Chand	Junior Engineer (Electrical)
92.	Sh. Chander Pal	Junior Engineer (Mechanical)
93.	Sh. Amarjit Singh	Junior Engineer (Mechanical)
94	Sh. Krishna Kumar	Junior Engineer (Civil)
95.	Sh. H. P. Vashisht	Electrician

RAJBHASHA (HINDI):

Aims and Scope

The aim of the Rajbhasha unit is to educate, train the employees of Institute to use Hindi language in day-to-day official work as per the rules of Rajbhasha. This unit also provides a platform to employees of the Institute to involve themselves and participate in various activities during celebration of the 'Hindi Pakhwara' and other activities organized by Nagar Rajbhasha Bhasha Karyanvyan Samiti, NOIDA.

The constitution of the Rajbhasha Committee of the Institute is as under:-

Dr. Surinder Singh	**Chairperson**
Dr. Reba Chhabra	**Vice Chairperson**
Shri S.K. Sharma	**Member**
Shri R.P Joshi	**Member**
Shri Sushil Kumar Dixit	**Member**
Shri J.P. Pant	**Member-Secretary**

The Committee has organized various programmes to promote the use of Hindi language in day-to-day official work.

Miscellaneous Academic activities

1. Sh. Sushil Kumar Dixit, Junior Hindi translator, participated in "84th Seminar and Hindi Workshop", held in Solan, Himachal Pradesh from 25.04.2018 to 27.04.2018, organized by the Official Language Institute, Vasant Vihar, New Delhi.
2. Sh. Sushil Kumar Dixit, Junior Hindi Translator and Sh. Praveen Kumar Pant, Computer Operator, participated in "Seminar and Hindi Workshop at the 85th meeting" held in Nainital, Uttarakhand from 31.10.2018 to 02.11.2018, organized by Raj Bhasha Institute, New Delhi.

Participation in Meetings / Workshops

Sh. J. P. Pant, Section Officer and Sh. Sushil Kumar Dixit, Junior Hindi Translator participated in "33rd All India Official Language Training Camp and Conference" from June 12- 14, 2018 in Kodaikanal, Tamilnadu organized by Indian Language and Culture Center, New Delhi.

Hindi Pakhwara

Hindi cell, National Institute of Biologicals, Noida organized "Hindi Pakhwara" from dated 31.08.2018 to 14.09.2018 as per guidelines issued by Rajbhasha Vibhag, Ministry of Home Affairs, Government of India. In this program talks were delivered by various officials of the Institute. Various types of competitions were also organized in this pakhwara programme for the officials of the Institute.


हिंदी पखवाड़ा
अगस्त 2018 से 14 सितंबर 2018
हिंदी को काम में लाना देश की एकता और
इसके प्रयोग में शर्म नहीं गर्व का

EMPOWERING CONSUMERS: RIGHT TO INFORMATION ACT, 2005

In terms of Section 4(1) (b) and 4(2) of the Right to Information Act, 2005, the Institute nominated the following officers as PIO and Appellate Authority under the RTI Act, 2005:

Sh. W. Z. Quazi	Procurement Officer & Administrative Officer I/c	Appellate Authority
Sh. P. K. Mohapatra	Section Officer (Admn.)	Public Information Officer (PIO)

During the year (2018-19), the Institute received the following number of applications to obtain various types of information under the RTI Act: -

	Opening Balance	**No. of Applications Received as transfer from other PA u/s 6(3)**	**Received (including cases transferred to other PAs)**	**No. of cases transferred to other PAs u/s 6(3)**	**Decision where request/ Rejected after appeal Rejected**	**Decision where request/ appeal Accepted**	**Registration Fee Collected (in Rs.) u/s 7(1)**
Request	0	35	0	1	0	5	144
First Appeals	0	6	0	0	6	0	0

AUDITOR'S REPORT
NIB

AAJV and associates
Chartered Accountants

205, Prerna Complex, B-3,
Subhash Chowk, Laxmi Nagar,
New Delhi-110092 (INDIA)
Tel.: 011-43086886
E-mail: anil@aajvca.com

INDEPENDENT AUDITOR'S REPORT

To
National Institute of Biologicals
A-32, Institutional Area, Sector-62
Noida (Uttar Pradesh)-201307

Opinion

We have audited the financial statements of **National Institute of Biologicals (herein after called "NIB")**, which comprise Balance Sheet as at 31st March,2019, the Income & Expenditure Account and Receipt and Payment Account for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

Subject to Emphasis of matters Para below, in our opinion, the accompanying financial statements give a true and fair view of the financial position of the **NIB** as at 31st March, 2019, and of its financial performance for the year then ended in accordance with the Accounting Standards issued by the Institute of Chartered Accountants of India (ICAI).

Basis for Opinion

We conducted our audit in accordance with the Standards on Auditing (SAs) issued by ICAI. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the **NIB** in accordance with the Code of Ethics issued by ICAI and we have fulfilled our other ethical responsibilities in accordance with the Code of Ethics. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Emphasis of Matters

We draw attention to Note No. 2, 3 & 12 of these financial statements which indicates that NIB is procuring certain Fixed Assets through its procurement consultant M/s. HLL Lifecare Ltd. The reconciliation/settlement with HLL Lifecare Ltd. is pending as on the date of Balance Sheet, hence, the Overstatement/Understatement of Capital Assets cannot be quantified. Our opinion is not Qualified in respect of this matter.

Other Matters

1. **Attention is also invited to the following :**
   - **Note No. 1 Reconciliation of Property, Plant & Equipment and its physical verification.**
   - **Note No. 6 regarding long outstanding creditors.**
   - **Note No. 7 regarding non confirmation of balances from third party.**

E-mail : aggarwalkanil@rediffmail.com Website : www.aajvca.com

- **Note No. 8 regarding non consideration of Pension Fund A/c in the books of NIB.**
- **Note No. 12 regarding advances to contractors & suppliers pending reconciliation and confirmation.**
- **Note No. 13 regarding maintenance of separate accounts for various projects funded by other agencies not included in NIB books.**
- **Note No. 16 regarding utilization of Grants.**

Responsibilities of Management and Those Charged with Governance for the Financial Statements

Management is responsible for the preparation of these financial statements that give a true and fair view of the state of affairs, results of operations and cash flows of the **NIB** in accordance with the accounting principles generally accepted in India. This responsibility includes the design, implementation and maintenance of internal control relevant to the preparation and presentation of the financial statements that give a true and fair view and are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the **NIB**'s ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the **NIB** or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the **NIB**'s financial reporting process.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with SAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

AAJV AND ASSOCIATES
Chartered Accountants
Reg. No. 07739N

ANIL KUMAR AGGARWAL
Partner
M. No. 098261
UDIN: 19098261AAAAAH7320

Place of Signature: NOIDA
Date: 12/09/2019

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare

BALANCE SHEET AS AT 31st MARCH 2019

Amount In ₹

CORPUS/CAPITAL FUND AND LIABILITIES	Schedule	Current Year	Previous Year
Corpus / Capital Asset Fund	1		
Gross Corpus Fund		23381,88,825.53	23222,62,755.59
Less : Accumulated Depreciation		10602,29,787.10	9989,83,407.70
Net Corpus Fund		12779,59,038.43	13232,79,347.89
Current Liabilities and Provisions	2	932,22,257.52	690,30,776.72
TOTAL		13711,81,295.95	13923,10,124.61

ASSETS	Schedule	Current Year	Previous Year
Property,Plant & Equipment	3		
Gross Block		23010,44,482.57	22768,92,757.46
Less : Accumulated Depreciation		10602,29,787.10	9989,83,407.70
Net Block		12408,14,695.47	12779,09,349.76
Current Assets, Loans & Advances	4	1303,66,600.48	1144,00,774.85
TOTAL		13711,81,295.95	13923,10,124.61
SIGNIFICANT ACCOUNTING POLICIES AND NOTES ON ACCOUNTS	12	-	-

As per our report of even date attached.

For AAJV AND ASSOCIATES
Chartered Accountants
FRN NO. 07739N

CA ANIL KUMAR AGGARWAL
Partner
(M.No. 098261)

Place: NOIDA
Date: 12.09.2019
UDIN : 19098261AAAAAH7320

FOR NATIONAL INSTITUTE OF BIOLOGICALS

S.K. Sharma
(Budget & Finance Officer)

Dr. Reba Chhabra
(Dy. Director & HOO)

Dr. Surinder Singh
(Director)

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare

INCOME AND EXPENDITURE ACCOUNT FOR THE YEAR ENDED 31st MARCH 2019

Amount In ₹

PARTICULARS	Schedule	Current Year	Previous Year
INCOME			
Receipts from Sales & Testing	5	1093,64,479.00	1264,73,203.00
Grants/Subsidies Utilized for Revenue Expenditure	6	2408,56,157.10	2152,59,897.95
Interest Earned	7	49,79,352.00	39,49,005.00
Other Income	8	21,11,734.00	25,75,503.00
Depreciation (as per contra)		612,46,379.40	594,62,834.99
TOTAL (A)		**4185,58,101.50**	**4077,20,443.94**
EXPENDITURE			
Establishment Expenses	9	1114,38,100.00	1176,03,128.00
Adminstration Expenses	10	937,20,785.13	871,67,284.65
Lab Services - Operation & Maintainance Exp	11	1521,52,836.97	1434,87,196.30
Depreciation (as per contra)		612,46,379.40	594,62,834.99
TOTAL (B)		**4185,58,101.50**	**4077,20,443.94**
Balance being Surplus/(Deficit) (A-B)		-	-
Less: Prior period Expenses			-
Prior period Expenses charged to Grant			-
SIGNIFICANT ACCOUNTING POLICIES AND NOTES ON ACCOUNTS	12		-

As per our report of even date attached.

