Report" to NABL indicating inadequacies, if any. The laboratory is then required to take necessary corrective action(s) within specified time and submit a report to the lead assessor marking a copy to NABL.

Pre-assessment

In case no inadequacies are pointed out in the adequacy report or after satisfactory corrective action by the laboratory, a pre-assessment visit of the laboratory is organized by NABL. The lead assessor undertakes the pre-assessment visit to the laboratory and reviews the documentation and implementation of the QMS.S/he then submits the pre-assessment report to NABL and the laboratory. Laboratory is then required to take the necessary corrective action(s) on the NCs as observed during pre-assessment, if any, within specified time and submit a corrective action report to the lead assessor with a copy to NABL.

Final Assessment

In case no inadequacies are pointed out in the pre-assessment report or after satisfactory corrective action by the laboratory, the final assessment of the laboratory is organized by NABL. The final assessment is conducted during a mutually agreed date/s by the assessment team comprising of the lead assessor, the technical assessor/s to cover the entire scope of accreditation. The assessment team reviews compliance to ISO 15189:2012, NABL specific criteria 112 and other NABL policy documents and technical compliance of the laboratory to perform specific tests. The lead assessor submits the detailed final assessment report along with the recommendations of the assessment team to NABL whilst providing a copy of the assessment summary and the non-conformities to the laboratory. The laboratory is then required to take necessary corrective action(s) on the non-conformities as observed during the final assessment, if any, within a specified time and submit the corrective action report to the lead and technical assessors under intimation to NABL for future course of action.

After the satisfactory corrective action by the laboratory and closure of NCs raised by the assessment team, the NABL secretariat scrutinizes the assessment report and places the report before the accreditation committee for examination. The NABL accreditation committee examines the assessment report, corrective action/s taken and additional information as sought from the laboratory and gives the appropriate recommendation/s for the grant of accreditation or otherwise to the chairman of NABL. Approval is sought from chairman NABL for grant of accreditation or otherwise based on accreditation committee's recommendation.

Issue of Accreditation Certificate: On approval from the chairman-NABL for grant of accreditation, NABL issues the accreditation certificate having a unique number for each field of testing and having specified validity period along with detailed scope of accreditation to the laboratory. The accreditation certificate is initially issued for a period of 2 years. The Laboratory must strictly adhere to the NABL document 131 regarding use of the NABL logo.

Maintenance of NABL Accreditation:

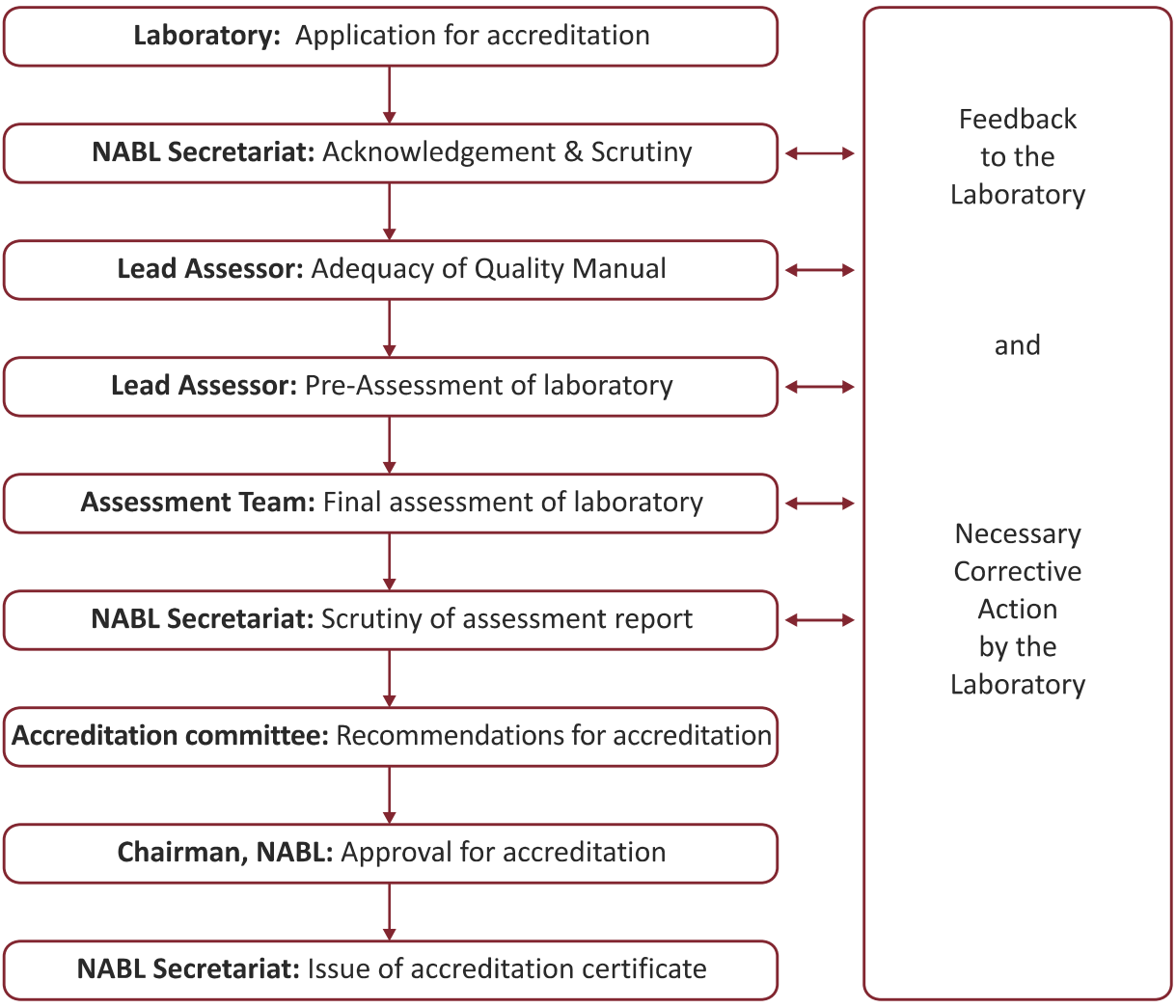
NABL conducts an annual surveillance of the accredited laboratory in its first accreditation cycle, to ensure that the laboratory continues to comply with the requirements of the standard. The surveillance is conducted by an assessment team which submits its detailed report to NABL. The laboratory takes necessary action(s) on the non-conformities observed, if any, during surveillance within specified time and submits a corrective action report to NABL.

