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NATIONAL INSTITUTE OF BIOLOGICALS NEWSLETTER

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Director's Desk



Another year has elapsed and we plan to move forward with a strong commitment for quality of Biologicals, Public Health and Academic Excellence. With continuous adhering to the spirit of sharing knowledge and to contribute in evaluating new products, we sincerely hope that in terms of progress and prosperity, year 2024 shall live up to all our expectations.

The beginning quarter of the year 2024, is highlighted with the participation of one of the scientist as adviser in the WHO Seventy-Ninth Expert Committee Meeting on Biological Standardization held from 11th to 14th March, 2024. NIB is represented in National and international forum by its scientists being part of Expert committees and also as subject expert in joint inspection with CDSCO for WHO GMP certification. More number of NIB scientists are being qualified as NABL assessors who can contribute in strengthening quality management systems of various testing laboratories in the country. I am happy to see that few scientists in addition to their notification as government analysts and Medical Device Testing Officer (MDTO) by the Central Government are now being notified for the state governments also.

Continuing with its tradition of training the students under National Skill Development and hands on Training on Quality Control of Biologicals, NIB trained Postgraduate students from various universities – Mizoram, Nagaland, Jammu and Kashmir and Himachal Pradesh. With an aim to bridge the gap of trained manpower in the field of Biologicals, the institute also offers a range of customized short term training courses in the field of Biopharmaceuticals, *In-vitro* Diagnostics, Therapeutics, Vaccines and *In-vivo* studies for professionals from Government and Private Institutes/ Hospitals/ Pathology Laboratories/ Industries/ Universities.

The visit of International Delegates from 17 countries who were participants of the 15th International Training Programme on “Competence and Management systems of Laboratories for Developing Countries” organized by National Institute of Training for Standardization (NITS) added to the global visibility of the institute.

Over the last three decades, 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. The impact of science, scientific research, technological development, Quality Assurance and Control as well as globalization on our daily life is vibrant and unavoidable. With this in mind, we continue to march steadily towards our aim to work for Public Health Safety.

I wish Good Luck to All!!

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NEED FOR AN ANTIBODY SCREENING RED CELL PANEL IN THE COUNTRY

Ms. Kanchan Ahuja, Scientist Grade-II, NIB

A safe supply of blood to the patients is an integral service in the field of medical sciences. In order to ensure the safe transfusion practices, pretransfusion testing is of high importance as it comprises of all critical procedures followed at the site of blood collection, its processing to the stage where the patient is just about to be transfused. Such activity includes serological testing like blood characterization, screening of irregular antibody and crossmatching testing that is performed in the laboratory.

It has been found that in a given population; approximately 2% to 4% of the population has irregular red cell alloantibodies. These antibodies are responsible for hemolytic disease in the newborn or lysis of the donor's red cells that has been transfused in the recipient.

The presence of alloantibodies is a big challenge for the transfusion therapy in a patient that makes the cross-matching of blood difficult. In order to prevent this, regular testing of unexpected antibodies should be performed at the transfusion centers. Blood transfusion requires the exact specificity of the antibody in order to provide blood lacking the corresponding antigen before transfusion to the patient. Most common examples of red blood cell alloantibodies are against Rh (D, C, E, c and e) and Kell (K) antigens that are most frequent apart from Duffy, Kidd, MNS and other minor blood group systems. Rh and Kell antibodies have been reported to be the most common clinically significant alloantibodies (Makroo *et al.*, 2014).

In a diverse country like India, indigenous Red Cell panel is the need of the hour to ensure safe blood transfusion. At present, transfusion services have been using commercially supplied 3 and 11 red cell panel from Bio Rad, Ortho, Immucor etc. to detect the presence of alloantibodies in thalassemic patients which is not prepared from our country and lacks certain rare antigens which are present in our population, thereby reducing the risk of alloantibodies that may go undetected. The development of in-house Red Cell panel will be extremely useful tool not only for detecting commonly prevalent antibodies in the population but also be helpful in screening and identification of rare alloantibodies present in our population. One such instance of preparing 'home made' reagent red blood cells for antibody screening during pre-transfusion compatibility testing has been reported by (Natukunda *et al.*, 2021). The Blood Reagent Laboratory at NIB has been preparing and maintaining rare red blood cell panel repository at -70°C using glycerolyte buffer since last 25 years. This repository consists of rare and a few routine red blood cells as they are required in Quality Control testing of blood grouping reagents.