For AAJV AND ASSOCIATES
Chartered Accountants
FRN NO. 07739N

CA ANIL KUMAR AGGARWAL
Partner
(M.No. 098261)

Place: NOIDA
Date: 12.09.2019
UDIN : 19098261AAAAAH7320

FOR NATIONAL INSTITUTE OF BIOLOGICALS

S.K. Sharma
(Budget & Finance Officer)

Dr. Reba Chhabra
(Dy. Director & HOO)

Dr. Surinder Singh
(Director)

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare

SCHEDULES FORMING PART OF BALANCE SHEET AS AT 31st MARCH 2019

SCHEDULE 1 -CORPUS/CAPITAL FUND	Amount In ₹ For Current Year ended on 31.03.2019		Amount In ₹ For Previous Year ended on 31.03.2018	
Balance as at the beginning of the year	20826,01,529.76		20807,90,336.76	
Add: Grant Utilised for Security Deposits	-		-	
Add: Increase in Stock of Fuel for Boillers & D.G Set	-30,22,422.00		18,11,193.00	
Less: Interest on Security Deposit- Electricity	-		-	
Less: Prior Period Adjustments	-		-	
Less: Cost of Assets Written Off			-	
Add: Grant utilised for Security Deposits - Electricity	-	-	-	-
Add: Receipts from sale of Assets	-	20795,79,107.76	-	20826,01,529.76
Add: Capital Assets Fund				
Balance at the beginning of the year	2276,05,084.83		1976,66,625.00	
Addition during the year	327,82,197.94		338,61,318.83	
Less: Adjustment on account of Sale of Capital Assets	-		-32,43,096.00	
Less: Adjustment for amount of fixed asset excess charged in P.Y	-	2603,87,282.77	-6,79,763.00	2276,05,084.83
Add: Grant utilised for advances of previous years		-62,83,035.00		111,36,918.00
Add: Grant Utilized for advances against Assets/Capital items during C.Y		22,00,000.00		65,471.00
Add: Grant Utilized for advances against Goods & Services during C.Y		20,62,684.00		-
Add: Grant utilised for Prepaid Expenses Increase/Decrease during the year - Electricity		2,42,786.00		8,53,752.00
BALANCE AS AT THE YEAR END		**23381,88,825.53**		**23222,62,755.59**

SCHEDULE 2 -CURRENT LIABILITIES AND PROVISIONS	For Current Year ended on 31.03.2019		For Previous Year ended on 31.03.2018	
A. CURRENT LIABILITIES				
1. Sundry Creditors				
a) HSCC	154,57,028.00		154,57,028.00	
b) Goods/Service	163,13,808.54	317,70,836.54	132,20,935.83	286,77,963.83
(Including Creditors outstanding for more than one year)				
2. Advances Received				
-Advance Received for Sale of Refrence standards	7,400.00		2,600.00	
Fund received for SERB Project	3,22,745.00		5,44,797.00	
Fund Received From DST- Nanomission	2,70,000.00		3,00,000.00	
-Receipts payable to MOH & FW, GOI	84,55,565.00		99,97,711.00	
-Earnest Money Deposit	27,51,700.00	118,07,410.00	14,99,100.00	123,44,208.00
3.Statutory Liabilities				
-TDS (Professional)	85,584.00		1,05,685.00	
-TDS (Contractors)	2,49,595.00		2,30,345.00	
-GST (TDS)	2,82,448.00	6,17,627.00	-	3,36,030.00
4. Other Current Liabilities				
-Security deposit/Retention Money	37,89,147.00		32,54,233.00	
-Salary Payable	84,00,598.00		76,89,186.00	
-Expenses Payable	33,51,406.67		23,81,281.54	
-Testing Fees Refundable	7,99,483.00		5,85,461.00	
-Claim Payable	49,316.00		1,40,468.00	
-TDS Payable to NIB-GPF	45,311.00		-	
-Audit Fee Payable	72,000.00		66,000.00	
-Employer Contribution to NPS (Payable)	2,81,318.00		2,63,800.00	
- CGHS Contribution	6,25,061.00		-	
- Grant Payable to MOHFW, GOI	233,11,701.31		49,61,493.35	
		407,25,341.98	-	193,41,922.89
B. PROVISIONS				
1. For Gratuity	39,86,642.00		40,16,252.00	
2. Accumulated Leave Encashment	43,14,400.00	83,01,042.00	43,14,400.00	83,30,652.00
TOTAL		**932,22,257.52**		**690,30,776.72**

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare

SCHEDULES FORMING PART OF BALANCE SHEET AS AT 31st MARCH 2019

SCHEDULE-3: PROPERTY, PLANT & EQUIPMENT AS ON 31.03.2019

Amount in ₹

FIXED ASSETS	GROSS BLOCK							DEPRECIATION					NET BLOCK	
	Cost as at 01.04.2018	Additions during the year	Transfer From WIP	Transfer In	Sold during the Year	Adjustments	Cost as at 31.03.2019	As at 01.04.2018	Depreciation Adjustment	During the year	Deduction/Sales /adjustements	Total up to 31.03.2019	As at 31.03.2018	As at 31.03.2019
LAND	1461,50,000.00	-			-	-	1461,50,000.00	-	-	-	-	-	1461,50,000.00	1461,50,000.00
BUILDING	8439,71,912.18	93,97,876.00			-	-	8533,69,788.18	1615,42,265.01	-	139,09,927.55	-	1754,52,192.56	6824,29,647.17	6779,17,595.62
A.C.PLANT	3914,04,302.95	9,49,230.00			-	-	3923,53,532.95	3800,86,792.67	-	1,32,037.89	-	3802,18,830.56	113,17,510.28	121,34,702.39
MACHINERY & EQUIPMENT	7289,25,142.17	115,73,744.83			-	-	7404,98,887.00	3983,66,561.22	-	362,02,062.87	-	4345,68,624.09	3305,58,580.95	3059,30,262.91
COMPUTER	257,87,138.50	5,59,201.00			-	-	263,46,339.50	212,80,917.01	-	47,09,898.57	81,980.00	260,72,795.58	45,06,221.49	2,73,543.92
COMPUTER SOFTWARE	118,02,364.00	2,84,054.11			-	-	120,86,418.11	65,91,313.07	-	15,94,906.45	-	81,86,219.52	52,11,050.93	39,00,198.59
FURNITURE & FIXTURES	329,08,332.47	10,95,290.00			-	-	340,03,622.47	144,91,293.94	-	19,16,066.30	-	164,07,360.24	184,17,038.53	175,96,262.23
OFFICE EQUIPMENTS	230,29,687.72	12,95,787.00			-	-	243,25,474.72	102,60,552.36	-	19,33,151.07	76,973.00	122,70,676.43	127,69,135.36	120,54,798.29
VEHICLES	7,55,248.00	-			-	-	7,55,248.09	(35,601.41)	-	71,748.56	2,04,771.00	2,40,918.15	7,90,849.41	5,14,329.85
TYPEWRITERS	2,00,970.64	-			-	-	2,00,970.64	1,90,922.10	-	-	-	1,90,922.10	10,048.54	10,048.54
BOOKS	68,09,074.00	34,329.00			-	-	68,43,403.00	61,69,418.30		4,06,320.80	-	65,75,739.10	6,39,655.70	2,67,663.90
CYCLE RICKSHAWS	9,000.00	-			-	-	9,000.00	3,510.00	-	877.50	-	4,387.50	5,490.00	4,612.50
TOOLS	1,19,112.00	-			-	-	1,19,112.00	35,463.43	-	5,657.84	-	41,121.27	83,648.57	77,990.73
CURRENT YEAR (A)	22118,72,284.63	251,89,511.94			-	-	22370,61,796.57	9989,83,407.70	-	608,82,655.40	3,63,724.00	10602,29,787.10	12128,88,876.93	11768,32,009.47
PREVIOUS YEAR	21898,84,534.63	252,30,846.00			32,43,096.00	-	22118,72,284.63	9427,63,968.71	28,79,672.00	594,62,834.99	3,63,724.00	9989,83,407.70	12471,20,565.92	12128,88,876.93

WORK IN PROGRESS:

ASSETS	OPENING AS AT 01.04.2018	ADDITIONS DURING THE YEAR	TRANSFER FROM CWIP	ADJUSTMENTS (NOTE)	DEDUCTIONS DURING THE YEAR	TRANSFER TO FIXED ASSETS	GROSS BLOCK AS AT 31.03.2019	DEPRECIATION					NET BLOCK	
								As at 01.04.2018	Depreciation Adjustment	During the year		Total up to 31.03.2019	As at 31.03.2018	As at 31.03.2019
WIP-WORKS	84,36,864.00		-	-	-	84,36,864.00	-	-		-		-	84,36,864.00	-
Capital WIP	565,83,608.83	75,92,686.00	-	-		1,93,608.83	639,82,686.00	-	-			-	565,83,608.83	639,82,686.00
CURRENT YEAR (B)	650,20,472.83	75,92,686.00	-	-	-	86,30,472.83	639,82,686.00	-	-	-		-	650,20,472.83	639,82,686.00
PREVIOUS YEAR	563,90,000.00	-	-	-	-	-	563,90,000.00	-	-	-		-	563,90,000.00	563,90,000.00