Accredited laboratories must apply for renewal of accreditation in the prescribed application form, at least 6 months prior to the expiry of validity of its accreditation so that the process of re-assessment is completed before the certificate expires.

The process for re-assessment is similar to that of the initial assessment. When the laboratory is recommended for renewal of accreditation, NABL will re-issue the accreditation certificate to the laboratory.

Table 12.2: Process for NABL accreditation

Flowchart for Accreditation Procedure



Chapter 12

A copy of the following documents should be available with the laboratory during NABL assessment.

http://www.nabl-india.org/nabl/index.php?c=publicaccredationdoc&m=index&docType=both&Itemid=199

1. ISO 15189:2012 Medical Laboratories - Requirements for Quality and Competence.
2. NABL 112: Specific Criteria for Accreditation of Medical Laboratories. Issue No. 3.
3. NABL 131: Terms and Conditions for Maintaining NABL Accreditation.
4. NABL 141: Guidelines for Estimation & Expression Of Uncertainty In Measurement.
5. NABL 142: Policy on Calibration and Traceability Of Measurements.
6. NABL 153: Application Form for Medical Testing Laboratories.
7. NABL 160: Guide for Preparing a Quality Manual.
8. NABL 161: Guide for Internal Audit & Management Review for Laboratories.
9. NABL 163: Policies & Procedures for Inter-Lab Comparisons and/or Proficiency Testing.

Key points

- "Accreditation" (national or international) is a voluntary process to confirm that standards have been met.
- Accreditation serves as a marker of quality to consumers and can have significant benefits in increasing confidence in laboratory services.

Further Reading

1. ISO 15189: 2012: International Standard: Medical Laboratories- Requirements for Quality and Competence. Third edition.
2. NABL 112: Specific Criteria for Accreditation of Medical Laboratories
   http://www.nabl-india.org/nabl/file_download.php?filename=201210170522-NABL-112-doc.pdf
3. CLSI. Quality Management System: A Model for Laboratory Services: Approved Guideline-4th Edition, CLSI Document GP26-A4, Wayne, PA: Clinical and Laboratory Standards Institute, 2011
4. Maintenance Manual for Laboratory Equipment, 2nd Edition, 2008, WHO Publications
   http://whqlibdoc.who.int/publications/2008/9789241596350_eng_low.pdf
5. Laboratory Biosafety Manual, 3rd Edition, 2004, WHO Publications
   http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/
6. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, 2009, Centers for Disease control and Prevention (US)
   http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf
7. Biomedical Waste (Management and Handling) Rules, 1998, Ministry of Environment and Forests, GOI
   http://envfor.nic.in/legis/hsm/biomed.html
   http://www.moef.nic.in/downloads/public-information/salient-features-draft-bmwmh.pdf
8. USAID | DELIVER PROJECT, Task Order 1. 2009. *Laboratory Logistics Handbook: A Guide to Designing and Managing Laboratory Logistics Systems*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1.
   http://pdf.usaid.gov/pdf_docs/PNADP082.pdf
9. NABL: 161: Guide for Internal Audit and Management Review for Laboratories
   http://www.nabl-india.org/nabl/file_download.php?filename=201206291053-NABL-161-doc.pdf
10. NABL 142: Policy on Tractability of Measurement Results
    http://www.nabl-india.org/nabl/file_download.php?filename=201206291050-NABL-142-doc.pdf