Due to huge diversity of antigens within the country there is a dearth to have an antibody screening panel from the local population. The rare blood lacks the high-frequency blood group antigen or multiple common antigens. "Bombay" (Oh) phenotype, -D -/- D -, In(a+b-), Co(a-b-), A host of weaker variants of A, B and H antigens, I-i-, CdE/CdE (ry ry), Mg are few of the red blood cells that are considered rare or ultra-rare in India (Joshi and Vasantha, 2012).

Red cell panel sourced from local population would be a better option for detection of antibodies as cell panels from non-indigenous populations may not detect certain antibodies against in local population. Red Cell panel will help to be highly cost-effective, increased shelf life as imported red cell panel takes time for packing, storage and shipping clearance and till the shipment reaches the testing site, the shelf life decreases. Preparation of Red Cell panel is a challenging task for the indigenous manufacturers as well as for transfusion services because of the limiting factors faced in India are (Ahuja *et al.*, 2015):

1. Ethical clearance for collection of samples from the voluntary donors from the Institutional Human Ethics Committee.
2. Lack of Awareness among the voluntary donors.
3. Lack of mass screening, identification and retention of donors of a specific profile to prepare the red cell panel which can be used for antibody screening and identification.
4. Lack of continuous education and training programs for the blood banking staff.
5. Lack of availability of rare type of antisera for screening of the donors
6. Validation of the panel for the viability of the antigens present.
7. Lack of storage and logistics for shipment of the red cell panel.

8. Lack of infrastructure to cryopreserve the panel to further extend the shelf life of the red cell panel.

Once the donors are identified, they should be informed, enrolled and educated regarding the significance of the red cell panel for alloantibody screening and identification. They should be made aware that their contribution will be helpful in saving hundreds and thousands of precious lives. For such situation, rare donor registry plays the lifesaving role by providing necessary blood from the identified donors having rare blood types (Nance *et al.*, 2016). A first-of-its-kind rare donor registry established in South India by Polavarapu *et al.*, 2021, a regional rare donor registry aims for screening the local donor population for rare phenotypes. It was found that after the inception of registry, there was a considerable decrease in turnaround time to provide the required rare blood to patients (Polavarapu *et al.*, 2021). In conclusion, there is an urgent need for the preparation of indigenous three and eleven red cell panel from the voluntary donors within the country to strengthen blood transfusion services. It is even proposed to collaborate with International and National Rare donor registry program and develop linkages for better availability of blood to patients.

References

1. Makroo, Raj Nath *et al.*, "Antibody screening & identification in the general patient population at a tertiary care hospital in New Delhi, India." *The Indian Journal of Medical Research* 140.3 (2014):401.
2. Natukunda, Bernard *et al.*, "The utility of 'home-made' reagent red blood cells for antibody screening during pre-transfusion compatibility testing in Uganda." *African Health Sciences* 21.2 (2021):782-787.
3. Joshi, Sanmukh R., and K.Vasanth. "A profile of rare bloods in India and its impact in blood transfusion service." *Asian Journal of Transfusion Science* 6.1 (2012):42.
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WHO SEVENTY-NINTH EXPERT COMMITTEE MEETING ON BIOLOGICAL STANDARDIZATION

Dr. Akanksha Bisht, Scientist Grade-II & Head, Immunodiagnostic Kit Laboratory was invited as an adviser by WHO and participated in WHO Seventy-Ninth Expert Committee Meeting on Biological Standardization – held virtually from 11th to 14th March, 2024.