GRAND TOTAL (A+B)	22768,92,757.46	327,82,197.94	-	-	-	86,30,472.83	23010,44,482.57	9989,83,407.70	-	608,82,655.40	3,63,724.00	10602,29,787.10	12779,09,349.76	12408,14,695.47
PREVIOUS YEAR	22462,74,534.63	338,61,318.83	-	-	32,43,096.00	-	22768,92,757.46	9427,63,968.71	28,79,672.00	594,62,834.99	3,63,724.00	9989,83,407.70	12471,20,565.92	12779,09,349.76

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare

SCHEDULES FORMING PART OF BALANCE SHEET AS AT 31st MARCH 2019

SCHEDULE 4 -CURRENT ASSETS , LOANS & ADVANCES	For Current Year ended on 31.03.2019		For Previous Year ended on 31.03.2018	
A. CURRENT ASSETS				
1. Cash balances in hand	99.68		20,022.68	
2. Balance with Banks :				
- Saving Accounts	945,53,152.45		685,94,127.26	
3. Stamps in hand	2,229.00	945,55,481.13	7,118.00	686,21,267.94
TOTAL (A)		**945,55,481.13**		**686,21,267.94**
B. LOANS, ADVANCES AND OTHER CURRENT ASSETS				
1. Loans				
(a) Staff Advances				
- Computer Advance	1,29,000.00		90,250.00	
- Scooter Advance	-		-	
- House Building Advance	19,52,250.00		1,30,230.00	
- Tour Advance	-		-	
- LTC Advance	16,700.00		-	
- Festival Advance	-		-	
- Motor Car Advance	42,000.00		78,000.00	
- Departmental Advances	-	21,39,950.00	-	2,98,480.00
(b) Other Entities engaged in activities of NIB				
- Advance to CPWD	10,00,000.00		10,00,000.00	
- Advance to DAVP	3,582.00		3,582.00	
- Advance to M/s Agarwal Sales Agency	3,780.00		-	
- Advance to HSCC (ETP)	5,69,091.00		5,69,091.00	
- Advance to HSCC (Other work)	6,48,934.91		6,48,934.91	
- Advance to IOCL	42,767.00		65,471.00	
- Advance to NICSI	12,32,061.00	35,00,215.91	-	22,87,078.91
2. Advances and other amount recoverable in cash or in kind or for value to be received:				
a) On capital Account				
-Advance to HLL/HITES against Equipments	12,35,107.00		173,40,107.00	
b) Deposits				
-Bank Deposit for sales tax registration	25,000.00		25,000.00	
-Security Deposit with Balmer Lorrie	3,00,000.00		3,00,000.00	
-Security Deposit with PVVNL	79,57,678.00		79,57,678.00	
-Security Deposit with Padam Petroleum	25,000.00		25,000.00	
-Security Deposit with NOIDA	9,30,750.00		9,30,750.00	
-Security Deposit with Telephone	10,000.00		10,000.00	
-Security Deposit with PNG(IGL)	1,92,000.00		1,92,000.00	
-Security Deposit with Gas (BPCL)	3,550.00	106,79,085.00	3,550.00	267,84,085.00
3. Claim Receivable				
Claim Receivable - Drug Survey		-		9,85,087.00
Claim Receivable - Haemovigilance		-		60,640.00
Claim Receivable - Others		2,52,442.00		4,41,900.00
4. Sundry Debtors		33,73,795.00		35,45,968.00
5. Pre-paid Expenses		13,87,510.00		11,44,724.00
6. Stock-Fuel for Boillers & D.G Set		32,69,384.00		62,91,806.00
7. TDS Receivable (2017-18)		2,62,455.00		39,453.00
8. TDS Receivable (2018-19)		6,11,079.00		2,64,735.00
9. GST Recoverable		103,35,203.44		35,73,099.00
10. CENVAT Recoverable		-		62,451.00
11. Grant Receivable/Payable to MOHFW, GOI		-		-
TOTAL (B)		**358,11,119.35**		**457,79,506.91**
TOTAL (A+B)		**1303,66,600.48**		**1144,00,774.85**

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare

SCHEDULES FORMING PART OF INCOME & EXPENDITURE FOR THE YEAR ENDED AS AT 31st MARCH 2019

SCHEDULE 5 - RECEIPTS FROM TESTING & SALES	For Current Year ended on 31.03.2019		For Previous Year ended on 31.03.2018	
1. Receipts from Testing				
-Sample testing receipts	1082,74,479.00	1082,74,479.00	1249,13,203.00	1249,13,203.00
2. Receipts from Sales				
-Sale of Refrence Standards	10,90,000.00	10,90,000.00	15,60,000.00	15,60,000.00
TOTAL		**1093,64,479.00**		**1264,73,203.00**

SCHEDULE 6 - GRANTS/SUBSIDIES (Irrevocable Grants & Subsidies Received)	For Current Year ended on 31.03.2019		For Previous Year ended on 31.03.2018	
Grant Received During the year		3915,88,000.00		3821,00,000.00
Grant unutilized b/f from the previous year		49,61,493.35		-44,62,839.87
Total		**3965,49,493.35**		**3776,37,160.13**
Grant Adjusted towards Revenue Expenditure:				
Current Year Expenditure	3573,11,722.10		3482,57,608.95	
Less: Expenses Adjusted from Current Year Income	1164,55,565.00	2408,56,157.10	1329,97,711.00	2152,59,897.95
(taken to income & expenditure Account)		**1556,93,336.25**		**1623,77,262.18**
Less: Grant Utilized for purchase of Fixed Assets		152,92,568.94		227,41,507.83
Less: Grant Utilized for advances against Assets/Capital items during C.Y		22,00,000.00		65,471.00
Less: Grant Utilized for advances against Goods & Services during C.Y		20,62,684.00		-
Less: Current Year income transferred to MOH & FW		1080,00,000.00		1230,00,000.00
Less: Current Year Income Payable to MOH & FW		84,55,565.00		99,97,711.00
Less: Increase/Decrease in Stock of Fuel for Boillers & D.G Set		-30,22,422.00		18,11,193.00
Add: Adjustment for amount of fixed asset excess charged in P.Y		-		6,79,763.00
Add: Previous Year's Advance adjusted towards Goods & Services		8,49,547.00		1,86,958.00
Less: Prepaid Expenditure during the year - Electricity		2,42,786.00		8,53,752.00
Add: Advance of Previous Year Refunded/Received During the Year		-		1,87,145.00
Less: Security Deposits - Electricity		-		-
Grant Payable/(Receivable) to Govt. of India (Refer schedule-2)		**233,11,701.31**		**49,61,493.35**

SCHEDULE 7 - INTEREST EARNED	For Current Year ended on 31.03.2019	For Previous Year ended on 31.03.2018
1) On Saving accounts	48,29,558.00	38,94,725.00
2) On Loans To Employees/Staff	1,49,794.00	54,280.00
TOTAL	**49,79,352.00**	**39,49,005.00**

SCHEDULE 8 - OTHER INCOME	For Current Year ended on 31.03.2019	For Previous Year ended on 31.03.2018
a) Usage receipts for Hostel, Guest House & Conference Hall	10,84,450.00	6,20,650.00
b) Sale of Tender Forms	23,500.00	38,584.00
c) Training Fees	3,15,000.00	3,20,000.00
d) Receipts from Sale of Assets	-	2,37,175.00
e) Misc Receipt	1,51,567.00	8,90,555.00
f) Interest Income - HSCC	-	-
g) Sale of Lab Animal	4,99,138.00	3,97,215.00
h) License Fees	38,079.00	33,656.00
i) Interest on Haemovigilance A/c	-	37,668.00
TOTAL	**21,11,734.00**	**25,75,503.00**

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare

SCHEDULES FORMING PART OF INCOME & EXPENDITURE FOR THE YEAR ENDED AS AT 31st MARCH 2019

SCHEDULE 9 - ESTABLISHMENT EXPENSES		For Current Year ended on 31.03.2019		For Previous Year ended on 31.03.2018
a) Salary and Wages		933,95,527.00		886,72,724.00
b) Allowances and Bonus		5,37,952.00		2,67,458.00
c) Employer's Contribution to NPS/ other Fund		30,78,922.00		27,15,978.00
d) Expenses on Employee's Retirement and Terminal Benefit		79,68,343.00		206,79,658.00
e) Others				
-Medical Reimbursement		27,53,974.00		17,62,217.00
-LTC Expenses		19,34,458.00		19,53,246.00
-Reimbursement of Tution Fees		17,59,924.00		14,34,094.00
-Honorarium		9,000.00		29,000.00
-Recruitment Expenses		-		88,753.00
TOTAL		**1114,38,100.00**		**1176,03,128.00**