Prototype of a Specimen Requisition Form

XYZ LABORATORY SPECIMEN REQUEST FORM

Name: ..... Age:.....Gender: M/F/TG
Unique Identification number (PID No.): .....
Location/Centre details: .....
Date of collection (DD/MM/YY): .....
Time of collection (HH:MM): .....
Name of requester: .....
Examination requested: .....
Type of specimen: .....
Reason for Investigation: .....
Clinical information relevant to the investigation: .....
Pre-test counselling done: Yes / No
Informed consent obtained: Yes / No

Signature of requester: .....

Date: .....

For Laboratory use only:

Specimen: accessed/rejected (reason for rejection: .....)
Laboratory specimen ID number: .....
Date of specimen receipt in the laboratory (DD/MM/YY): .....
Time of specimen receipt in the laboratory (HH:MM): .....
Signature of laboratory staff receiving the specimen: .....

Prototype of a Specimen Accession Log/Register

SPECIMEN ACCESSION LOG/REGISTER

Serial No.	Name	Age/ Gender	PID No.	Received from	Date and time of collection	Date and time of receipt in lab	Lab ID No.	Specimen accepted/ rejected	Initial of receiver

Name and signature of Laboratory Supervisor: .....

Date: .....

ICTC HIV Test Report

HIV TEST REPORT FORM

(Form to be filled in duplicate)

Name and address of ICTC center: .....

.....

Surname: ..... Middle Name: .....First Name: .....

Gender: M / F / TG Age: .....Years PID # ..... Lab ID # .....
Date and time blood collected: ..... (DD/MM/YY): ..... (HH:MM):.....

Test Details

Type of Specimen used for testing: Serum / Plasma / Whole Blood

Date and time specimen tested: ..... (DD/MM/YY): ..... (HH:MM):.....

Note :

- Column 2 and 3 to be filled only when HIV 1 and 2 antibody discriminatory test(s) used
- No cell has to be left blank; indicate as NA where not applicable.

Column 1	Column 2	Column 3	Column 4
Name of HIV test kit	Reactive/Nonreactive(R/NR) for HIV-1 antibodies	Reactive/Nonreactive (R/NR) for HIV-2 antibodies	Reactive/Nonreactive (R/NR) for HIV antibodies
Test I :			
Test II :			
Test III :			

Interpretation of the result : Tick (✓) relevant

- ☐ Specimen is negative for HIV antibodies
- ☐ Specimen is positive for HIV-1antibodies
- ☐ *Specimen is positive for HIV antibodies (HIV 1 and HIV 2; or HIV 2 alone)
- ☐ Specimen is indeterminate for HIV antibodies. Collect fresh specimen in two weeks.

** Confirmation of HIV 2 sero status at identified referral laboratory through ART centers*

....

Name and Signature of Lab Tech Name and Sign of Lab In-charge

In House Preparation of External Positive Control

(Borderline Reactive)

Steps for preparing a borderline reactive external quality control specimen:

1. Select a high titer HIV positive plasma/serum for dilution.
2. Select a HIV, HBV and HCV negative specimen as diluent. Diluent must be centrifuged and should be free from fibrin clots and non-lipaemic.
3. Arrange tubes for serial dilution
4. Perform two fold serial dilution of properly pooled and mixed specimen using negative specimen as a diluent as follows:

a) 100 µl (as per requirement of kit) normal serum (Negative Specimen) is added to each tube (assay requiring 10 µl of specimen.
b) 100 µl positive specimen is added to the first tube.
c) Mix by moving the pipette plunger up and down at least 3 times. Ensure that fresh pipette tips are used for each dilution.
d) Transfer 100 µl from tube 1 to tube 2 and mix well.
e) Repeat this step for the remaining tubes.
f) Dilution in tube 10 is 1:1024.
g) Test each titration in the same run for the particular assay for which the QC is being prepared.

