NATIONAL INSTITUTE OF BIOLOGICALS

सत्यमेव जयते

NEWSLETTER

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स्वस्थ नारी सशक्त परिवार अभियान

17 सितम्बर से 2 अक्टूबर 2025

#SwasthNariSashaktParivar

DIRECTOR'S DESK

Dr. Neelima Mishra

It gives me great pleasure to present NIB Newsletter for the period July–September, 2025. This quarter has been remarkable for the Institute, reflecting our continued commitment to strengthening the national framework for quality assurance of biologicals, diagnostics and vaccines. I am pleased to share that the total number of biologicals evaluated at NIB up to September, 2025 has reached 323, reiterating our growing role in safeguarding public health.

This period witnessed significant progress across our laboratories—be it advancements in quality control, initiatives in development of reference standards, or strengthening of quality assurance in in-vitro diagnostics through EQAS. Our scientists actively contributed to national initiatives, expert committees, regulatory deliberations, and capacity-building programmes. The extensive participation of our teams in workshops, technical meetings, and training events underscores NIB's dedication towards scientific excellence and regulatory preparedness.

A highlight of this quarter has been the successful organization of multiple training programmes under the Annual Capacity Building Plan 2025–26, including hands-on sessions in digital pathology, molecular diagnostics, recombinant Factor C-based endotoxin testing and laboratory quality management systems. The One-Month Induction Training Programme for newly recruited Technical Assistants of ICMR, conducted jointly with ICMR, was yet another milestone demonstrating NIB's leadership in training and skill development.

We are also proud of the achievements of our scientists who have brought laurels through awards, publications, invited talks and expert contributions at various national and international platforms. Their dedication continues to strengthen NIB's reputation as a premier institution in biological quality assessment.

I would also like to acknowledge the coordinated efforts of all divisions during the visit of Hon'ble Union Minister Shri Nitin Gadkari under the "Swasth Nari, Sashakt Parivar Abhiyan". The professionalism and teamwork demonstrated by our staff reflect the ethos of NIB.

As we move forward, NIB remains committed to expanding its scientific capabilities, enhancing regulatory support systems, and contributing meaningfully to national health priorities. I extend my appreciation to all staff members for their hard work and to the Editorial Team for compiling this insightful newsletter.

Let us continue to uphold the highest standards of quality, integrity and scientific excellence in all our endeavours.

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EDITORIAL TEAM

ARTICLE

MALARIA, IT'S DIAGNOSTICS AND QUALITY CONTROL

Ms. Y. Madhu, Scientist Grade - III, working in Quality Control of Biologicals over 29 years at NIB, NOIDA has experience in testing of various Diagnostics, Biotherapeutics and Vaccines along with expertise in establishing a QMS for ISO/IEC17025:2017 at NIB. Presently working as Head, Malaria Testing Laboratory.

MALARIA

Malaria is a parasitic infectious disease, which is preventable and treatable through various effective measures like vector control, improved living conditions and accurate diagnosis followed by reliable treatment. Female anopheles mosquito infected with plasmodium parasites transmit the disease to humans. There are more than 200 plasmodium parasite species exist, but only five cause malaria in humans with variable prevalence and severity.

About half of the world's population is at risk of the disease, children and adolescents being the vulnerable group and is one of the major causes of child mortality. Malaria is one of the public health problems in our country. Around 95% of country's population resides in malaria endemic areas. Technical guidelines/ policies have been prepared by the Directorate of National Vector Borne Disease Control Programme (NVBDCP) and it also provides resources for the programme.

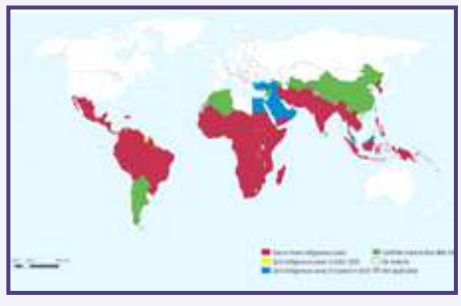

Figure 1 Countries with Cases of Malaria in 2023 (Source: WHO)