SCHEDULE 10 - OTHER ADMINISTRATIVE EXPENSES		For Current Year ended on 31.03.2019		For Previous Year ended on 31.03.2018
a) Consultants/Cont. Emp.Payment		407,90,696.00		296,23,163.00
b) Purchase of office consumables		1,40,746.00		5,69,880.00
c) Office Maintenance		76,39,876.30		118,95,166.00
d) Rent, Rates and Taxes		2,39,058.00		3,30,859.00
e) Vehicles Running and Maintenance		1,99,486.00		1,62,585.00
f) Postage, Telephone and Communication Charges		6,83,156.00		7,10,724.00
g) Printing & Stationary		22,81,937.00		27,79,849.00
h) Travelling and Conveyance Expenses		15,08,880.00		16,60,934.00
i) Expenses on Seminar/Workshops		2,38,860.00		2,86,367.00
j) Hospitality/Staff Welfare Expenses		8,34,714.00		12,66,879.00
k) Auditor's Remuneration		72,000.00		66,000.00
l) Professional Charges		11,19,002.00		12,06,231.00
m) Advertisement and Publicity		25,14,458.00		18,83,687.00
n) Other Expenses:				
- Miscellaneous Expenses		334.32		17,428.00
- Security Services expenses		196,89,578.00		164,58,978.00
- Honorarium (others)		5,88,000.00		5,44,000.00
- House Keeping Charges		67,78,865.00		66,47,070.00
- Hiring of Vehicles		45,20,475.00		40,07,411.00
- Hindi Promotion		1,18,400.00		77,395.00
- Bank Charges		26,143.51		237.65
- Internet Access Charges		10,26,719.00		7,82,255.00
- Travelling (others)		12,27,926.00		5,30,028.00
- Newspapers & Periodicals		1,87,043.00		2,79,710.00
- Other Office Expenditure		4,28,828.00		7,75,485.00
- Cenvat Credit Written Off		62,451.00		-
- Pest Control Charges		1,72,041.00		2,00,115.00
- Swachheta Action Plan (SAP)		4,42,317.00		-
- Recruitment Expenses		1,85,569.00		-
- Freight & Cartage		3,226.00		-
- Consultancy Charges- HLL		-		5,27,820.00
o) Expenditure on Haemovigilance Programme		-		38,77,028.00
TOTAL		**937,20,785.13**		**871,67,284.65**

SCHEDULE 11 - LAB SERVICES - OPERATION & MAINTENANCE EXP		For Current Year ended on 31.03.2019		For Previous Year ended on 31.03.2018
a) Electricity and Water Charges		658,61,390.00		669,83,950.00
b) Repair & Maintenance - Lab Equipments		120,95,654.89		94,25,390.00
c) Operation & Maintenance - Electrical		42,44,196.00		40,84,181.00
d) Operation & Maintenance - DG Sets		54,52,020.00		20,19,312.00
e) Operation & Maintenance - HVAC Plant		109,08,513.00		76,34,469.00
f) Operation & Maintenance - Boiler		20,46,770.00		17,40,285.00
g) Operation & Maintenance - Water Supply system		51,17,136.00		51,93,049.00
h) Operation & Maintenance - Air Compressor		97,833.00		13,750.00
i) Operation & Maintenance - Cold Room		41,81,887.00		25,45,819.00
j) Operation & Maintenance - BMS		1,19,408.00		10,38,888.00
k) Operation & Maintenance - Lifts		6,37,950.00		6,17,969.00
l) O & M Acces Control System		16,47,914.00		10,84,210.00
m) Purchase of Lab Consumable		119,73,719.00		139,92,810.00
n) Purchase of Lab Chemicals		18,64,970.00		35,48,440.00
o) Purchase of Kits & Reagents		179,67,158.47		158,68,847.30
p) Purchase of Lab Animal		60,000.00		2,77,000.00
q) Lab Misc. Expenses		1,03,638.61		2,85,583.00
r) Consumption of Fuel for Boilers & D.G Set				
Opening Balance of Fuel	62,91,806.00			
Add: Purchases	45,59,393.00			
Less: Closing stock	32,69,384.00	75,81,815.00		70,48,287.00
s) Bio-Waste Disposal Charges		1,90,864.00		84,957.00
TOTAL		**1521,52,836.97**		**1434,87,196.30**

NATIONAL INSTITUTE OF BIOLOGICAL
(Ministry of Health & Family Welfare, GOI)
RECEIPTS AND PAYMENTS ACCOUNT FOR THE YEAR ENDED 31ST MARCH 2019

Amount in ₹

RECEIPTS	Current Year	Previous Year	PAYMENTS	Current Year	Previous Year
1. Opening Balance			1. Expenses		
-Cash in Hand	20,022.00	18,713.00	-Establishment Expenses	871,05,959.00	960,74,356.00
-Bank Balance	685,94,127.26	992,98,718.47	-Administrative Expenses	79,36,780.51	87,28,123.65
-Stamps in Hand	7,118.00	8,425.00	-Lab Services- O&M Exp	957,81,228.01	1030,60,025.76
			-Expenditure/Transfer for Haemovigilance Programme	30,10,000.00	39,00,000.00
2. Grants Received			2. Payments made against funds		
-From Government of India	3915,88,000.00	3821,00,000.00	-Advance to HLL Lifecare Limited (Net)	22,00,000.00	-
			-Advance to IOCL	60,00,000.00	88,98,000.00
3. Interest Received:			-Advance to CPWD	-	-
-On Bank deposits	48,08,710.00	58,94,725.00	-Advance to CDSCO - Drug Survey	-	10,00,000.00
-Interest Recovered from Scooter, HBA & Computer advance	-	-	-Advance to DGS&D (Computer)	-	-
			-Advance to Contractors & Suppliers (Net)	8,20,269.70	32,74,867.00
4. Other Income			-Advance to A-Hartrodit Pvt. Ltd.	-	-
-Receipts from Hostel/Guest houses	10,82,200.00	2,44,350.00	-Advance to PNB Custom	-	-
-Sale of Tenders Forms	26,320.00	41,930.00	-Advance to Sunhare kal ki Pahle	-	-
-Sample Testing Receipts & Sale of Ref. Standards	1275,15,368.48	1406,20,792.00	-Advance to NICSI	-	1,58,522.00
-Training fees	3,15,000.00	3,20,000.00	-Funds Received from NHM - U.P. State	-	18,70,500.00
-Miscellaneous Receipts	94,077.20	4,34,384.00	-Advances Received	1,24,833.00	4,13,002.00
-Sale of Lab Animals	4,93,250.00	3,97,215.00	-Fund Received from WHO	96,937.00	12,28,186.00
5. Other Receipts			3. Expenditure on Fixed Assets & Capital Work-in-Progress		
-Tour Advance	38,093.00	79,824.00	-Machinery & Equipment	11,39,344.00	6,31,369.00
-Motor car Advance			-Computers	-	-
-LTC Advance	58,183.00	74,102.00	-Computers & Computer Software	5,74,201.00	3,26,588.00
-Festival Advance	-	-	-Furniture & Fixture	3,23,101.00	6,05,187.00
-Departmental Advance	35,366.00	22,488.00	-Office Equipments	1,28,829.00	7,27,770.00
-Advances to Contractors Utilized during the year during the year	-	-	-Vehicle	-	-
-Advance Received for Reference Standards	12,25,600.00	14,40,800.00	-Books	16,436.00	4,68,121.00
-Advance Received from NISCI	-	1,59,619.00	-Tools	-	-
-EMD received during the year	74,42,200.00	57,30,100.00			
-Security Deposit/Retention Money Received during the year	5,79,765.00	5,57,316.00	4. Payment of Internal Receipts/Unspent Balances		
-Net Claims received during the year	15,64,463.00	53,05,548.00	-To the Government of India	1080,00,000.00	1230,00,000.00
-TDS Receivable received	33,744.00	-	-Previous Year Receipts Paid to Ministry	99,97,711.00	465,37,358.00
-Received from IPC - Haemovigilance	30,00,000.00	-			
-Decrease in Debtors	-	1,93,537.00	5.Other payments		
-Adv Rec From CDSCO	-	10,00,000.00	Advances disburted during the year		
-Adv for Sale of Waste LA/Oil	-	1,56,704.00	-Medical Advance	2,31,200.00	-
-Funds Received from WHO	96,937.00	12,28,186.00	-Festival Advance	-	-
-Funds Received from DST - Nanomission	-	3,00,000.00	-Computer Advance	1,00,000.00	1,00,000.00
-Funds Received from NHM - U.P. State	-	18,70,500.00	-Tour Advance	1,89,500.00	2,97,000.00
			-LTC Advance	15,31,440.00	15,03,928.00
			-Departmental Advance	1,64,725.00	2,06,950.00
			-Motor Car Advance	-	-
			-Other Advance	22,18,241.00	71,338.00
			-Security Deposit (Travelling)	-	-
			-Security Deposit (Electricity)	-	-
			-Security Deposit released during the year	17,96,335.00	-
			-Security Deposit (Gas-BPCL)	-	-
			-Security Deposit (PNG-IGL)	-	-
			-EMD released during the year	60,28,500.00	89,57,803.80
			-Statutory Liabilities Paid	234,00,134.00	218,21,213.00
			-Receivable from IPC - Haemovigilance	-	-
			-Net Service Tax paid during the year	-	-
			-Payment made for Expense Payable	94,892.00	1,16,205.00
			-Payment to Suppliers of Goods & Services	1510,00,390.83	1364,88,458.00
			-Net GST paid during the year	39,50,104.44	64,11,838.00
			6.Closing Balances		
			-Cash in Hand	99.00	20,022.00
			-Bank Balance	945,53,152.45	685,94,127.26
			-Stamps in Hand	2,229.00	7,118.00
TOTAL	6086,18,573.94	6454,97,976.47	TOTAL	6086,18,573.94	6454,97,976.47

As per our report of even date attached.