5. Calculate mean of duplicate value of each dilution.
6. Calculate E ratio i.e. OD/cut off.
7. Plot a graph of E. ratio v/s dilution. The result usually shows a sigmoid curve (chart no. 1). An appropriate dilution should be selected from the section of the graph where results variability can be followed. I.e. linear position of the curve.
8. Select suitable dilution:-
   - 8.1 The dilution of EPC should be between the positive kit control value and the Calculated cut off value preferably a little above the cut off value.
   - 8.2 If a QC specimen is chosen with an OD that is too low, then the OD may fluctuate above and below the cut off due to normal variations.
   - 8.3 A specimen chosen with an OD that is too high will be of limited use for border line monitoring and may not identify subtle changes.
9. Large Batch production:-
   - 9.1 Centrifuge specimens at 3500 rpm for 10 minutes.
   - 9.2 Prepare required amount of bulk dilution as per requirement e.g. If dilution selected is 1:256 and required quantity is 25 ml then dilute 100 µl positive specimen in 25.5 ml Negative specimen (diluent).

9.3 Mix properly.

10. Batch validation:-
    a. Test the prepared QC specimen in duplicates in the assay for which the specimen was designed and calculate Specimen OD/Cut Off ratio. It is imperative to check the Specimen OD/cut off ratio of large batch to ensure that it is appropriate and comparable to the target value.
    b. If the QC specimen is of a small volume (<1litre) and the Specimen OD/Cut Off result were appropriate then dispense the batch into aliquots of a smaller 'user friendly' volume such as 1ml (ensure that the specimen has been mixed properly before aliquoting into smaller volume).

12. Batch validation-Homogeneity:-
    a. Once the batch has been dispensed into smaller volumes, a specimen from each of the aliquots must be tested to ensure that each aliquot will produce the same results, the batch is reproducible and homogenous
    b. Randomly select some aliquots from the dispensed batch
    c. Test these aliquots in at least one assay system for which the QC specimen was designed to quality control.
    d. If OD of above aliquots is close to each other this data is used for calculation of standard deviation.
    e. Calculate the S.D. and C.V. for selected specimens. The batch is acceptable if the C.V. of the results is less than 15%

$$S.D. = \sqrt{\frac{\Sigma (X - \bar{X})^2}{n - 1}}$$

Σ - Sum of
$\bar{X}$ - Average Value
X - Any single observed Value
n - Total number of observed Value

$$C.V.\% = \frac{S.D.}{Mean\ \bar{X}} \times 100$$

13. The label on the QC specimen should include, the
    a. Name of the QC specimen
    b. Batch no.
    c. Mfg. Date
    d. Exp. Date (usually 12 months from the date of production)

14. Stability:-
    a. All the QC specimens (prepared vials) are stored at -200c for up to one year.
    b. While aliquots in use should be stored at 40c these should be discarded after 7 days and

a new 1 ml vial should be introduced.

15. Daily run the QC specimen along with the routine specimens and kit controls, at the end of the assay.
16. Data Collection:-
    Collect data from daily run; calculate specimen S/CO ratio, mean, standard deviation, upper limit and lower limit.
17. Plot the Levy-Jennings control chart (chart no. 1) that is for E-ratio and the day run. Include mean, upper limit and lower limit on chart.
18. Test the QC specimen using two or three different reagent batches (lot number of assay) for observing lot to lot variation.
19. Result must be within control limits ± 2SD (upper limit and lower limit).
20. To prepare the external control for the Rapid tests, determine the dilution required to give a borderline reactivity with individual brands of kits.