National Strategic Plan (NSP) is designed with a Vision of a "Malaria Free India" and a Mission of "Malaria elimination" in India by 2030 in coordination with the Global Technical Strategy 2016-30 and National Framework for Malaria Elimination 2016- 30. As per World Malaria Report (WMR) 2023 India contributed to 65.7% of the estimated Malaria cases in the South-East Asia Region. Early and accurate diagnosis and treatment of malaria reduces disease, prevents deaths and reduce transmission leading to effective management of the disease control. Diagnosis of malaria demonstrates the presence of parasites in erythrocytes. Several Diagnostic techniques have been developed for this purpose. The current diagnostics for malaria include microscopy, serologic assays, and molecular diagnostics. Malaria in-vitro diagnostic (IVD) devices have a low to moderate risk profile and based on this they are classified as Class B under the Indian Medical Device Rules, 2017, Central Drugs Standard Control Organization (CDSCO), that require specific performance compliance criteria for approval, such as sensitivity and specificity.

MALARIA DIAGNOSTICS

Microscopy – The Gold Standard Test

Malaria microscopy has been the gold standard test for malaria since more than 100 years. Thick and thin blood smears are prepared for microscopic examination. The advantages include accuracy, availability, low cost, quantification of parasites and monitoring of parasite clearance. The disadvantages being need of expertise of microscopist, variation in results from one to other microscopist, availability of good quality microscope, etc. Regular training of microscopist; time to time participation in Proficiency Testing Studies (PTS) & External Quality Assessment Scheme (EQAS) are certain quality management recommendations for microscopy to achieve accurate results by any laboratory.

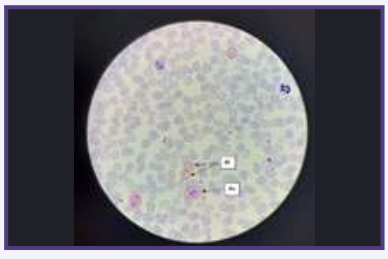

Fig.2 Blood smear from a patient with mixed infections of malaria; arrows show Plasmodium falciparum (Pf) & Plasmodium Vivax (Pv) parasites infecting some red blood cells (Source: MTL, NIB photo).

Rapid Diagnostic Tests – The Hero in Control of The Disease

Rapid Diagnostic Tests (RDTs) have been replacing microscopy as a promising alternative for the diagnosis of malaria in the past decade. World Health Organisation (WHO) also listed malaria RDTs (mRDTs) as an acceptable diagnostic tool. These are immunochromatographic tests like other rapid tests, detect parasite specific antigen in blood samples with the help of monoclonal antibodies immobilised on the membrane of the test strip by means of capillary lateral flow technology. Internal QC is incorporated in each test strip to monitor the test validity and quality. mRDTs are safe, effective, easy to use, can be performed at any point of care and can give results within 20 minutes. Different countries select mRDTs as per their national policies, testing guidelines, strategies, and nationally validated testing protocols. In view of improving its quality worldwide, WHO initiated RDT evaluation program worldwide along with its partners. There are two WHO malaria RDT Quality Assurance (QA) programs on the different malaria RDT available (Table 1).

Fig.3 Malaria RDT showing positive & negative results

Quality Assurance Initiative	Description
WHO Global Malaria Programme (GMP)	- Issues mRDT selection guidance and recommendations. - Forms the basis for WHO mRDT procurement and shared through an information note for use by countries and organizations, published on WHO's GMP website.
WHO Prequalification of In Vitro Diagnostics Programme	- WHO's prequalification programme assesses and evaluates mRDTs for performance, quality, and safety through the review of the dossier, laboratory performance evaluation, and manufacturer site inspections. Products that successfully meet the acceptance criteria are included in the list of prequalified products and are eligible for UN procurement. - Currently, WHO has 25 prequalified mRDT products from 9 suppliers: • 10 *Pf*; 8 *Pf-Pv*; 6 *Pf*-pan

Table 1: WHO Malaria Rapid Diagnostic Tests Product Testing and QA Programmes (Source: UNICEF Supply Division)

Malaria RDTs detect antigens including the histidine-rich protein II (HRP-II), aldolase, and the parasite lactate dehydrogenase (pLDH). HRP-II is a naturally occurring protein in Plasmodium falciparum (Pf), and can detect Pf malaria. pLDH is produced by malaria parasites, and can detect all four species of Plasmodium. This helps to differentiate between Pf and non-Pf species, but cannot differentiate Plasmodium malariae (Pm), Plasmodium ovale (Po), and Plasmodium vivax (Pv).