GAZETTE NOTIFICATION AS MEDICAL DEVICE TESTING OFFICER (MDTO)

Dr. Rajesh Kumar Sharma (for in vitro diagnostic kits for HIV, HBsAg and HCV); Ms. Kanchan Ahuja (for Blood Grouping Reagent) and Ms. Ajanta Sircar (for Glucose test strips and fully automated analyzer-based glucose reagents) have been notified as Medical Device Testing Officer (MDTO) for the Government of Jharkhand on 15th March, 2024.

NABL ASSESSORS

- Rashmi Shrivastava, Scientist Grade-III, had attended the training and qualifying exam conducted by NABL on 16th-20th January, 2024 and has now qualified as NABL Assessor as informed by NABL on 15th March, 2024.
- Dr. Subhash Chand, Scientist Grade-III had undergone NABL Assessors' Training Course based on ISO/IEC 17025:2017 held from 18th-22nd March, 2024.

PARTICIPATION IN INTERNATIONAL COLLABORATIVE STUDY

Centralised Facility for Bioassay, NIB participated in the International Collaborative Study with National Institute for Biological Standards and Control (NIBSC) for development of 1st WHO International Standard for Ranibizumab, NIB as participant laboratory, evaluated the candidate materials for biological activity and submitted the raw data of the performances to NIBSC dated 05th January, 2024 for further assigning the potency value to the suitable candidate material and declaration of International Standard for Ranibizumab.

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

- Recombinant Products Laboratory, Enzymes and Hormones Laboratory and Therapeutic Antibodies Laboratory have participated in proficiency testing programme PT Round-04, 2023 for SDS-PAGE with Indian Pharmacopoeia Commission (IPC) in the month of March and scored a satisfactory performance.
- Immunodiagnostic Kit Laboratory organized one day workshop under EQAS (External Quality Assessment Scheme) for distribution of HIV proficiency test panel for HIV serology (Round 2, 2023-24) to State Reference Laboratories of Uttar Pradesh and Uttarakhand by NACO-NRL on 19th February, 2024. Technical Officers of 10 SRLs participated in the program which was presided by Dr. Rajesh Kumar Sharma, Head-IDKL & In-charge NRL and joined by Mr. Ajith Kumar and Dr. Manoj Kumar from Share India team.
- Biochemical Kit Laboratory has received yearly summary report for its participation in ACBI/CMC External Quality Assessment Scheme (EQAS) – 2023 for Chemistry II (Glucose, Cholesterol, Albumin, Creatinine, Uric acid & Triglyceride), conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore. The results for all six Clinical Chemistry parameters were Excellent (Grade A).



CONTRIBUTION TO THE DEVELOPMENT OF INDIAN PHARMACOPOEIA MONOGRAPH

- Recombinant Products Laboratory gave expert opinion on amendment proposed in Teriparatide Injection Monograph of IP 2022, in the draft monograph incorporated on the basis of testing results obtained at NIB.
- Blood Products Laboratory submitted proposal for amendment in monograph of Human Normal Immunoglobulin (IM/IV) in Indian Pharmacopoeia under Blood and Blood Related Products.

EXPERT COMMITTEE MEETINGS

- Dr. Harish Chander, Deputy Director (Quality Control) attended National Biodesign Steering Committee meeting as an expert member on 5th February, 2024.
- Dr. Harish Chander, Deputy Director (Quality Control) attended Brainstorming meeting on 'Validation of Cancer kits/Probes' at ICMR Headquarters, New Delhi on 28th March, 2024.
- Dr. Shikha Yadav, Scientist Grade-I has been nominated as member of Institutional Animal Ethics Committee (IAEC) of JNU, New Delhi by CCSEA, Ministry of Fisheries, Animal Husbandry & Dairying and attended the meeting on 29th March, 2024 to review and approve the research protocols of the university.
- Dr. Gauri Misra, Scientist Grade-II, as an external expert attended the expert committee meeting virtually to conduct the clinical performance evaluation of IVDs Medical Device to ensure safety, essentiality, desirability, effectiveness and clinical performance of new IVD product i.e., Breath Analyzer along with sample card (filter card) for detection of COVID-19 held on 30th January, 2024 organized by CDSCO.
- Dr. Gauri Misra, Scientist Grade-II as an external expert attended meetings to review the progress of the ad-hoc projects and fellowships at ICMR-Headquarters, New Delhi on 16th - 17th January, 2024.
- Dr. Gauri Misra, Scientist Grade-II as an external expert have virtually attended the advisory committee meeting of ICMR-MedTech Mitra on 24th January, 2024 to handhold stakeholders
- Dr. Gauri Misra, Scientist Grade-II, has attended First Hub Version of DBT-BIRAC as an external expert on 02nd February, 2024.
- Dr. Gauri Misra, Scientist Grade-II, has attended 5th TAC meeting of Medtech Mitra as an external expert on 19th February, 2024.
- Dr. Gauri Misra, Scientist Grade-II, has attended meeting for Malaria IVD PE as an external expert on 20th February, 2024.

