

## **Proficiency Testing Provider Unit at ICMR National Institute of Translational Virology and AIDS Research (ICMR-NITVAR), formerly ICMR National AIDS Research Institute**

### **About Us**

External Quality Assurance Scheme (EQAS) is one of the valuable tools to assess the performance of laboratory and their attainment of quality service to generate accurate results. ICMR-NITVAR has established a Proficiency Testing Provider Unit for providing external quality assurance (EQA) to the Indian laboratories working in the field of HIV. The EQA is being provided for serological diagnosis of HIV infection, CD4 count estimation and HIV-1 viral load testing.

The institute has been currently accredited by NABL, India as a proficiency testing provider for HIV serology, CD4 Count Estimation and HIV-1 viral load testing as per standard ISO/IEC 17043.

### **HIV Serology EQAS**

In India, under the National AIDS Control Programme, National AIDS Control Organization (NACO) has established more than 5000 laboratories to carry out diagnosis of HIV infection. HIV infection is routinely diagnosed by detecting HIV antibodies using tests like ELISAs and Rapid tests based on various principles. To monitor the performance of these laboratories, a three tier system has been established where all the testing centers (ICTCs) have been grouped under different State Reference Laboratories (SRLs). The SRLs are grouped under different National Reference Laboratories (NRLs) and NRLs come under an Apex Laboratory (ICMR-NITVAR)

HIV Serology EQAS is conducted twice a financial year wherein Apex laboratory (ICMR-NITVAR) sends proficiency panels to 13NRLs (12 under NACO network and to National Institute for Research in Tuberculosis) and 18 SRLs from the states of Goa, Gujarat and Maharashtra. In addition to NRLs & SRLs, the PT Unit is also open to private laboratories involved in HIV testing. The private laboratories have to register in the EQAS programme on payment basis.

### **CD4 EQAS**

CD4 count is being used as a marker of disease progression in HIV infection. It is used to monitor the response to antiretroviral therapy. Hence, it is of utmost importance that the testing laboratory could provide accurate and reproducible CD4 count for making correct decisions in clinical settings. ICMR-

NITVAR is conducting the CD4 EQAS activity in India since 2005. ICMR-NITVAR functions as an Apex laboratory for conducting the CD4 EQAS and currently around 450 laboratories under national network are enrolled under the program.

CD4 count Proficiency Testing is conducted twice a financial year. Two samples with different CD4 counts are sent to participating laboratories. Since 2015, this activity has been extended to the private laboratories also on payment basis. The laboratories willing to participate in this program have to enroll by sending the registration form. The dully filled registration form can be sent to the PT provider by email before commencement of the round.

### **HIV-1 Viral Load Proficiency Testing**

HIV-1 viral load testing is a critical parameter for guiding antiretroviral therapy and accurately estimating HIV-1 RNA levels. Assessing the performance of laboratories conducting HIV-1 viral load (VL) testing is an integral component of the standard external quality assurance (EQA) program. This is vital for strengthening quality assurance systems and maintaining high testing standards.

The Division of Virology at ICMR-NITVAR conducts HIV-1 Viral Load Proficiency Testing viral load testing laboratories under the National AIDS Control Program since 2018. Currently, 80 viral load testing laboratories under NACP across India participate in this initiative.

HIV-1 Viral Load Proficiency Testing is conducted twice a financial year. Five samples with different viral load concentrations are sent to participating laboratories, which are assessed for quality based on their results. Laboratories achieving 100% satisfactory results in two consecutive rounds of proficiency testing are awarded certification.

### **Confidentiality:**

The PT provider ensures the confidentiality of the participant's demographics, results, reports, or any information obtained or created during the performance of PT activities. However, confidentiality is waived for the participants under NACO umbrella as their results will be disclosed to NACO and respective states AIDS societies for the purpose of improving performance.

### **Appeal:**

Participants may submit appeals against performance evaluations directly by sending an email to [ptprovidernari@gmail.com](mailto:ptprovidernari@gmail.com)

The designated staff from PT Unit will address the appeals giving proper justifications.

The respective participant will receive the reply to the appeals made via an email from PT unit.