For AAJV AND ASSOCIATES
Chartered Accountants
(FR No. 07739N)

CA ANIL KUMAR AGGARWAL
Partner
M. No. 098261

Place: NOIDA
Date: 12.09.2019
UDIN: 19098261AAAAAH7320

FOR NATIONAL INSTITUTE OF BIOLOGICALS

S.K.Sharma
(Budget & Finance Officer)

Dr.Reba Chhabra
(Dy. Director & HOO)

Dr. Surinder Singh
(Director)

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare

DETAILS OF GRANT UTILISATION FOR THE FINANCIAL YEAR 2018-19

Amount In ₹

PARTICULARS	GIA - SALARY	GIA - GENERAL	GIA - ASSETS	GIA - SAP	TOTAL
RECEIPTS					
Grant unutilized b/f from the Previous Year	-122,65,628.00	-31,85,550.82	204,12,672.17	-	49,61,493.35
Grant in Aid Received From Ministry	1140,00,000.00	2625,00,000.00	145,88,000.00	5,00,000.00	3915,88,000.00
TOTAL RECEIPTS (A)	**1017,34,372.00**	**2593,14,449.18**	**350,00,672.17**	**5,00,000.00**	**3965,49,493.35**
LESS:- EXPENDITURE INCURRED & PROVISION					
Establishment Expenses	1114,38,100.00	-	-	-	1114,38,100.00
Administrative Expenses	-	932,78,468.13	-	4,42,317.00	937,20,785.13
Lab Services-Operation & Maintainance Exp	-	1521,52,836.97	-	-	1521,52,836.97
Increase in Stock of Fuel for Boillers & D.G Set	-	-30,22,422.00	-	-	-30,22,422.00
Payment made for Fixed Assets during the year:					
Additions in Fixed Assets	-	-	327,82,197.94	-	327,82,197.94
Less: Advance of Previous year Utilized against Fixed Assets	-	-	-174,89,629.00	-	-174,89,629.00
Less: Adjustment for amount of fixed asset excess charged in P.Y	-	-	-	-	-
Advance against Fixed Assets, Goods & Services (Net)	-	20,62,684.00	22,00,000.00	-	42,62,684.00
Less: Advance of Prev. Year Utilized/Refunded against Goods & Services	-	-8,49,547.00	-	-	-8,49,547.00
Add: Grant Utilised for Prepaid Expenses Increase/Decrease	-	2,42,786.00	-	-	2,42,786.00
TOTAL CURRENT YEAR EXPENDITURE / UTILISATION (B)	**1114,38,100.00**	**2438,64,806.10**	**174,92,568.94**	**4,42,317.00**	**3732,37,792.04**
GRANT RECEIVABLE / PAYABLE TO GOI (A) - (B)	**-97,03,728.00**	**154,49,643.08**	**175,08,103.23**	**57,683.00**	**233,11,701.31**

SCHEDULE-12

NATIONAL INSTITUTE OF BIOLOGICALS
(Forming part of Financial Statement as on 31.03.2019)

(A) SIGNIFICANT ACCOUNTING POLICIES

1. **Basis of Accounting**
   The financial statements have been prepared as prescribed by ICAI in accordance with generally accepted accounting principles. The National Institute of Biologicals (hereinafter referred to as NIB) adopts accrual system of accounting, however, the incomes i.e. receipts from Training Fee received, and Rent received from Hostel/Guest House and Interest on advances are recognized on cash basis.

   The accounting policies adopted and applied in the preparation of financial statements by NIB are consistent with those used in the previous years.

2. **Property, Plant & Equipment and Depreciation**
   a) Property, Plant & Equipment (herein after commonly called Fixed Assets) are stated at cost less accumulated depreciation.

   b) Depreciation has been provided to the extent of 95% on S.L.M on the basis of rates as prescribed in schedule XIV of the Companies Act 1956. The depreciation rates applied on various assets is given below –

RATES OF DEPRECIATION CHARGED ON PROPERTY,PLANT & EQUIPMENT		
Machinery & Equipment	-	4.75%
Office Equipment	-	7.07%
Building	-	1.63%
Furniture & Fixtures	-	6.33%
Typewriter	-	13.91%
Vehicles	-	9.50%
Air Conditioner	-	13.91%
Computer& Computer Software	-	16.21%
Cycle Rickshaws	-	9.50%
Tools	-	4.75%
Books	-	40.00%

   c) The depreciation has been provided for the full year in respect of additions, if any, made during the year in Fixed Assets. In respect of sale/disposal of fixed assets, no depreciation has been provided for in the year of sale/disposal, but it has no financial implication due to this deviation from the prescribed provisions of the ICAI.

SCHEDULE-12

NATIONAL INSTITUTE OF BIOLOGICALS

(Forming part of Financial Statement as on 31.03.2019)

d) The depreciation has been charged to the grant (Corpus Fund/Capital Fund) and is recognized in the Income & Expenditure account over the useful life of the asset as a contra item as per AS-12 prescribed by the ICAI.

e) During the year, the depreciation has been charged from the year of original purchase of assets, procured through procurement consultant M/s HLL/HITES irrespective of the year of capitalization in respect of additions in fixed assets.

3. **Grant-in-Aid**

a) The Grant-in-Aid received from the Ministry of Health & family Welfare (MOH&FW), Government of India is accounted for on accrual basis. Accordingly, any deficit/surplus of grant has been shown as Grant Receivable / Payable to the MOH &FW.

b) The grants utilized for the purchase of fixed assets have been shown under the head of Capital Assets Fund.

c) Further grants utilized for advances against fixed assets, goods & services have also been shown under the head of Corpus/Capital Assets Fund.

d) A chart for receipt and utilization of Grant according to its grant head has been prepared and shown at Sr. No. 16 to Notes on Accounts to the financial statement. The inter head adjustments have been made in case of excess/deficit of grants received.

4. **Inventory Valuation**

Stock of Diesel has been valued at cost based on First in First Out (FIFO) method.

5. **Employee Remuneration & Benefits**

All Retirement and other Terminal Benefits such as Gratuity, Leave Encashment and Bonus etc. are not accounted on year to year basis and the same are recognized in the year of occurrence of event.

6. **Revenue Recognition**

a) Income and expenditure are accounted for on accrual basis, as they are earned or incurred, however, the incomes i.e. rent received from Hostel/Guest House, Bank Interest and Interest on Staff Advances are accounted on Cash basis.

b) The Consultancy charges paid for procurement of Fixed Assets is being considered as revenue expenditure

SCHEDULE-12

NATIONAL INSTITUTE OF BIOLOGICALS
(Forming part of Financial Statement as on 31.03.2019)

7. **Provision**
A provision is recognized, when an enterprise has a present obligation as a result of past event; it is probable that an outflow of resources will be required to settle the obligation, in respect of which a reliable estimate can be made. Provisions are determined based on best estimate required to settle the obligation at the balance sheet date. These are reviewed at each balance sheet date and are adjusted to reflect the current best estimates.

8. **Contingent Liabilities and Contingent Assets**
A disclosure for a contingent liability is made when there is a possible obligation that may, but probably will not, require an outflow of resources. Where there is a possible obligation or a present obligation but the likelihood of outflow of resources is remote, no provision or disclosure is made.

(B) NOTES ON ACCOUNTS

1. NIB has maintained Fixed Assets detail in soft format and keeping hard copy of the same for records. The reconciliation for physical verification of fixed assets is under process at the balance sheet date. The Depreciation has been charged at old rates till the reconciliation of all assets is being completed. Quantitative reconciliation of Fixed Assets items are also pending as on the Balance Sheet date.

2. The depreciation of Rs.6,12,46,379.40/- (Includes additional depreciation of Rs.5,00,907/- in respect of fixed assets procured through M/s HLL Lifecare Ltd. in the different previous years and capitalized during the year) has been charged to the Income & Expenditure account. Since, the Institute is fully aided by the Government of India, therefore depreciation is charged to the Grant (Corpus Fund/Capital Fund) and is recognized in the Income & Expenditure account over the useful life of the asset as a contra item.

3. The assets procured through the Procurement Consultant HLL Lifecare Ltd. are being capitalized in the year in which adjustment vouchers are received from HLL Lifecare Ltd. irrespective of the original date of purchase of assets, it is noticed due to this, in many cases, the capitalization of assets and adjustment of depreciation thereon have been delayed.

4. All liabilities are recognized to the extent information available.

SCHEDULE-12

NATIONAL INSTITUTE OF BIOLOGICALS

(Forming part of Financial Statement as on 31.03.2019)

5. NIB transfers all the receipts earned during the year from its various operations to the Ministry of Health & Family Welfare, GOI and already transferred an amount of Rs.10,80,00,000/-out of total receipts of Rs.11,64,55,565/-.The balance amount of Rs.84,55,565/- is shown as "Receipts Payable" to MOH&FW under the head of "Current Liabilities".

6. Sundry Creditors includes a sum of Rs.1,54,57,028/-, which is payable to M/s HSCC (I) Ltd. on account of construction of Laboratory & Animal House and consultancy fee. This amount is payable from the last many years, due to some technical defects intimated to HSCC and which was not yet rectified. The Institute is in process of final settlement of various project accounts with the HSCC.