Chart no 1

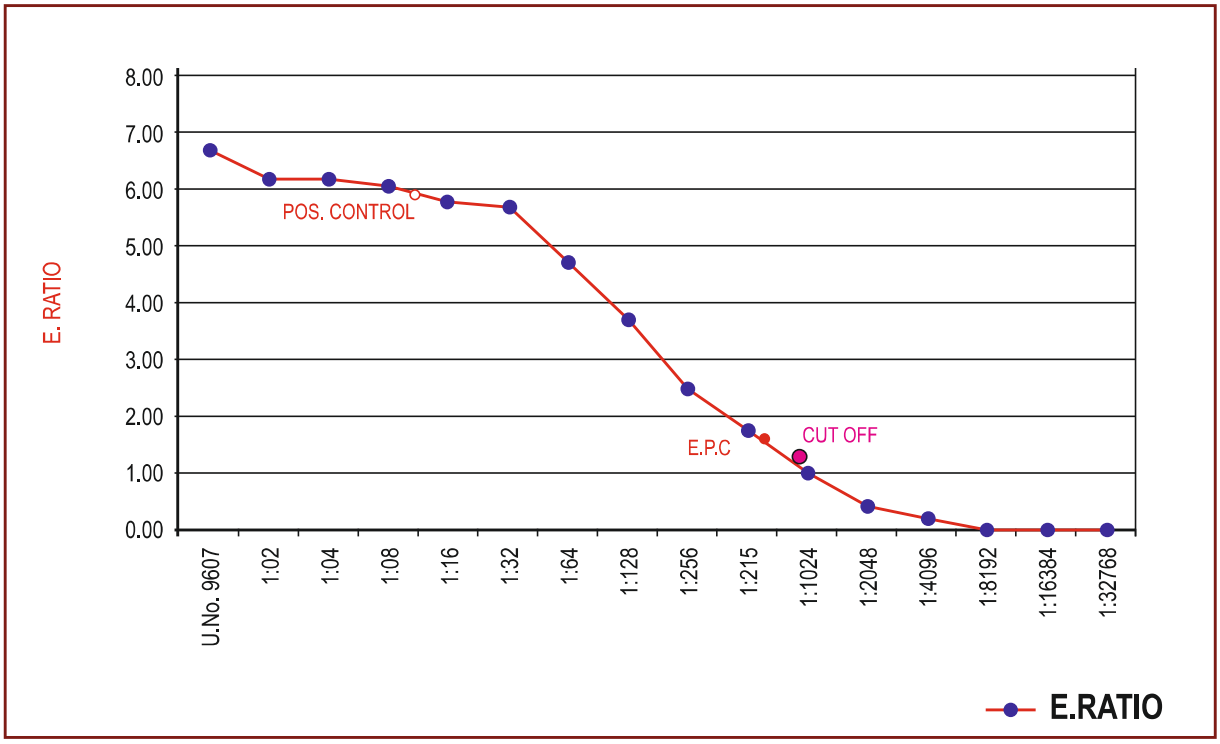
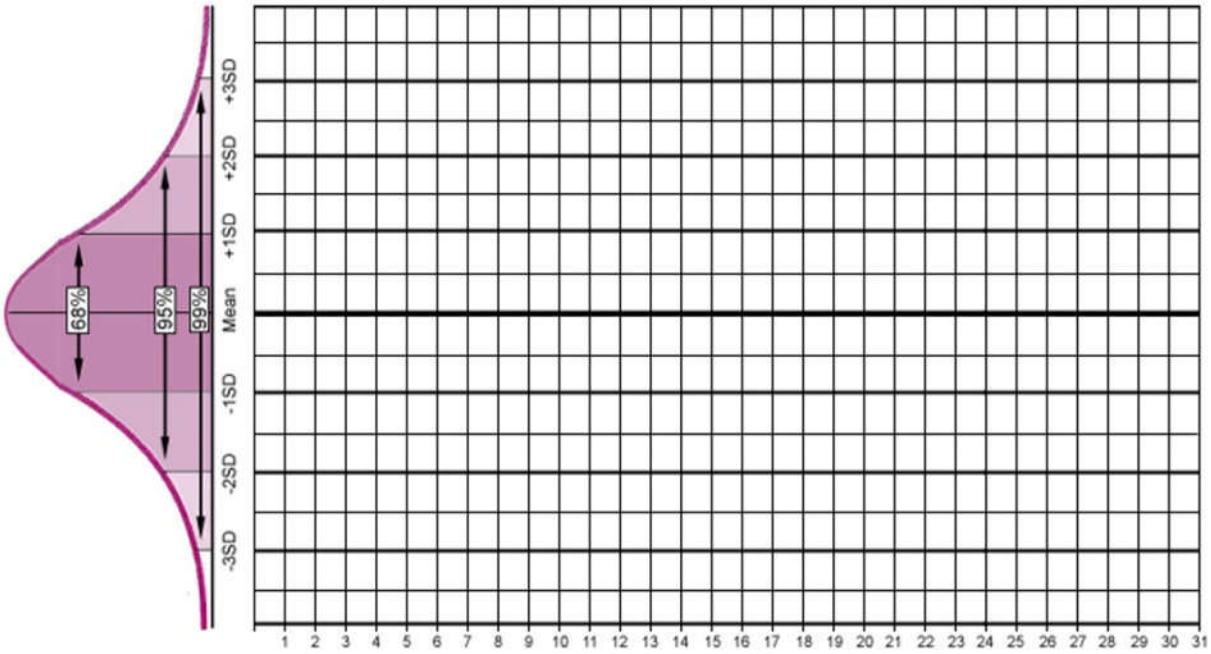