## **Registration under HIV serology and CD4 EQAS**

- ❖ Laboratories involved in HIV testing may participate in HIV serology EQAS and /or CD4 EQAS.
- ❖ The HIV Serology EQAS cycle consist of two rounds from April to March (Financial Year). The first round is conducted in months of June / July and second round in December / January.
- ❖ EQAS for CD4 count estimation consist of two rounds conducted in the months of February/March and October/November.
- ❖ Participation certificate will be issued after the completion of yearly cycle.
- ❖ The certificate will be issued in the name of the laboratory and not in individual's name.
- ❖ Registration can be done anytime between the cycle.
- ❖ The dully filled registration form - must reach PT Provider's address one month in advance before commencement of the EQAS round.
- ❖ The total amount for HIV serology EQAS (two rounds per year) is Rs. 15,000/- (Charges for one EQA round= Rs.7,500/-)
- ❖ The total amount for CD EQAS (two rounds per year) is Rs. 25,000/- (Charges for one EQA round= Rs.12,500/-)
- ❖ Payment in full is required before the first shipment date.
- ❖ Payment can be done by RTGS or demand draft / cheque from Nationalized banks in favor of "The Director, NARI, Pune". Confirmation of participation will be done after the clearance of the cheque.
- ❖ Withdrawal from scheme can be done by sending request letter for withdrawal at PT provider's address. Emails will not be considered for withdrawal.
- ❖ New member and existing participant both have to send registration form for every new EQAS cycle.
- ❖ Unique participant ID will be provided to each laboratory which has to be used in all correspondence.

## ICMR-NITVAR

Plot No.73, 'G' Block, M.I.D.C, Bhosari, Pune-411026

Phone No. 020-27331200 Fax: 020-27121071

Email: [ptprovidernari@gmail.com](mailto:ptprovidernari@gmail.com)

### External Quality Assessment Scheme for HIV Serology REGISTRATION FORM

New Participant       Existing Participant

**Participant ID**

Shipping Address Organization:.....  
 Department:.....  
 Street:.....  
 City:..... State:.....  
 Postal Code:.....

Contact Persons Name Laboratory Head:.....  
 Tel:.....email ID:.....  
 Designee Laboratory Head:.....  
 Tel:.....email ID:.....

Payment Options  By Demand Draft       Through Cheque       RTGS  
 Demand Draft No.:.....Date:.....  
 Payable to "The Director, NARI Pune" of amount: Rs.....  
 Cheque No.:.....Date:.....Amount: Rs.....

- Terms & Condition
- Shipment date will be informed to participants on the provided email address one month in advance.
  - The total amount for two EQA rounds per year is Indian Rupees 15,000/- (Charges for one EQA round= Rs.7,500/-)
  - Payment in full is required before the first shipment date.
  - Cancellation if any will not be accepted after the date of shipment.
  - Performance report will be provided at the end of each round.

Authorization We accept the terms & conditions to participate in the EQAS.  
 Authorization Name:..... Signature:.....

**National Institute of Translational Virology and AIDS Research**

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**Phone No. 020-27331200, Fax: 020-27121071,**

**Email: [ptprovidernari@gmail.com](mailto:ptprovidernari@gmail.com)**

**External Quality Assessment Scheme for CD4 Count  
 REGISTRATION FORM**

**Participant ID**

New Participant       Existing Participant

Name Laboratory-in-charge:.....

Tel :..... E-mail: :.....

Name Laboratory Technician:.....

Tel:.....E-mail:.....

FAX:.....

**Shipping Details**

Institution:.....

Department:.....

Street:.....

City..... State.....

Postal code:.....

Mode of payment for the participation fees (Rs.12500/round) :

Please tick :    Cheque     NEFT     RTGS

**CD4 testing Survey:** Please complete the following. Tick wherever applicable

CD4 test Monthly load:.....Name of the Instrument used:.....

Manufacturer of the antibody:.....Antibody combination: 1/2/3/4 color

Panel used with the dyes (e.g. CD3-FITC) :.....

Preparation: Lysed no wash  No lyse no wash  OptiLyse  Guavalysse  FacsLysing

Gating strategy: CD45/SSC  CD3  FSC/SSC  Panleucogate  Other  mention:.....

Platform:    Single     Dual

Absolute count Beads: Trucount    Reference beads    Volumetric    Flowcount    other:.....

If the Absolute counts are derived from CBC, mention machine used for CBC

**Terms and Conditions:** Shipment date will be informed to participants on the provided email address.

Payment in full is required one month before the scheduled month.

Cancellation if any will not be accepted after the date of shipment.

Performance report will be provided at the end of each round.

**Authorization :** We accept the terms & conditions to participate in the EQAS

Authorization Name:..... Signature:.....

## **Contact Us**

Proficiency Testing Provider Unit  
ICMR- NITVAR  
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M.I.D.C, Bhosari  
Pune-411026  
Phone No. : 020-27331200  
Email ID: ptprovidernari@gmail.com

**Director, ICMR-NITVAR: Dr. Sheela Godbole**

**PT Coordinator: Dr. Ashwini Shete, HIV Serology and CD4 EQAS**

**PT Coordinator: Dr. Swarali Kurle, HIV-1 VLPT**