- Dr. Gauri Misra, Scientist Grade-II, nominated as a member from NIB, attended the MHD20-Medical Biotechnology & Medical Nanotechnology Meeting conducted by Bureau of Indian Standards virtually on 06th March, 2024.
- Dr. Gauri Misra, Scientist Grade-II, virtually attended the first Hub meeting of DBT-BIRAC special session on 'Funding & Investments Insights' on 08th March, 2024.
- Dr. Suresh Kumar, Scientist-III was nominated by CCSEA, Ministry of Ministry of Fisheries, Animal Husbandry & Dairying for performing the inspection of animal house of Delhi University on 15th March, 2024 for the purpose of renewal of registration.
- Dr. Meena Kumari, Scientist-II has attended the meeting of the regular committee of UG/PG Board of Studies in Biotechnology, UIET, Kurukshetra University, Haryana on 20th March, 2024 through online mode.
- Dr. Charu Mehra Kamal, Scientist Grade-I, Dr. Hemant Kumar Verma, Scientist Grade -II and Mr. N. Nanda Gopal, Scientist Grade-III of Enzymes and Hormones Laboratory attended the Technical Meeting to finalize the technical matter related to recombinant Human Follicle Stimulating Hormone Drug Substance (DS) and Drug Product (DP) convened by Biological Division of CDSCO, New Delhi through hybrid mode on 04th March, 2024.

INVITED TALKS / LECTURES

- Dr. Harish Chander, Deputy Director (Quality Control) delivered a talk on 'Challenges for Pharmacy Education and Role of Biological Products to make India Healthy' on 9th-10th February, 2024 Pharmacy College, Ropar, Punjab.
- Dr. Shikha Yadav, Scientist Grade-I was invited as resource person in "Course on Laboratory Animal Science" organized by CSIR-IGIB, Delhi from 13th-15th March, 2024 and delivered lecture on "Pain and Analgesia in Laboratory Animals" as well as assisted in hands on sessions.
- Dr. Gauri Misra, Scientist Grade-II participated as an Invited Speaker in the 8th World Cancer Congress – 2024 held at JNU, New Delhi from 18th - 20th March, 2024.
- Dr. Gauri Misra, Scientist Grade-II participated in virtual mode as an invited speaker in the International Conference on Current Trends in Biological Sciences conducted by Mizoram University, Tanhril Aizawl, Mizoram from 18th - 20th March, 2024.



WORKSHOPS/ CONFERENCES/ SEMINARS

- Dr. Gauri Misra, Scientist Grade-II participated in two days' workshop on 'Medical Device Rules (MDR-17) Regulations' organized by MedTech Mitra (MDMS ICMR New Delhi) mPRAGATI (IIT Delhi) at Research and Innovation Park, Hauz Khas, IIT Delhi held from 09th-10th January, 2024.
- Scientific Staff of Enzymes and Hormones Laboratory, Recombinant Products Laboratory and Blood Products Laboratory attended one day workshop on "Recombinant LAL and Bacterial Endotoxin test" conducted by M/s Charles River Laboratories India Ltd. at NIB on 23rd February, 2024.
- Mr. Anirban Mukherjee attended a demonstration programme at M/s Biomerieux for the CO₂ based Rapid Microbial Method during 20th – 27th February, 2024.