7. Party's balances are subject to confirmation.

8. During the Financial Year 2018-19, NIB has transferred Rs.70,00,000/- to "NIB Pension Fund Account" and shown as an expense in the books of NIB. This amount has been kept in a separate bank account and balance of that bank is not reflected/shown in the books of NIB along with the interest thereon. The abstract of this accounts given below:-

Account Type	Opening Balance as on 01.04.2018 (Rs.)	Fund T/F from NIB A/c (Rs.)	Interest Earned (Rs.)	Fund Utilized for disbursement of Pension (Rs.)	Balance as on 31.03.2019 (Rs.)
NIB-Pension A/C	6,43,563	70,00,000	47,596	69,83,688	7,07,471

Due to non-consideration of above mentioned figures income and assets are understated to the extent of Rs. 47,596/- and Rs. 7,07,471 /- respectively.

9. During the Financial Year 2018-19, Rs.30,00,000/- has been received in NIB account from Indian Pharmacopeia Commission (IPC) for Haemovigilance programme which was transferred to separate "NIB Haemovigilance Account" during the year maintained for this purpose.

10. Purchase of Diesel to the extent utilized during the year has been recognized as expenditure and the balance amount is shown as stock forming part of Current Assets.

SCHEDULE-12

NATIONAL INSTITUTE OF BIOLOGICALS

(Forming part of Financial Statement as on 31.03.2019)

11. During the year, The NIB has made efforts to collect information from suppliers/service providers about their status under Micro, Small and Medium Enterprises (Development) Act, 2006. On the basis of information so gathered, no dues payable to Micro, Small and Medium Enterprises as on 31.03.2019 and hence the interest payable, if any, are not recognized.

12. The advances to contractors & suppliers includes the following:

Sl. No.	Party's Name	Amount in Rs.	Remarks
1.	M/s HSCC (I) Ltd.	12,18,026/-	Amount of Rs.5,69,091/- was provided for Effluent Treatment Plant (ETP) & Rs.6,48,935/- for other work is subject to confirmation. This amount is outstanding for last many years and under process for final settlement with HSCC.
2.	M/s HLL Lifecare Limited	12,35,107/-	Amount still lying under Advances to Contractors & Suppliers and the same is yet to be utilized / capitalized.
3.	CPWD	10,00,000/-	The amount is lying as Advances for work which is yet to be adjusted/settled.

13. Separate bank accounts are maintained for various projects/schemes on behalf of other entities by the Institute. Their balances in the Bank as on 31.03.2019 are given below. Interest income therefrom and balances therein belong to other entities and hence are not included in the books of accounts of NIB.

S. No.	Account Type	Interest Earned (Net) Rs.	Bank Balance as on 31.03.2019 Rs.
1.	NIB-Haemovigilance A/c	33,871	21,80,864
2.	NIB-UPSAC A/c	16,527	1,66,580
3.	NIB-Training & Workshop	1,18,681	23,70,160

14. In order to strengthen the internal audit system, an Audit Committee was formed.

15. Previous year's figures have been regrouped/reclassified/rearranged, wherever necessary.

SCHEDULE-12

NATIONAL INSTITUTE OF BIOLOGICALS
(Forming part of Financial Statement as on 31.03.2019)

16. The summary of Grants Received and Utilized during the year is as under:

Sl. No.	Nature of Grant	Opening Balance	Amount Received	Amount Utilized	Surplus / (Shortfall)
1.	GIA-Assets	2,04,12,672	1,45,88,000	1,74,92,569	1,75,08,103
2.	GIA-Salary	(1,22,65,628)	11,40,00,000	11,14,38,100	(97,03,728)
3.	GIA-General	(31,85,551)	26,25,00,000	24,38,64,806	1,54,49,643
4.	GIA-SAP	0	5,00,000	4,42,317	57,683
Total		**49,61,493**	**39,15,88,000**	**37,32,37,792**	**2,33,11,701**

For AAJV AND ASSOCIATES
Chartered Accountants
(FR No. 07739N)

CA Anil Kumar Aggarwal
Partner
(M. No. 098261)

FOR NATIONAL INSTITUTE OF BIOLOGICALS

S.K. Sharma
(Budget & Finance Officer)

Dr. Reba Chhabra
(Dy. Director /H.O.O)

Dr. Surinder Singh
Director

Place: Noida
Date: 12/09/2019
UDIN: 19098261AAAAAH7320

AUDITOR'S REPORT
NIB-GPF

AAJV and associates
Chartered Accountants

205, Prerna Complex, B-3,
Subhash Chowk, Laxmi Nagar,
New Delhi-110092 (INDIA)
Tel.: 011-43086886
E-mail: anil@aajvca.com

INDEPENDENT AUDITOR'S REPORT

The Members,
General Provident Fund,

National Institute of Biologicals,
Ministry of Health & Family Welfare
Government of India,
A-32, Sector-62 (Institutional Area)
Noida-201307

Opinion

We have audited the financial statements of **National Institute of Biologicals General Provident Fund (hereinafter called NIB-GPF)**, which comprise Balance Sheet as at 31st March,2019, the Income & Expenditure Account and Receipt and Payment Account for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

Subject to Emphasis of matters Para below, in our opinion, the accompanying financial statements give a true and fair view of the financial position of the **NIB-GPF** as at 31st March, 2019, and of its financial performance for the year then ended in accordance with the Accounting Standards issued by the Institute of Chartered Accountants of India (ICAI).

Basis for Opinion

We conducted our audit in accordance with the Standards on Auditing (SAs) issued by ICAI. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the **NIB-GPF** in accordance with the Code of Ethics issued by ICAI and we have fulfilled our other ethical responsibilities in accordance with the Code of Ethics. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Emphasis of Matters

We draw attention to the Note no.2 regarding non receipt of Interest on Bonds of PSIDC since 2013-14. The amount of interest accrued as on 31.03.2019 includes Rs.10,86,000/- receivable from PSIDC. Furthermore three maturities of Rs.4 lakh each for 2016-2017, 2017-

2018 and 2018-2019 are also outstanding as per the agreed terms. Our opinion is not Qualified in respect of this matter.

Responsibilities of Management and Those Charged with Governance for the Financial Statements

Management is responsible for the preparation of these financial statements that give a true and fair view of the state of affairs, results of operations and cash flows of the **NIB-GPF** in accordance with the accounting principles generally accepted in India. This responsibility includes the design, implementation and maintenance of internal control relevant to the preparation and presentation of the financial statements that give a true and fair view and are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the **NIB-GPF**'s ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the **NIB-GPF** or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the **NIB-GPF**'s financial reporting process.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with SAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

AAJV AND ASSOCIATES
Chartered Accountants
Reg. No. 07739N

ANIL KUMAR AGGARWAL
Partner
M. No. 098261
UDIN: 19098261AAAAAG3815

Place of Signature: NOIDA
Date: 12/09/2019

NATIONAL INSTITUTE OF BIOLOGICALS GENERAL PROVIDENT FUND
(Ministry of Health and Family Welfare)
Balance Sheet as at 31st MARCH 2019

Amount In ₹

Liabilities	Schedule	For Current Year ended on 31.03.2019	For Previous Year ended on 31.03.2018	Assets	Schedule	For Current Year ended on 31.03.2019	For Previous Year ended on 31.03.2018
Capital				**Investment**			
Subscription & Contributions	1	787,14,825.00	654,89,085.00	Fixed Deposit with Bank	3A	237,18,934.00	75,00,000.00
				Investment PSU Bond	3B	497,00,000.00	526,00,000.00
				G.O.I. Securities	3C	40,32,500.00	40,32,500.00
Balance being Excess of Income/Expenditure	2	43,14,039.28	37,65,643.28	**Current Assets**			
				Advance to Members	4	6,74,312.00	8,06,312.00
				Accrued Interest (Investment)		25,92,629.00	19,13,916.00
				TDS Recoverable		1,89,111.00	1,73,552.00
				TDS Recoverable-NIB		45,311.00	
				Claim Recoverables		-	1,566.00
				Bank Balance		20,76,067.28	22,26,882.28
Total		**830,28,864.28**	**692,54,728.28**	**Total**		**830,28,864.28**	**692,54,728.28**
		-	-			-	-
Significant Accounting Policies and Notes to Accounts		5					

As per our report of even date attached.

For AAJV & ASSOCIATES
Chartered Accountants
FRN NO. 007739N

CA Anil Kumar Aggarwal
Partner
(M.No. 098261)

Place : Noida
Date : 12.09.2019
UDIN: 19098261AAAAAG3815

FOR NATIONAL INSTITUTE OF BIOLOGICALS
General Provident Fund

S.K.Sharma
(Budget & Finance Officer)

Dr.Reba Chhabra
(Dy. Director & HOO)

Dr. Surinder Singh
(Director)

NATIONAL INSTITUTE OF BIOLOGICALS GENERAL PROVIDENT FUND
(Ministry of Health and Family Welfare)
Income & Expenditure Account for the year Ended 31st MARCH 2019

Amount In ₹

Expenditure	For Current Year ended on 31.03.2019	For Previous Year ended on 31.03.2018	Income	For Current Year ended on 31.03.2019	For Previous Year ended on 31.03.2018
Interest on subscription	53,36,478.00	47,95,277.00	Interest on Investment (Bonds)	57,59,421.00	52,80,178.00
Misc Exp.	2,352.00	-	Interest on Saving A/c	1,16,084.00	2,14,113.00
Excess of Income over Expenditure	5,49,962.00	6,99,014.00	Misc. Receipts	13,287.00	-
Total	**58,88,792.00**	**54,94,291.00**	**Total**	**58,88,792.00**	**54,94,291.00**
	-	-		-	-
Significant Accounting Policies and Notes to Accounts	**5**				

As per our report of even date attached.

