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Azadi Ka
Amrit Mahotsav

NATIONAL INSTITUTE OF BIOLOGICALS NEWSLETTER



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Director's Desk



Over the last 30 years since its foundation, the NIB has gradually ascended the success ladder in the highly specialised scientific field of quality control of Biologicals, with its knowledgeable well trained competent and highly motivated staff. Impact of science, scientific research, technological development, globalization on our daily life is vibrant and unavoidable. With this mind, we continue to march steadily towards our aim to work for our Nation's public health safety.

On 30th June 2022 NIB Celebrated our Nation's Azadi Ka Amrit Mahotsav under the theme "Three decades of Service to the Nation". The Honourable Minister of State (MoS) Dr. Bharati Pravin Pawar was the Guest of Honour at this prestigious event. Shri Rajesh Bhushan, Secretary, Ministry of Health and Family Welfare & Dr. Balram Bhargava, Secretary, DHR & DG ICMR also graced the occasion along with other dignitaries.

On this auspicious occasion of NIB's 30th Anniversary & HvPI's 10th Anniversary, a Booklet on "30 years of NIB" & "Guidance Document for Reporting Blood Donor Adverse Reactions" under the National Blood Donor Vigilance Programme (NBDVP) and a Video on NIB activities were released by The Honourable Minister of State (MoS) Dr. Bharati Pravin Pawar. The employees who had completed 25 years of service and contributed to the progress of the institute were felicitated by the dignitaries..

To promote academic and skill development activities in the field of Biologicals, NIB, Noida signed a MoU with DPSRU, Delhi on 17th May 2022 to start a Certificate Course on Quality Assurance of Biopharmaceuticals.

NIB continued its tradition of conducting National Skill Development & Hands-on Training Programme on Quality Control of Biologicals for M.Sc. Biotechnology Students under "Pradhan Mantri Kaushal Vikas Yojna". Training for 32 Students from Sant Gahira Guru Vishwavidyalaya, Sarguja Ambikapur (Chhattisgarh) & Bodoland University, Kokrajhar (Assam) was held from 06th June to 17th June 2022 at NIB.

I wish Good Luck to All!!

Anup Anvikar

Director

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Editorial Team

Ms. Y. Madhu
Editor

Mr. Jaipal Meena
Associate Editor

Dr. Manjula Kiran
Associate Editor

Ms. Apoorva Anand
Associate Editor

Quality Control Validation of COVID-19 Diagnostic Kits

Dr. Gauri Misra, Scientist Grade-II



SARS-CoV-2, the causative agent of coronavirus disease 2019 (COVID-19) was discovered in the late 2019 in Wuhan, China. It has caused a global pandemic as declared by WHO in March 2020. The virus is a member of Coronaviridae family, genus Beta coronavirus, and has a positive-sense single-stranded RNA genome. The genome is about 30kb and encodes sixteen non-structural proteins (NSP1-NSP16) and four structural proteins (nucleocapsid, envelopes, membrane, and spike glycoprotein).

The spike (S) protein is involved in SARS-CoV-2 entry into host cells through binding with angiotensin-converting enzyme 2 (ACE2) receptor. The receptor binding domain (RBD) in the S protein interacts with ACE2 receptor that eventually leads to the fusion of virus to host cell membranes. The fast spread of the COVID-19 pandemic became a major challenge for national healthcare systems, infecting millions of people, burdening daily life and causing huge economic losses. Therefore, the testing for the viral agent has become an important step so as to contain and control the spread..

The demand for testing of SARS-CoV-2 increased worldwide exponentially and the most commonly collected specimens are nasopharyngeal (NP) swabs placed in Viral Transport Media (VTM). Real Time-polymerase chain reaction (RT-PCR) is the current gold standard to detect the presence of SARS-CoV-2 virus during infection. National Institute of Biologicals (NIB) has been entrusted to undertake the quality control validation and Batch Testing of COVID-19 diagnostic kits by Ministry of Health & Family Welfare, Govt. of India.

Quality control validation is needed as it verifies whether the quality standards and compliance are being met by the product in real time and it also determines whether the facility meets the current good manufacturing practice (CGMP) guidelines that are set for the industry by concerned regulatory bodies. COVID-19 Kit Testing Laboratory established at NIB is doing the Quality Control evaluation of COVID-19 diagnostic kits forwarded by Indian Council of Medical Research (ICMR) on regular basis. The laboratory has the required infrastructure and expertise for testing different types of Viral RNA Extraction Kits, VTM/MTM, RT-PCR and RT-LAMP based kits for Covid-19.