POSTER PRESENTATIONS



- Poster presented on 'Antimicrobial resistance (AMR) in TB, the ticking time bomb' by Dr. Nupur Garg, (Postdoctoral Fellow) and Dr. Charu Mehra Kamal, Scientist Grade-I, on the occasion of World TB Day on 25th March, 2024 in collaboration with Institute of Structural and Molecular Biology (ISMB- UCL and Birkbeck), University of London and Dr Challoner's Grammar School (Amersham, UK) to be held at the Great Ormond Street Hospital, London, UK.
- Ph.D. students of Dr. Gauri Misra, Scientist Grade-II presented two posters i.e. Development and validation of a novel molecular assay for the differentiation of SARS-CoV-2 variants and Identifying novel regulatory players LNC RNAse and miRNA in GADD45 signaling to combat breast cancer in the India International Science Festival (IISF) at DBT THSTI-RCB Campus, Faridabad, Haryana from 17th to 20th January, 2024.

TRAININGS

- NIB organized two-weeks National Skill Development and Hands on Training in Quality control of Biologicals for 27 Post Graduate students from Mizoram University (Mizoram) & Nagaland University (Nagaland) from 08th - 19th January, 2024.
- NIB organized two-weeks National Skill Development and Hands on Training in Quality control of Biologicals for 28 Post Graduate students from Jammu University & Himachal Pradesh University from 05th – 16th February, 2024.
- Two-days training course on “Cryopreservation of RBCs for Panel Preparation Used in QC evaluation of Blood Grouping Reagents & Blood Grouping IVDs” held from 22nd - 23rd January, 2024 in Blood Reagent Laboratory.
- 05 Days training course on “Ethical use & care of laboratory Animals in Research and Regulatory Testing”, held from 05th–09th February, 2024 at In-Vivo Bioassay Laboratory & Animal Facility.
- 05 Days training course on “Bacterial Endotoxin Testing (BET)”, held from 19th-23rd February, 2024 at Enzymes and Hormones Laboratory.

VISITS

- NIB hosted a Laboratory visit of 35 International Delegates from 17 countries along with 01 NITS representative on 06th February, 2024. The delegates were participating in the 15th International Training Programme on “Competence and Management systems of Laboratories for developing Countries” conducted by NITS, NOIDA.
- Laboratory visit of the Pharmacy students from JSS College of Pharmacy, Sri Shivarathreeswara Nagara, (Mysuru) held on 30th January, 2024.
- Laboratory visit of M. Pharmacy Students of Rayat Bahra Institute of Pharmacy, Hoshiarpur, Punjab, held on 21st March, 2024.

PUBLICATIONS

- Anoop Kumar, Niraj Kumar, Anup Anvikar, Gauri Misra; Monkeypox virus: insights into pathogenesis and laboratory testing methods, 3 Biotech. 2024 Mar; 14(3):67.
- Sanjay Mendiratta, Gurminder Bindra, Sukhwinder Singh, Poonam Katoch, Kritika Pandey, Harish Chander, Anupkumar R Anvikar, Charu Mehra Kamal; "Less is more: "Validating a single method for comprehensive rh Insulin analysis" has been accepted for publication in Journal of Pharmaceutical and Biomedical analysis.
- Shalini Tewari, Niharika Trivedi, Sanchi Goel, Rashmi Shrivastava, Sudha.V. Gopinath, Ayushi Khurana, Anupkumar R. Anvikar; Measurement uncertainty in testing of biologicals in national control laboratories for ISO/IEC 17025: practical approaches, Accepted for publication on 09.03.2024 in Accreditation and Quality Assurance Journal, Springer.

WOMEN'S DAY CELEBRATIONS

NIB celebrated International Women's Day with a great enthusiasm and spirit by organizing various competitions and cultural activities on 8th March, 2024.



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