For AAJV & ASSOCIATES
Chartered Accountants
FRN NO. 007739N

CA Anil Kumar Aggarwal
Partner
(M.No. 098261)

Place : Noida
Date : 12.09.2019
UDIN: 19098261AAAAAG3815

FOR NATIONAL INSTITUTE OF BIOLOGICALS
General Provident Fund

S.K. Sharma
(Budget & Finance Officer)

Dr. Reba Chhabra
(Dy. Director & HOO)

Dr. Surinder Singh
(Director)

NATIONAL INSTITUTE OF BIOLOGICAL
General Provident Fund
RECEIPTS AND PAYMENTS ACCOUNT FOR THE YEAR ENDED 31st MARCH 2019

Amount In ₹

Receipts	Current Year	Previous Year	Payments	Current Year	Previous Year
Opening Balance			**Payments made out of GPF Fund**		
- Bank Balance	22,26,882.28	21,55,728.28	- Towards Withdrawls	32,04,000.00	15,05,000.00
			- Towards Final Settlement	-	115,58,634.00
Contribution Receipts					
- Contribution received during the year	110,91,696.00	101,81,976.00	**Payments made towards Investments**		
			- In PSU bonds	-	100,00,000.00
Interest Received			- In Government Securities	-	-
- On Bank deposits	1,16,084.00	2,14,113.00	- Fixed Deposit	192,18,934.00	75,00,000.00
- Interest on Investment	49,39,465.00	64,81,699.00	- Interest paid on Investments Purchased Cum-Interest	-	-
Other Receipts			**Other payments**		
- Misc. Receipts	13,287.00	-	- Advance paid during the year	-	1,50,000.00
- Advance recovered during the year from members	1,32,000.00	1,17,000.00	- Bank charges	-	-
- Refund of Tax Deducted at Source	78,023.00	-	- Claim Recoverable	-	1,566.00
- Receipt from matured PSU Bond	29,00,000.00	37,90,000.00	**Closing Balances**		
- Receipt from matured FD	30,00,000.00	100,00,000.00	- Bank Balance	20,76,067.28	22,26,882.28
- Claim Recoverable	1,564.00	1,566.00			
	244,99,001.28	**329,42,082.28**		**244,99,001.28**	**329,42,082.28**

As per our report of even date attached.

For AAJV & ASSOCIATES
Chartered Accountants
FRN NO. 007739N

CA Anil Kumar Aggarwal
Partner
(M.No. 098261)

Place : Noida
Date : 12.09.2019
UDIN: 19098261AAAAAG3815

FOR NATIONAL INSTITUTE OF BIOLOGICALS
General Provident Fund

S.K. Sharma
(Budget & Finance Officer)

Dr. Surinder Singh
(Director)

Dr.Reba Chhabra
(Dy. Director & HOO)

Summary of Subscription & Contribution as on 31.03.2019

Schedule 1

Opening Balance	Subscriptio/ Contribution.	Recovery	Advance	Withdrawal	Final Settlement	Previous Year Adjustments (Excess/Short)	Interest	Balance
64682773	11091696	132000	0	3204000	0	1566	5336478	78040513
			ADD : ADVANCE ADJUSTED SHOWN SEPARATELY					
			OPENING ADVANCE: 01.04.2018				806312	
			ADD: ADVANCE GIVEN DURING THE YEAR				0	
			LESS ; ADVANCE RECOVERY DURIN GTHE YEAR				132000	674312
			TOTAL SUBSCRIPTION AS PER B/S					78714825

SCHEDULE - 2 : Excess of Income/Expenditure for the year

PARTICULARS	As on 31.03.2019	As on 31.03.2018
Opening Balance	37,65,643.28	30,66,891.28
Add/Less: Income/Expenditure for the year	5,49,962.00	6,99,014.00
Less: Adjustment of previous year excess/deficit	-1,566.00	-262.00
Balance Carried forwarded to Balance Sheet	**43,14,039.28**	**37,65,643.28**

NATIONAL INSTITUTE OF BIOLOGOCALS
GENERAL PROVIDENT FUND
DETAILS OF GPF INVESTMENT AS ON 31.03.2019

Schedule-3 : Investments

Sl No	FDR / Receipt NO	DATE OF INVESTMENT	AMOUNT INVESTED (Rs.)	PERIOD OF DEPOSIT (MM/DD)	RATE OF INTEREST(%)	DATE MATURITY / REDEMPTION	AMOUNT DUE ON MATURITY (Rs.)	REMARKS
1	**A- SHORT TERM DEPOSIT WITH BANK OF BARODA**							
	26290300041620	29.05.2018	10,00,000	366 Days	6.70%	30.05.2019	10,68,898	Receipt No.863308
	26290300041621	29.05.2018	10,00,000	366 Days	6.70%	30.05.2019	10,68,898	Receipt No.863309
	26290300041622	29.05.2018	10,00,000	366 Days	6.70%	30.05.2019	10,68,898	Receipt No.863310
	26290300041623	29.05.2018	10,00,000	366 Days	6.70%	30.05.2019	10,68,898	Receipt No.863311
	26290300041624	29.05.2018	10,00,000	366 Days	6.70%	30.05.2019	10,68,898	Receipt No.863312
	26290300037559	28.06.2018	10,72,978	370 Days	6.70%	03.07.2019	11,47,746	Receipt No. 061687
	26290300037558	28.06.2018	10,72,978	370 Days	6.70%	03.07.2019	11,47,746	Receipt No. 061688
	26290300037560	28.06.2018	10,72,978	370 Days	6.70%	03.07.2019	11,47,746	Receipt No. 061691
	26290300043284	22.10.2018	15,00,000	400 Days	6.75%	26.11.2019	16,14,223	Receipt No. 863576
	26290300043285	22.10.2018	15,00,000	400 Days	6.75%	26.11.2019	16,14,223	Receipt No. 863577
	26290300043286	22.10.2018	15,00,000	400 Days	6.75%	26.11.2019	16,14,223	Receipt No. 863578
	26290300044370	17.01.2019	10,00,000	444 Days	7.00%	05.04.2020	10,88,054	Receipt No. 863756
	26290300044371	17.01.2019	10,00,000	444 Days	7.00%	05.04.2020	10,88,054	Receipt No. 863757
	26290300044372	17.01.2019	10,00,000	444 Days	7.00%	05.04.2020	10,88,054	Receipt No. 863758
	26290300044373	17.01.2019	10,00,000	444 Days	7.00%	05.04.2020	10,88,054	Receipt No. 863759
	26290300040515	28.02.2018	15,00,000	365 Days	6.70%	28.02.2020	17,08,978	Receipt No. 863121
	26290300040516	28.02.2018	15,00,000	365 Days	6.70%	28.02.2020	17,08,978	Receipt No. 863122
	26290300040517	28.02.2018	15,00,000	365 Days	6.70%	28.02.2020	17,08,978	Receipt No. 863123
	26290300045259	22.03.2019	25,00,000	444 Days	7.00%	08.06.2020	27,19,623	Receipt No. 863969
	Total - 3A		**237,18,934**				**258,29,170**	
	B - INVESTMENTS IN PSU BONDS/DEPOSITS							
2	**Tamil Nadu Etect. Board** Series-2/2009-10 Disnt. No Allotment Lt. No.	06.01.2010	12,00,000	7 YY	8.40% (semi Annually)	06.01.2018 06.01.2019 06.01.2020	900000(30%) 900000(30%) 1200000(40%)	Part Maturity Amount Received Part Maturity Amount Received 3 No. Bond ISIN No.: INE084G09222
3	**PSIDC BOND** Regd Folio No. PSIDC-XXVIII-N2 Allotment Lt. No. 46 Distictive no. 1420-1439 2010-2nd Series, ISIN 973F09113	17.02.2011	20,00,000		9.05%. p.a.	17.02.2017 17.02.2018 17.02.2019 17.02.2020 17.02.2021	Rs.4 Lakh (20%) Rs.4 Lakh (20%) Rs.4 Lakh (20%) Rs.4 Lakh (20%) Rs.4 Lakh (20%)	
4	**IFCI Tier II Bonds Series- I**	July, 2011	20,00,000	10 YY	10.50% p.a	01.08.2021	10.5 BD 01AG21 FVRS10000 LOA UPTO 29SP11	200 Bonds of Rs 10000/- each in Demat Form Demat form ISIN No. INE039A09N17
5	**IFCI Tier II Bonds Series- I** Application No. 804536	01.11.2011	10,00,000	10 YY	10.50% p.a	31.10.2021	10.5 BD 31OT21 FVRS10000 LOA UPTO 07FB12	100 Bonds of Rs 10000/- each in Demat Form Demat form ISIN No. INE039A09NV2
6	**IFCI Tier II Bonds Series- I** Application No.	07.02.2012	10,00,000	10 YY	10.50% p.a	28.02.2022	OP-1 10.5 BD 28FB22 FVRS10000 LOA UPTO 26AP12	100 Bonds of Rs 10000/- each in Demat Form Demat form ISIN No. INE039A09OL1
7	**IFCI Tier II Bonds Series- I** Application No. 62909751	01.12.2014	20,00,000	5 YY	9.80% p.a	30.11.2019	20,00,000	2000 Bonds of Rs. 1000/- each. in Demat Form ISIN No. INE039A07751
8	**KTDFC** FDR No.300503 Deposit ID 001031300503	03.02.2018	10,00,000	36 MM	8..25 % p.a.	03.02.2021	10,00,000	Periodic Interest Rs.20767/- per Quarter
9	**KTDFC** FDR No.300824 Dated: 07.04.18	07.04.2018	10,00,000	36 MM	8.25% p.a.	07.04.2021	10,00,000	Periodic Interest Rs.20767/-
10	**KTDFC** FDR No. 300823	29.04.2018	10,00,000	36 MM	8.25%	29.04.2021	10,00,000	Periodic Interest Rs 20767/-
11	**TANGEDCO** Bond Series 3/2014-15	11.06.2015	10,00,000	10 YY	9.00% (Semi annually)	11.06.2023 (8th YY) 11.06.2024 (9thYY) 11.06.2025(10thYY)	30%- Rs 300000/- 30%- Rs 300000/- 40%- Rs 400000/-	ISIN No.INE340M08145 SR-III 9 BD 11JU25 FVSR10 LAC 11th June and 11th December every year ISIN No. INE340M08145