Serological Test Kits (Enzyme Linked Immuno Sorbent Assay - ELISA)

Diagnosis of malaria using serological methods are usually based on the detection of antibodies against malaria parasites. This type of kits are useful in epidemiological surveys, for screening potential blood donors, and for providing evidence of recent infection. ELISA based kits are simple and sensitive. Antigen detecting ELISA kits are also available with recent advances in diagnosis based on serological tests.

Molecular Diagnostic Methods

Developments in molecular diagnostic techniques, like Polymerase Chain Reaction (PCR), Loopmediated Isothermal Amplification (LAMP), microarray, Mass Spectroscopy (MS), and Flow Cytometric (FCM) assay, are contributing in characterization of the malaria parasite and generating new strategies for malaria diagnosis. PCR-based molecular diagnostic techniques for malaria, are to be one of the most specific and sensitive diagnostic methods, particularly for malaria cases with low parasitaemia or mixed infection, and to identify drug resistance. PCR can detect as low as 1-5 parasites/µl of blood (≤ 0.0001% of infected red blood cells) and also facilitate to process large numbers of samples at a time.

Quality Control

Weeding off substandard and counterfeit IVDs will protect patients from being exposed to poor-quality IVDs. The availability of quality assured IVDs is a critical prerequisite for effective and safe healthcare. Countries that lack resources also, lacks the means to ensure appropriate regulatory control and hence exposed to the risk of low quality products. 'Substandards' are genuine drug produced by legitimate manufacturers that do not meet quality specifications set for them, whilst 'counterfeits' are deliberately and fraudulently mislabelled with respect to identity and/or source. Designing of QC compliance requirements and evaluation is essential to assess the presence of such substandard/counterfeit IVDs and their impact on global health. In 2008, WHO and the Foundation for Innovative New Diagnostics (FIND) established an international quality assurance scheme, executed in collaboration with the United States Centres for Disease Control and Prevention. The aim was to support regulatory approval of malaria RDTs in many endemic countries, considering the heterogeneous diagnostic performance of malaria RDTs in the market. Since 2019, WHO prequalification of malaria RDTs has become a requirement for procurement of all HRP2, pan-LDH and/or pv-LDH combination RDTs by WHO and several international agencies.

DISCUSSION & CONCLUSION

Quality control of In-vitro diagnostics (IVDs) are essential requirement to assure accurate diagnosis and to reduce the rate of detection of false positive and false negative results. False positive results will be responsible for unnecessary treatments with associated increased financial burden, side effects and development of drug resistance in malaria parasite population. On the other hand, false negative results will lead to increase in morbidity and mortality rate, and play a significant role in further disease transmission. These reasons stress on the essential need of regulatory control in coordination with Quality Control (QC) of IVDs intended for diagnosis of malaria. Monitoring of sensitivity and specificity of diagnostics is utmost important to achieve accuracy in the diagnosis/screening of patients. Rapid advances in development of IVDs are generating challenges in quality assurance for manufacturers and regulators. WHO launched prequalification of in vitro diagnostics in 2010, that

provides a valuable service to procurers about the knowledge these products that are not only quality-assured but also appropriate for their intended setting of use. With the continuously growing industry of manufacturing IVDs for malaria diagnosis, regular QC of IVDs along with an effective regulatory monitoring is essential for quality assured IVDs that help in accurate diagnosis. WHO and NCVBDC developed several guidelines for QA/QC of malaria diagnostics, focussing on malaria microscopy and malaria RDT. QC of other serological and molecular based IVDs which are recently coming into the market also need to be addressed, for effective control of malaria along with the quality of the product. The knowledge sharing and hand-holding regarding details of panel size to choose for performance evaluation/ performance validation during development stage of an IVD are the need of the hour to get a quality assured IVD for malaria diagnosis. This must be accompanied by standard protocols and acceptance criteria to check quality of an IVD after manufacturing before intended for public health use along with the access to well characterised QC panel. Lack of such knowledge and resources become one of the reasons for manufacturing of substandard kits/IVDs.