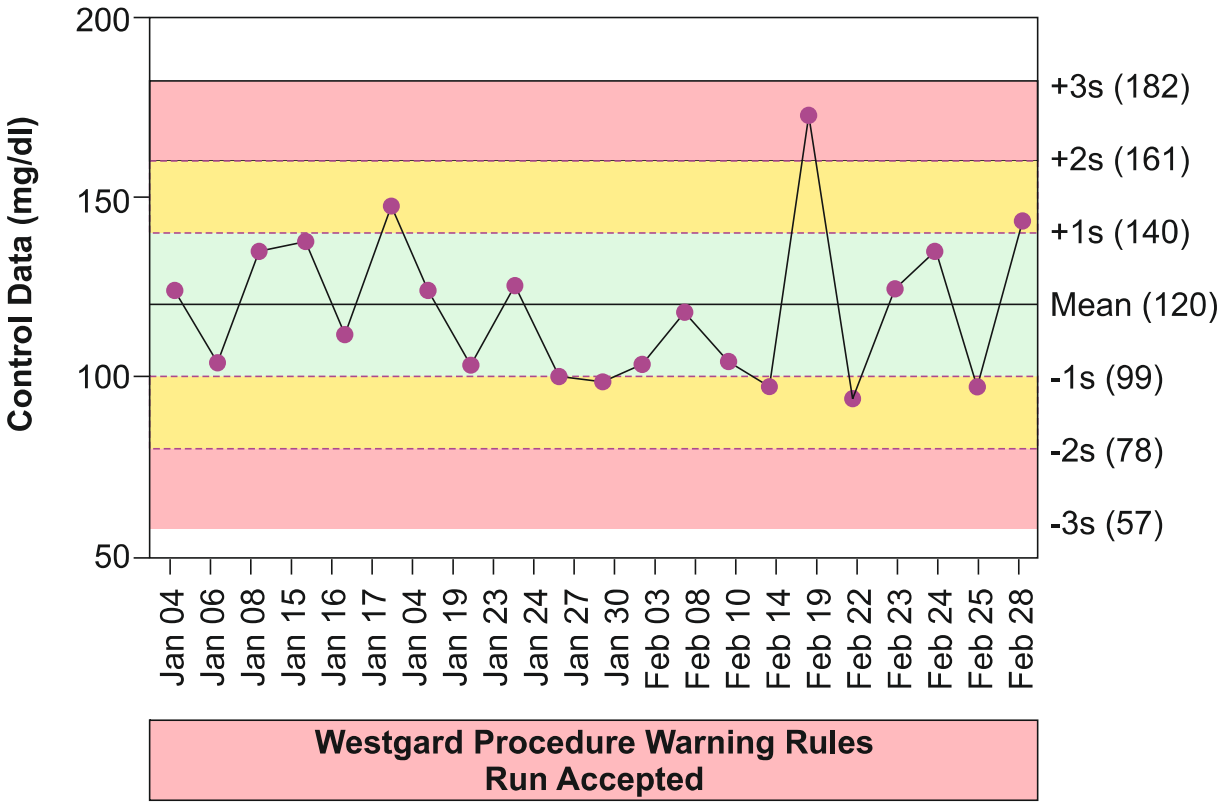
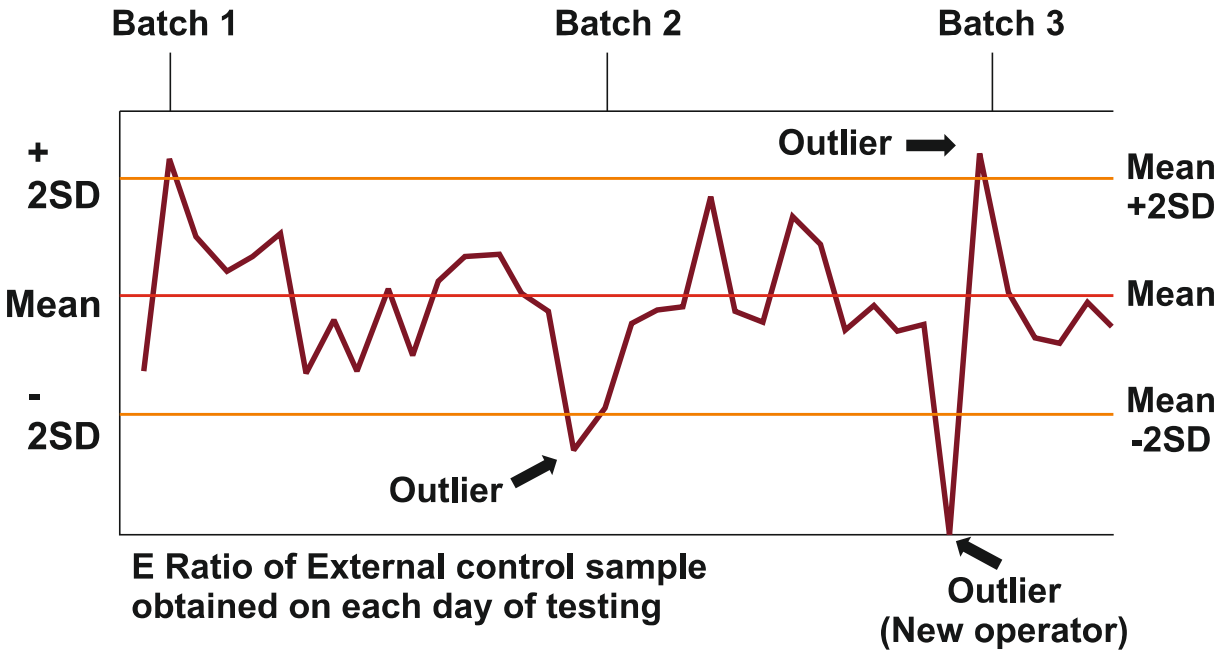