Diagnostic kits are evaluated on the basis of Sensitivity (i.e. the ability of the test to identify correctly affected individuals) and specificity (i.e. the ability of the test to identify correctly non-affected individuals). The Laboratory has a Quality Management System in place and is NABL accredited for testing of Viral RNA Extraction Kits, VTM/MTM, RT-PCR and RT-LAMP kits for Covid-19 in accordance with ISO/IEC 17025:2017 "General Requirements for the Competence of Testing and Calibration Laboratories", vide certificate no. TC-7725. The laboratory has participated in the Inter-laboratory Comparison Proficiency Testing (ILC-PT) with NIV-Pune for SARS-CoV-2 RT-PCR with 100% concordance. Moreover, the laboratory has also been imparting trainings to under-graduate and Post-graduate students from different universities of the country to strengthen their hands on skills for molecular biology techniques. Covid-19 Kit Testing Laboratory remains in solidarity in our nation's battle against COVID-19 and is constantly devoted for the cause of public health safety of its compatriots.



AZADI KA AMRIT MAHOTSAV - THREE DECADES OF SERVICE TO THE NATION

National Institute of Biologicals (NIB), Ministry of Health and Family Welfare, celebrated the 'Azadi Ka Amrit Mahotsav', on 30th June 2022 under the theme “Three decades of Service to the nation”. The Honourable Minister of State (MoS) Dr. Bharati Pravin Pawar was the Guest of Honour for this prestigious event. Shri Rajesh Bhushan, Secretary- Ministry of Health and Family Welfare, Dr. Balram Bhargava, Secretary- DHR & DG ICMR, Prof Rajender Singh Sangwan- Director ACSIR, Dr Rajani Kant Srivastava- Director RMRC- Gorakhpur, Dr Shalini Singh- Director NICPR, Dr Kiran Kumar Karlapu- Deputy Secretary- MoHFW, Dr. Rubina Bose –Deputy Drugs Controller- CDSCO and Dr Mallika Gope- Director NABL, graced the occasion.



A Booklet and a Video on 30 years of NIB along with a Guidance Document for Reporting Blood Donor Adverse Reactions under the National Blood Donor Vigilance Programme (NBDVP) were released by the Hon'ble Minister of State, Ministry of Health & Family Welfare. The employees who had completed 25 years of service and contributed to the progress of the institute were felicitated by the dignitaries. The Honourable Minister of State, in her keynote address, highlighted NIB's role in promoting and safeguarding public health and appreciated its substantial Contribution to the Nation's Drug Regulatory system.



MOU BETWEEN NIB AND DPSRU

NIB signed a MoU with DPSRU on 17th May 2022 for Scientific Collaborations including a "Certificate programme on Quality Control of Biopharmaceuticals". The Hon'ble Vice-Chancellor Prof. Ramesh K Goyal along with Senior Officials of Delhi Pharmaceutical Sciences and Research University (DPSRU) and Dr. Anup Anvikar, Director and Senior Scientists of NIB participated in this ceremony.



PROFICIENCY TESTING (PT)/ EXTERNAL QUALITY ASSURANCE SCHEME (EQAS)

- NIB is enrolled on the Association of Clinical Biochemists of India/ Christian Medical College (ACBI/CMC) External Quality Assessment Scheme (EQAS) - 2022 for Chemistry II (Glucose, Cholesterol & Triglycerides), conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore. The test was put up on 04.04.2022, 09.05.2022 & 06.06.2022 for Chemistry II and the generated results were uploaded on the CMC-EQAS website.
- Recombinant Product Laboratory participated in Proficiency Testing Scheme of the European Directorate for the Quality of Medicines and HealthCare (EDQM) - France, on Liquid Chromatography (PTS 226) for assay of atenolol

TECHNICAL EXPERT COMMITTEE MEETINGS:

- Dr. Gauri Misra, Scientist Grade-II & Head CKTL attended First Hub Meeting held on 8th April, 2022 organised by BIRAC on virtual platform as an External Expert.
- Dr. Suresh Kumar, Scientist Grade-III attended the meeting as an expert member to facilitate the setting up a nude mice facility on 11th April 2022 at the University of Delhi South Campus, New Delhi.
- Dr Shikha Yadav, Scientist Grade-II & Head Animal Facility participated in the "NC3Rs workshop: Implementing the 3Rs in WHO guidelines - understanding the impact on quality control and batch release testing of Biologicals in Asia", organized on 28th April.2022 (online) by the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs), UK.
- Dr. Harish Chander I/c DDQC, Mr. Subhash Chand, Scientist-III, Dr Charu M Kamal, Scientist Grade-II and Head (RPL & EHL) and Ms Gurminder Bindra, Scientist Grade-III attended the "12th Meeting of the Expert Working Group -Biologicals and rDNA Products" held on 2nd May 2022 through Video Conferencing organised by Indian Pharmacopoeia Commission (IPC), Ghaziabad.
- Dr. Gauri Misra, Scientist Grade-II attended the 6th Convocation of AcSIR held on 12th May 2022 at CSIR-National Physical Laboratory auditorium, New Delhi.
- Ms Rashmi Shrivastava, Scientist Grade-III invited as a guest speaker for a panel discussion- Global Regulatory Perspective For Biosimilars – Strategies & Challenges at 2nd India Biopharma Leaders Bio Conclave organised by Bluetech Media on 26th & 27th May 2022 at Hyderabad.
- The first meeting of the newly constituted Expert Committee for Diagnostics was conducted on 10th June 2022 in Hybrid mode, under the chairmanship of Dr. V.M. Katoch, Former Secretary, Dept. of Health Research and Director General- ICMR, to provide inputs on quality testing of Diagnostics as well as Research being carried out by Labs working on Diagnostics.
- The 60th Institutional Animal Ethics Committee (IAEC) meeting of NIB was conducted on 20th June 2022 to review and approve protocols for in-vivo QC testing of biologicals and research proposals of NIB. The annual Inspection of Animal Facility was also conducted by IAEC on 20th June 2022.



RESEARCH AND PUBLICATIONS

- Innovation Technological Research division, ICMR has accepted funding of Research Project entitled "Development of in-vitro bioassay for biological activity of anti-HER2 therapeutic monoclonal antibodies based on variability in the expression of HER2 in breast cancer cell lines", submitted by Dr. Harish Chander, Scientist Grade -I and Mr. Subhash Chand, Scientist Grade-III.
- Project titled "Harmonization of COVID-19 RT-PCR Kits Efficiency Data towards Enhancing their Specificity and Sensitivity for Different Strains of SARS-Cov-2" has been awarded by ICMR to Dr. Gauri Misra, Scientist Grade-II & Head COVID Kit testing Laboratory.
- Kumar S, Perumal N, Raj VS. A Comparative Evaluation of the Impact of High Fat and High Salt Dietary Components on Human and Mice Gut Microbiota. International Journal of Biology, Pharmacy and Allied Sciences. 2022; 11(5):2340-2359; doi:10.31032/IJBPAS/2022/11.5.6081.

- Mehta, V., Meena, J., Kasana, H., Munshi, A., & Chander, H. (2022). Prognostic significance of CHAC1 expression in breast cancer. *Molecular Biology Reports*, 1-10. <https://doi.org/10.1007/s11033-022-07673-x>
- Suresh Kumar, Ruby Dhiman, Carlos R Prudencio, Antonio Charlys da Costa, Arpana Vibhuti, Elcio Leal, Chung-Ming Chang, V Samuel Raj, Ramendra Pati Pandey, Chitosan: Applications in Drug Delivery System *Mini Rev Med Chem*. 2022 Jun 9 (Impact factor-3.862)
- Anoop Kumar, Utkarsha Sahu, Pratima Kumari, Anshuman Dixit, Prashant Khare, "Designing of multi-epitope chimeric vaccine using immunoinformatic platform by targeting oncogenic strain HPV 16 and 18 against cervical cancer" *Scientific Report*, 12, 9521 (2022) (Impact factor-4.380)
- Amritpal Kaur, Yash Sharma, Anoop Kumar, Madhumita P. Ghosh & Kumud Bala. In-vitro antiproliferative efficacy of *Abrus precatorius* seed extracts on cervical carcinoma. *Scientific Report* 12, 10226 (2022) (Impact factor-4.380).