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Visit of Hon'ble Union Minister Shri Nitin Gadkari at NIB under the "Swasth Nari, Sashakt Parivar Abhiyan" on 17th September 2025

1. The "Swasth Naari, Sashakt Pariwar Abhiyan" was successfully organized by the National Institute of Biologicals (NIB), Noida with the objective of promoting women's holistic health, nutrition, mental well-being, and empowerment. This initiative was part of the nationwide campaign "Swasth Naari, Sashakt Pariwar Abhiyan" launched by Hon'ble Prime Minister Shri Narendra Modi Ji on 17th September 2025 from Dhar, Madhya Pradesh. The mission aims to strengthen families and society through awareness and initiatives focused on women's health, hygiene, and wellness. In line with this vision, under the guidance of Dr Neelima Mishra, Director, NIB implemented a series of impactful activities that encouraged participation, awareness, and empowerment among women employees.
2. The campaign began with a grand inaugural session, graced by the esteemed presence of Hon'ble Shri Nitin Gadkari, Minister for Road Transport and Highways, Government of India, as the Chief Guest. The occasion was further honoured by the presence of Hon'ble Dr. Mahesh Sharma, Member of Parliament and former Union Minister; Dr. Sudhanshu Trivedi, Member of Rajya Sabha; and Shri Pankaj Singh, MLA, Noida. The dignitaries appreciated the initiative as a vital step toward women's health and empowerment and motivated the NIB fraternity to actively contribute to the campaign's success. A free Diabetics check and awareness camp coordinated by Biochemical kit lab of NIB was as well organised the same day.
3. As part of the program, a Poster making Competition, essay writing competition and poetry recitation was too part of 16-day abhiyan at NIB on the theme "Swasth Naari, Sashakt Parivar" , allowing staff to express their creative ideas on women's health and highlighting the strength, resilience, and vital role of women in family and society.

4. To enhance awareness, informative posters, banners, and pamphlets on health and nutrition were presented and distributed majorly among the housekeeping staff to bring awareness and inform them about the upcoming free health camps.
5. A special lecture on “Reproductive Health and Hygiene” was delivered by Dr. Manasi Mishra, Head of Research and Knowledge Management, Centre for Social Research. She sensitized participants to self-care, hygiene, and women’s health rights. Another important session on “Mental Health and Awareness” was conducted by Dr. Shalini Sharma, focusing on stress management, emotional resilience, and positive lifestyle practices.
6. Dr. Neelam Lohia delivered an insightful talk on “Women’s Health: The Key to Family Strength and Prosperity”, emphasizing balanced nutrition and preventive care. Additionally, Dr. Neelam Lohia and Ms. Sneha Shukla jointly conducted a session on Nutrition, discussing malnutrition and dietary balance in women and children. A Free health camp on bone densitometry tests along with Orthopaedic consultation provided by Dr. Kulwant Rai Lohia, were conducted in association with Emcure Pharma. Dietician. Ms. Priyanka Jhamb from My Roots also provided personalized diet and nutrition counselling.
7. A Yoga Session for women and children was conducted by Dr. Gauri Misra as an Expert Member, focusing on physical flexibility, stress relief, and mindfulness.
8. In collaboration with Kailash Hospital, NOIDA, a Free Health Camp was organized. The camp included general health check-ups for women and children.
9. A Blood Donation Camp in collaboration with Post Graduate Institute of women and child welfare and Hemovigilance Unit NIB, saw enthusiastic participation from NIB employees, reflecting their commitment to social service and community well-being.
10. The successful implementation of the entire campaign was made possible through the dedicated efforts of the Committee for Women Welfare, who supervised planning, execution, and coordination of all activities with exemplary teamwork and commitment. Due support was provided by Engineering, IT, Finance, Administration and all the assigned coordinators for each program for successful completion of all the programs.
11. The “Swasth Naari, Sashakt Pariwar Abhiyan” at NIB has not only fostered health awareness and empowerment among women employees but also set a strong example of institutional commitment toward a healthier and more empowered society.

AWARDS

Dr. Swati Shalini, Junior Scientist, was awarded the First Prize in the Essay Competition organized during Hindi Pakhwada, and was honored by Hon’ble Shri Nitin Jairam Gadkari, Union Minister, Ministry of Road Transport and Highways.

Ms. Rashmi Shrivastava, Scientist Grade–III, participated and secured the Second Prize in the self composed poetry recitation competition organized by the Nagar Rajbhasha Karyanvayan Samiti on 26th August, 2025 at the National Institute of Open Schooling, Sector–62, Noida.