Chart no 2: Levey-Jennings Charts:





Levey-Jennings Control Chart



Preparation of Panel Plasma for Proficiency Testing by NRL

The preparation process comprises of these steps:

1. Collection of plasma specimens from different Blood Banks
2. Aliquoting
3. Storage of the specimens
4. Characterization of specimens

1. Collection of plasma specimens from different Blood Banks
   - Donor units which are not used for transfusion are collected appropriately from various Blood Banks by NRL staff.
   - Lipaemic, Icteric, contaminated, haemolysed units are not included in the reference panel.
   - Relevant information pertaining to testing undertaken at source is documented and a separate identification code is assigned to each specimen and entered into assigned registers.
   - These specimens are aliquoted under aseptic conditions observing Biosafety Level II practices into 50 ml and 1.8 ml cryovials.

2. Aliquoting of the specimens: To be performed inside biosafety cabinet
   - Bring the plasma bag to room temperature and keep it in upright position.
   - Mix the bag for homogenization of the contents.
   - Apply pressure, discard a small amount into 1% Sodium hypochlorite
   - Hold the tubing over the 50 ml cryovial, fill to ¾ capacity, subsequently five 1.8 ml cryovials are prepared from the 50 ml vial.
   - One1.8 ml vial is stored in panel cryovial box at 2 to 8oC. Rest of the vials is stored in the chest of the refrigerator and 50 ml vials are to be stored at –20o C or lower temperatures.
   - Documentation and inventory of the aliquots is done carefully.

3. Storage of the specimens
   - 1.8 ml cryovials to be stored at 2 to 8o C for a maximum of one week.
   - For longer storage, the specimens should be stored at –20o C or lower temperatures.
   - Avoid glass vials for storage of specimens as they may eventually crack under frozen conditions.
   - Avoid repeat freezing and thawing of the specimens as it affects the quality of the panel.
   - A register/log is maintained having details of number of vials of each panel member used and left over.

4. Characterization of Panel members
   - Characterization studies are carried out by two different assays i.e. screening and

confirmatory assays. Characterization studies are carried out on these freshly aliquoted members using baseline kits for HIV testing

- Screening assay include Rapid tests. Confirmatory assay include Western Blot/Line immunoassay (HIV).
- The characterized specimen should be positive/negative for the selected marker/ infection and non-reactive for other infection / marker such as HBsAg and HCV.

Reporting results of proficiency panel from SRL to NRL and ICTC to SRL

EXTERNAL QUALITY ASSESSMENT SCHEME FORM

Name of Proficiency Testing Provider: .....
Date of proficiency panel distribution: .....
Date of testing proficiency panel: .....
Date report sent: .....

HUMAN IMMUNODEFICIENCY VIRUS TYPE-1 (HIV-1)
ANTIBODY TESTING

NOTE :

The HIV-1 performance evaluation samples are undiluted, unaltered individual donor material. It is the intention to provide laboratories with performance evaluation samples that closely resemble the types of specimens that laboratories encounter in their routine daily testing.

EQAS Laboratory Identification No.: ☐☐☐☐ (Number can be found on your panel box)

Laboratory Name : .....

Type of Laboratory: NRL/SRL/ICTC/PPTCT/FI-ICTC/PPP-ICTC/Blood Bank

Address of Laboratory (where testing is undertaken): .....

Street : .....

State: ..... Postal Code: ..... Telephone No. .....

e-mail: ..... Fax No.: .....

Name of nodal officer: .....
& Signature

GENERAL INSTRUCTIONS

PLEASE READ ALL INSTUCTIONS COMPLETELY BEFORE SAMPLE TESTING.

RECORD ALL INFORMATION LEGIBLY AND WITHIN THE APPROPRIATE SPACES.