TRAININGS & WORKSHOPS



Animal Facility conducted a 5-day structured hands-on training program on “Ethical Use and Care of Laboratory Animals in Research and Regulatory Testing” from 18th-22nd April 2022 .for Post Graduate & Ph.D. students of various institutes.

- National Skill Development & Hands-on Training Programme on Quality Control of Biologicals has been conducted from 06th to 17th June 2022 for 32 M.Sc. Biotechnology Students of Sant Gahira Guru Vishwavidyalaya, Sarguja Ambikapur (Chhattisgarh) & Bodoland University, Kokrajhar (Assam) at NIB.



- A one-day workshop was organised on intellectual property rights (IPR) on 25th June 2022 covering topics viz. Overview and its importance in Research and Development domains of Public Funded Institutions; innovation from inventor's view; Patent procedures & issues: Legal perspective with speakers from Central University Punjab and ICMR IPR- unit.
- NIB hosted a laboratory visit to 12 students of Post Graduate Diploma in Clinical Research (PGDCR) of Apollo Hospital Educational and Research Foundation, New Delhi on 28th June 2022. The students along with their faculty members interacted with senior scientists of various laboratories at NIB.



CELEBRATIONS OF INTERNATIONAL YOGA DAY

With great enthusiasm, NIB celebrated International Yoga day on 21st June 2022 under the guidance of Yoga Acharya Vijaya Kumar, Chairman & CEO, Universal Yoga Group, Gurugram. He emphasised the purpose of the Yoga and its impact on individual/s health and asked everyone to introduce yoga in their daily activities.



Calendar for Upcoming Training Programme at NIB (April, 2022 to March, 2023)

Month & Date	Programme	Who can participate
April-2022 18 th – 22 nd	LBT-1 Ethical use & care of laboratory animals in research and regulatory testing	PG & PhD Students, Post Docs, Scientists, veterinarians who plan to use laboratory animals for research or regulatory testing
May-2022 23 rd - 27 th	LBT-2 Basics of Cell Culture & Bioassays	Students/ Faculty/ Industry professionals
June-2022 20 th -24 th	LBT-3 Cell Culture based techniques for evaluation of Biologicals and Vaccines	Students/industry professional/Regulatory officials
July-2022 04 th -08 th	LBT-4 Short-term training course on RT-PCR including RNA extraction	Students/ Medical Professionals
August-2022 22 nd -26 th	LBT-5 Quality Control of Blood Products using Atomic Absorption Spectrophotometer (AAS)	PG Students/ Researchers/ Industry professional/ Manufacturing units / Regulatory officials
Sept.-2022 05 th -09 th	LBT-6 Internal Quality Control & Method Validation Basics	Students/ Clinical Laboratory Personnel, Researchers, Personnel of Testing & Manufacturing unit.
October-2022 17 th -21 st	LBT-7 Quality Control testing of Immunodiagnostic Kits	Students/ Medical Professionals
Dec.-2022 26 th -30 th	LBT-8 Application of Reverse Phase High Performance Liquid chromatography (HPLC) for Identification and potency testing of Human Insulin	PG Students/ Research Scholars
January-2023 23 rd -24 th	LBT-9 Cryopreservation of RBCs for panel preparation used in QC evaluation of Blood Grouping Reagent & Blood Grouping IVDs	Medical Professional/ Manufacturers
Feb.-2023 20 th -24 th	LBT-10 Bacterial Endotoxin Testing (BET)	UG/PG Students of Microbiology/ Biochemistry /Biotechnology /M. Pharm./ B. Pharm.
March-2023 20 th -24 th	LBT-11 Quality Control of Blood Products using Coagulation Analyser (CA) special reference to Human coagulation factor VIII potency assay	PG Students/ Researchers/ Industry professional/ Manufacturing units / Regulatory officials
For further details, please refer to the NIB website (www.nib.gov.in)		

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National Institute of Biologicals

A-32, Sector-62, NOIDA - 201309, Uttar Pradesh

NIB website: <http://nib.gov.in>, Email: info@nib.gov.in

Tel: 0120-2400072, 2400022, Fax: 0120-2403014



For any other Information/ Suggestions/ Queries related to Newsletter kindly contact: Dr. Manjula Kiran, Associate Editor, Email: mkiran@nib.gov.in. Please feel free to share your valuable thoughts & feedback for the betterment of the edition. We look forward to hear from you!!!