12	**KTDFC** FDR No. 200315 Deposit ID : 002002200315	21.01.2019	40,00,000	24 MM	8.50%	21-01-2021	40,00,000	Periodic Interest Rs 8560/- (Renwed in Jan 2019)
13	**LIC Housing Finance Ltd** Deposit Receipt No. 663329 Folio/KYC/No.0031051	28.01.2019	10,00,000	24MM	8.20%	28.01.2021	10,00,000	Non-Cummulative Deposit (Renwed in Jan 2019)
14	**LIC Housing Finance Ltd** Deposit Receipt No. 639737 Folio/KYC/No.: 0033670	03.06.2016 (31.05.2016)	100,00,000	36 MM	8.40%	03.06.2019	100,00,000	Non-Cummulative Deposit
15	**KTDFC** FDR No. 60507 FNo.KTDFC/DEC/2016/131090/TVP	28.11.2016	25,00,000	36 MM	8.50%	28.11.2019	25,00,000	Periodic Interest Rs 5350 2/-
16	**TANGEDCO** Bond Series 3/2016-17	27.03.2017	10,00,000	10 YY	9.25% (Semi annually)	27.03.2025 (8th Yr) 27.03.2026 (9thYr) 11.06.2027(10thYr)	30%- Rs 300000/- 30%- Rs 300000/- 40%- Rs 400000/-	27th March and 27th September every year ISIN No. INE340M08178
17	**KTDFC** FDR No. 62894 FNo.KTDFC/JUN/2017/132452/TVP	31.05.2017	25,00,000	36 MM	8.50%	31.05.2020	25,00,000	Periodic Interest Rs 53502/-
18	**KTDFC** FDR No. 200122 Scheme- PIPS GEN	09.06.2017	20,00,000	36 MM	8.50%	09.06.2020	20,00,000	Periodic Interest Rs 42802/-
19	**KTDFC** Deposit ID. 002031300113 FDR No. 300113	11.08.2017	20,00,000	36 MM	8.25%	11.08.2020	20,00,000	Periodic Interest Rs 41534-
20	**PNB Housing Finance Ltd** **Customer ID 1327374**	19.01.2018	15,00,000	44 MM	7.55%	19.09.2021	15,00,000	Non-Cummulative Deposit
21	**HDFC Ltd** **CP/927912 dated 22.01.2018**	19.01.2018	15,00,000	33 MM	7.55%	19.10.2020	15,00,000	Non-Cummulative Deposit
22	**KTDFC** Deposit ID. 002031300423 FDR No.300423	19.01.2018	20,00,000	36 MM	8.25%	19.01.2021	20,00,000	Periodic Interest Rs 41534-
23	**KTDFC** FDR No. 300724	05.02.2018	5,00,000	36 MM	8.25%	05.02.2021	5,00,000	Periodic Interest Rs 10384/-
24	**KTDFC** FDR No. 200453	04.03.2019	5,00,000	24 MM	8.50%	04.03.2021	5,00,000	Renewed Periodic Interest Rs. 10700/-
25	**KTDFC** FDR No. 200454	04.03.2019	5,00,000	24 MM	8.50%	04.03.2021	5,00,000	Renewed Periodic Interest Rs. 10700/-
26	**KTDFC** FDR No. 200455	04.03.2019	5,00,000	24 MM	8.50%	04.03.2021	5,00,000	Renewed Periodic Interest Rs. 10700/-
27	**KTDFC** FDR No. 200465	12.03.2019	25,00,000	24 MM	8.50%	12.03.2021	25,00,000	Renewed Periodic Interest Rs. 53502/-
28	**KTDFC** FDR No. 200435	19.03.2019	20,00,000	24 MM	8.50%	19.03.2021	20,00,000	Renewed Periodic Interest Rs. 42802/-
	Total - 3B		**497,00,000**				**219,00,000**	
	C - G.O.I SECURITY							
29	**8.28% GOI 2027** Govt. of India Security (Amt paid for investment Rs 492500)	30.01.2012	4,92,500	15 YY	8.28%	21.09.2027	5,00,000	07012 GOI 21SP27 8.28 FV RS 100 Puchased 5000 no @ Rs. 98.50/100.00 Demat form ISIN No. IN0020070069
30	**8.83% GOI 2023** Govt. of India Security (Amt paid for investment Rs 1000000)	30.12.2013	10,00,000	10 YY	8.83%	25.11.2023	10,00,000	16575 GOI 25NOV23 8.83 FV RS 100 Puchased 10000 no @ Rs. 100/100.00 Demat form ISIN No.IN0020130061
31	**9.39% GUJ SDL 2023** Govt. of India Security (Amt paid for investment Rs 1510500)	30.12.2013	15,10,500	10 YY	9.39%	20.11.2023	15,00,000	16575 GUJ 20NV23 9.39 FV RS 100 Puchased 15000 no @ Rs. 100.70/100.00 Demat form ISIN No. IN1520130122
32	**8.35% GOI 2022** Govt. of India Security (Amt paid for investment Rs 10 Lacs)	19.01.2016	10,29,500	36 MM	8.35%	14.05.2022	10,00,000	ISIN No. IN0020020072 8.35 FV RS 100 02011 GOI 2022
	Total - 3C		**40,32,500**				**40,00,000**	
	GRAND TOTAL (3A+3B+3C)		**774,51,434**					

SCHEDULE - 4 : Advances to Members during the year

PARTICULARS	As on 31.03.2019	As on 31.03.2018
Opening Balance	8,06,312.00	7,73,312.00
Add: Advances given during the year	-	1,50,000.00
Less: Advances recovered during the year	-1,32,000.00	-1,17,000.00
Balance of Advances	**6,74,312.00**	**8,06,312.00**

NATIONAL INSTITUTE OF BIOLOGICALS **SCHEDULE-5**

General Provident Fund (Forming part of Financial Statement as on 31.03.2019)

A. SIGNIFICANT ACCOUNTING POLICIES

1. **Method of accounting:**
   The accounts have been prepared under the Historical cost convention on accrual basis.

2. **Revenue Recognition:**
   The Revenue has been recognized on accrual basis.

3. **Fixed Assets:**
   There are no fixed assets.

4. **Investments:**
   Investments are Non Trade Investments and are stated at cost and are held in the name of the "National Institute of Biologicals General Provident Fund" (herein after referred to as "NIB-GPF").

B. NOTES TO ACCOUNTS

1. Investment in the bonds have been stated at the cost therefore the effect of the change in the value of the bond as on date of balance sheet has not been quantified and considered.

2. The interest on Investment in bonds of Punjab State Industrial development Corporation Ltd. (PSIDC), a Punjab State Govt. Undertaking, is not recovered since 2013-14. The accumulated amount of interest receivable as on the balance sheet date was Rs.10,86,000/-. However, the Company (PSIDC) has in its letter dated 9th January, 2019 stated that the Punjab Govt. has made budgetary provisions for the same and the interest will be disbursed in due course.

3. TDS Recoverable of F.Y. 2018-19 from NIB is shown in the current assets.

4. The previous year's figures have been regrouped/reclassified/rearranged, wherever necessary to confirm to the current period presentation.

For AAJV ANDASSOCIATES.
Chartered Accountants
(FRN. 007739N)

CA ANIL KUMAR AGGARWAL
Partner
(M. No. 098261)

Place: Noida
Date: 12/09/2019
UDIN: 19098261AAAAAG3815

FOR NATIONAL INSTITUTE OF BIOLOGICALS
General Provident Fund

S.K. SHARMA
(Budget & Finance Officer)

Dr.Reba Chhabra
(Dy. Director & HOO)

Dr. Surinder Singh
(Director)

NATIONAL INSTITUTE OF BIOLOGICALS
(Ministry of Health and Family Welfare)
Government of India
Plot No. A-32, Sector-62
Institutional Area,
NOIDA-201 309 (UP), INDIA
Phone: +91 0120 2400022, 2400072
Fax:+91 0120 2403014
E-mail: info@nib.gov.in
http://www.nib.gov.in

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