FILL RELEVANT PAGES

PERFORM THE TEST PROCEDURE (S) ON THESE SAMPLES, IN THE SAME MANNER AS THE PATIENT SPECIMENS FOLLOWING NACO STRATEGY III. DO NOT HEAT INACTIVATE THESE SAMPLES.

Do not report for more than three tests
Enter your EQAS laboratory identification number in the boxes provided at the of each results form. Your EQAS number can be found on the identification label affixed to the panel box containing your samples.

Follow all the instructions as per kit insert.

NON REPORTING CODES

CODE	REASONS FOR NOT REPORTING RESULTS
T	Test not performed in this laboratory
L	Samples lost or destroyed in laboratory
R	Test reagents not available
I	Insufficient sample volume to perform test
O	Other (please specify on results form)

INSTRUCTIONS FOR EQAS SAMPLES

1. As far as possible use the kits provided by NACO.
2. Enter the name of the test kit in the spaces provided.
3. Enter in the spaces provided the complete sample code (one digit code) exactly as it appears on each vial, e.g. A B
4. For each sample, circle an Interpretation code indicating your interpretation of the reporting test results. Interpretation Codes appropriate for each test procedure are found in the Specific Instructions section for each test.
5. Wherever differentiating kits are used, kindly specify the results as HIV-1 / HIV-2 / HIV-1+2.
6. NOTE: Any clarification required regarding EQAS programme, please contact the Director at the following address.

Address of Proficiency Testing Provider

Annexure 2.6A

EQAS Lab ID No. ☐☐☐☐

LABORATORY RESULTS FORM FOR 1st RAPID TEST

NON REPORTING CODE ☐

Name of the test: ..... Type of assay: .....
Manufacturer: .....
Lot #: .....
Date of expiry: .....

TEST CONTROLS RESULTS

POSITIVE CONTROL: ..... NEGATIVE CONTROL: .....

EQAS SAMPLES RESULTS

Sample Code	Enter Results Applicable as per the procedure	Interpretation (Circle One)
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**

R: Reactive **NR** : Nonreactive

EQAS Lab ID No. ☐☐☐☐

LABORATORY RESULTS FORM FOR 2nd RAPID TEST

NON REPORTING CODE ☐

Name of the test: ..... Type of assay: .....
Manufacturer: .....
Lot #: .....
Date of expiry: .....

TEST CONTROLS RESULTS

POSITIVE CONTROL: ..... NEGATIVE CONTROL: .....

EQAS SAMPLES RESULTS

Sample Code	Enter Results Applicable as per the procedure	Interpretation (Circle One)
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**

R: Reactive **NR**: Nonreactive

Annexure 2.6A

EQAS Lab ID No. ☐☐☐☐

LABORATORY RESULTS FORM FOR 3rd RAPID TEST

NON REPORTING CODE ☐

Name of the test: ..... Type of assay: .....
Manufacturer: .....
Lot #: .....
Date of expiry: .....

TEST CONTROLS RESULTS

POSITIVE CONTROL: ..... NEGATIVE CONTROL: .....

EQAS SAMPLES RESULTS

Sample Code	Enter Results Applicable as per the procedure	Interpretation (Circle One)
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**
☐	_____	**R NR**

R: Reactive **NR**: Nonreactive

FINAL RAPID RESULTS

Sample Code	Results

Test Interpretation Codes:

P: Positive; **I**: Indeterminate; **N**: Negative

.....
Signature of Technician
Date: .....

.....
Signature of Nodal Officer
Date: .....

EQAS Lab ID No. ☐☐☐☐

ENZYME IMMUNOASSAY LABORATORY RESULTS INITIAL EIA FORM

NON REPORTING CODE ☐

INITIAL EIA
(To be filled for all samples)

REAGENTS

Manufacturer: .....

Lot # .....

Kit Name: .....

Date of expiry: .....

TEST CONTROLS

INITIAL EIA	**ABSORBANCE**
HIV-1 Positive Control (Mean)	☐☐☐☐
HIV-2 Positive Control (Mean)	☐☐☐☐
Negative Control (Mean)	☐☐☐☐
Cutoff Value	☐☐☐☐

INITIAL EIA RESULTS

Sample Code	Absorbance 1	Interpretation (Circle One)
☐	☐☐☐☐	**R NR**
☐	☐☐☐☐	**R NR**
☐	☐☐☐☐	**R NR**
☐	☐☐☐☐	**R NR**
☐	☐☐☐☐	**R NR**
☐	☐☐☐☐	**R NR**
☐	☐☐☐☐	**R NR**
☐	☐☐☐☐	**R NR**

R : Reactive ; NR : Nonreactive