Mr. Praveen Kumar, PTS-III, Malaria Testing Laboratory, achieved WHO-Certified Level 1 Microscopy Competence at the External Competence Assessment of Malaria Microscopy (ECAMM) held from 8th to 19th September, 2025, at Bengaluru, organized by the National Centre for Vector Borne Diseases Control (NCVBDC), Delhi.

Quality Assurance / Quality Control of Bio-Therapeutics, Prophylactics and In-Vitro Diagnostics

A one-day workshop under the External Quality Assessment Scheme (EQAS) for the distribution of HIV Proficiency Test Panels for HIV Serology (Round 1, 2025-26) to State Reference Laboratories (SRLs) of Uttar Pradesh and Uttarakhand was organized by NACO-NRL, NIB on 1st August, 2025. Laboratory Technicians and Technical Officers from 10 SRLs participated in the program, which was presided over by Dr. Akanksha Bisht, Scientist Grade - I and Dr. Richa Baranwal, Scientist Grade – III.

Nomination/ Participation of NIB Scientists in various Meetings/ Workshops

1. Dr. Suresh Kumar, Scientist Grade-III, attended the Institutional Animal Ethics Committee (IAEC) meeting as the CCSEA Nominee to review research protocols on 3rd July, 2025, at the National Institute of Immunology, New Delhi.
2. Dr. Gauri Misra, Scientist Grade-I, attended the Technical Committee meeting of the MHD20 Sectional Committee of the Bureau of Indian Standards (BIS) as a Principal Expert Member through virtual mode on 15th July, 2025.
3. Dr. Gauri Misra, Scientist Grade-I, participated virtually in the meeting of the 3rd Institutional Disaster Management Committee of Med Therapy Biotech as a DBT-nominated expert on 17th July, 2025.
4. Dr. Harit Kasana, Scientist Grade-II, Mr. Jaipal Meena, Scientist Grade - III and Dr. Manjula Kiran, Scientist Grade-III, from the Vaccine and Antisera Laboratory, attended the 15th Meeting of the Expert Working Group (EWG) – Vaccine & Immunosera for Human Use, held on 5th August, 2025, through video conferencing.
5. Dr. Charu Mehra Kamal, Scientist Grade – I and Dr. Meena Kumari, Scientist Grade – II attended a one-day workshop on "XMLisation of Standards and Online Standard Development" at the National Institute of Training for Standardization, NOIDA, Uttar Pradesh, on 12th August, 2025.
6. Dr. Shikha Yadav, Scientist Grade-I, delivered lectures on "Perioperative Care, Anesthesia, Surgical Techniques and Analgesia" and "Pain: Its Causes, Category Monitoring and Distress in Laboratory Animals", and conducted hands-on practical training on "Handling, Demonstration, Injections, and Suturing" during the Workshop on Handling and Care of Laboratory Animals at the School of Life Sciences, Jawaharlal Nehru University (JNU), New Delhi, on 21st August, 2025.
7. Dr. Gauri Misra, Scientist Grade-I and Head, delivered an invited talk on "Molecular Diagnostics of Infectious Diseases for Safeguarding Public Health" during the Continuing Education Programme (CEP) organized by DIPAS, DRDO, on 21st August, 2025, at DIPAS, DRDO, New Delhi.
8. Dr. Shikha Yadav, Scientist Grade-I, delivered a lecture on "Severity Classification and Humane Endpoints and Group Work: Search for Alternatives" during the FELASA-accredited Certificate Course in Laboratory Animal Science (CCLAS) at the Laboratory Animal Medicine Unit, CAHS, TANUVAS, Chennai, on 19th July and 23rd August, 2025.

9. Dr. Harish Chander, Deputy Director (QC), virtually delivered a lecture on "Comparative Evaluation of Biological Activity of Anti-Breast Cancer Monoclonal Antibodies" at the 12th Edition of the Global Insight Conference on Breast Cancer, held from 7th to 8th July, 2025, at Vienna, Austria.
10. Dr. Meena Kumari, Scientist Grade-III, attended the 49th meeting of the "नगर राजभाषा कार्यान्वयन समिति (कार्यालय)" held on 26th August, 2025 at the National Institute of Open Schooling (NIOS), NOIDA.
11. Dr. Gauri Misra, Scientist Grade-I, was nominated by DBT as an Expert Member in the 6th Institutional Biosafety Committee (IBSC) meeting of Med Therapy Biotechnology held on 29th August, 2025.
12. Dr. Gauri Misra, Scientist Grade-I, attended the VRDL Conclave in person on 11th September, 2025, for the launch of the Performance Evaluation of In-Vitro Diagnostic Protocol in the presence of the Hon'ble Minister of State, MoHFW, at Zorawar Hall, Delhi Cantonment, New Delhi.
13. Dr. Meena Kumari, Scientist Grade-III and Ms. Y. Madhu, Scientist Grade-III, attended a lecture on "Rational Use of Blood: Blood Component Therapy" on 8th September, 2025 at the Indian Pharmacopoeia Commission (IPC), Ghaziabad.
14. Dr. Charu Mehra Kamal, Scientist–I and Head & Member, IBSC, attended an online Interactive Session for Researchers on 18th September, 2025 organized by the Indian Biosafety Knowledge Portal, RCGM Secretariat, Department of Biotechnology
15. Dr. Akanksha Bisht, Scientist Grade-I, and Dr. Rajesh Kumar Sharma, Scientist Grade-III, attended the Two-day National Conference on "Prioritising Patient Safety in Health Institutions" organized by AIIMS Mangalagiri, Andhra Pradesh, from 19th – 20th September, 2025.
16. Scientists of Therapeutic Antibodies Laboratory, Recombinants Products Laboratory and Enzyme and Hormones Laboratory virtually attended the 16th Meeting of the Expert Working Group – Biologicals and rDNA Products on 24th September, 2025.

TRAININGS

1. Six-weeks Summer Training for the students pursuing Post-graduation in Biotechnology/ Biochemistry/ Microbiology and M. Pharm. Subject enrolled in Central or State Govt./ Private universities/ Institutes of the country. 23 students completed the training at NIB.
2. Five-days training course on "on RT-PCR including RNA extraction" conducted from 7th - 11th July, 2025 in Covid-19 Kit Testing Lab & Molecular Diagnostic Lab. Total 1 participant (an Industry professional) attended this training course.
3. Two-days training course on "Fundamentals of Laboratory Quality Management Systems (ISO/IEC 17025: 2017)" conducted from 16th -17th July, 2025 in Quality Management Unit (QMU) NIB. Total 01 participant (Officer from IIT Hyderabad) attended this training course.
4. Two weeks training course on "ELISA and allied areas" conducted from 18th to 29th August, 2025 at Biotherapeutic Research Laboratory, NIB. Total 03 Research Scholar from Bodoland University, Assam participated in this training programme.
5. Sh. Varun Pandey, Administrative Assistant- (Finance division) participated in the Three-Days Offline Workshop on "Financial Management in Government (WFM-13)" held from 4th to 6th August, 2025 at ISTM (Institute of Secretariat Training and Management), Delhi.
6. Half-Day visit of class XI & XII students from Indus Valley Public School, Noida to NIB, held on 24th July, 2025 .The participant students were familiarized to the Quality Control testing of Biologicals at NIB by a Video Demonstration and involved Scientific Lectures by Scientists and NIB-AcSIR PhD Scholars, and visit to some laboratories of NIB.
7. NIB staff attended Lecture Session Genetic Surveillance of Zoonotic Malaria in India" held on 28th July, 2025 at NIB. The session was governed with an invited talk by Dr. Aparup Das, Director ICMR-Regional Medical Research Centre, Sri Vijaya Puram (Port Blair)
8. NIB staff attended Half-Day scientific event on "Digital microscopy demonstration cum-functional on 30th July, 2025 supported by M/s BioPixel 23X Pvt Ltd., New Delhi
9. NIB organized One-Month Induction Training Program for Technical Assistants of ICMR (organized jointly by the Indian Council of Medical Research (ICMR) and National Institute of Biologicals (NIB) held from 1st – 26th September, 2025. The training programme involving 40 Participants, consisted of one week Online and three weeks Onsite residential module at NIB Campus.
10. One-Day training Workshop on "Recombinant Factor C (rFC) Technology in Bacterial Endotoxin Testing" conducted on 18th September, 2025 at bioMerieux India– Centre of Excellence, Delhi.
11. One-Day Laboratory visit of Postgraduate Students (Pre and Para Clinical Departments) from Government Institute of Medical Sciences (GIMS), Greater Noida, held on 18th September, 2025. A total 20 PG Medical Students involving Pre and Para Clinical Departments accompanied by 02 Faculty staff were part of this one-day visit.

PUBLICATIONS

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