EQAS Lab ID No. ☐☐☐☐

ENZYME IMMUNOASSAY LABORATORY RESULTS SECOND EIA FORM

NON REPORTING CODE ☐

SECOND EIA
(To be filled for only reactive samples)

REAGENTS

Manufacturer: .....

Lot # .....

Kit Name: .....

Date of expiry: .....

TEST CONTROLS

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

SECOND 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

Annexure 2.6A

FINAL EIA 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. ☐☐☐☐

WESTERN BLOT FORM
(To be filled for only reactive samples)

NON REPORTING CODE ☐

REAGENTS

Manufacturer: .....

Lot # .....

Kit Name: .....

Date of expiry: .....

TEST CONTROLS

WESTERN BLOT RESULTS

Positive Control .....

Negative Control .....

WESTERN BLOT RESULTS

Sample Code	Enter Results Applicable as per the procedure	Interpretation (Circle One)
☐	_____	**P I N**
☐	_____	**P I N**
☐	_____	**P I N**
☐	_____	**P I N**
☐	_____	**P I N**
☐	_____	**P I N**
☐	_____	**P I N**
☐	_____	**P I N**

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

Annexure 2.6A

FINAL WESTERN BLOT RESULTS

Sample Code	Results

Test Interpretation Codes:

P: Positive ; I : Indeterminate ; N : Negative

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

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

Results of Proficiency Panel of ICTC attached to SRL ……

Serial No.	Centre Name	Centre Code	Results				Proficiency

Annexure 2.6 c

Report format for reporting Results of Proficiency panel results of SRL from NRL

	Results of Proficiency Panel								Remarks
PP Nos.									
SRL NAME									
NRL NAME									

RECHECKING SPECIMEN ACCESSION

(CHECKLIST FOR SRLs)

(Fill in duplicate, one copy to be retained by the testing centre and the other copy for the site)

1. Name of the Testing centre: .....
2. Name of the site: .....
3. Date of specimen received: .....
4. Total number of specimens received: .....
5. No. of specimens rejected: ☐
   Hemolysed ☐ Lipaemic ☐ Insufficient ☐
6. No. of vials leaking: ☐
7. No. of vials with improper labeling ☐
8. Cold chain maintained: Yes ☐ No ☐
9. Details on the transport sheet: Complete ☐ Incomplete ☐
10. Data forms matched with the specimens: Yes ☐ No ☐

Verified by: ....
(Name) (Signature with Date)

Technical officer ....
(Name) (Signature with Date)

Laboratory In-charge ....
(Name) (Signature with Date)

ACCEPTED SPECIMEN REGISTER for SRL

(Rechecking Specimens from ICTC)

Serial Number	Date of Receipt	Name of the Testing Centre and Code No.	Specimen ID at Testing Centres	Specimen ID at SRL	Reactivity status of the specimens	Signature of the receiver

Lab Supervisor: .....

Date: .....

REJECTED SPECIMEN REGISTER for SRL

(Rechecking Specimens from ICTC)

Serial Number	Date of Receipt	Name of the Testing Centre and Code No.	Specimen ID at Testing Centres	Rejected on (date)	Rejected Due to	Rejected By (sign)	Date of Discard	Sign of Person Discarding

Lab Supervisor: .....

Date: .....

Format for Sending Report of Re-checking Samples from SRL to ICTC

Name of the Testing Centre: ..... Code number: .....

S. No.	Patient I D No	Tested Date	Blood Bank		Testing Centres (ICTC)		Final Result	Date Sent
			Kit Name:		Kit Name:			
			Lot No:		Lot No:			
			Exp. Date:		Exp. Date:			
1								
2								
3								
4								

Total No. of Specimens received from 1st to 7th at the centre	
Total Positive	
Total Negative	
Total Indeterminate	

Total No. of specimens sent to the SRL	
Total Positive	
Total Negative	
Total Indeterminate	

Specimen sent by : ....
(Name) (Signature)

Specimen received by: ....
(Name) (Signature)

LABORATORY ASSESSMENT CHECKLIST

Date(s) of Assessment: .....

GENERAL INFORMATION

Laboratory Name: .....
Address: .....
Telephone# .....
Fax# .....
Email: .....
Laboratory In charge: .....
Laboratory staff: .....

S No.	Organization and Personnel	Yes	No	Remarks
1.1	Is an organizational chart for laboratory personnel present?			
1.2	Are job description/delegation of duties documentation present?			
1.2a	For each laboratory position is there a job description			
1.3	Has the laboratory staff undergone Good Laboratory Practice (GLP) training?			
1.3a	Are training, education records for personnel kept on file?			
1.4	Is documentation maintained, indicating the laboratory has assessed the competency of each employee to perform his or her assigned duties?			
1.5	When the lab was last audited?			
II	**Equipment**			
2.1	Is the equipment installed and placed as specified in the operator's manual and uniquely labelled or marked?			
2.2	Is all laboratory equipment listed on an inventory document?			
2.3	Are there documented Preventive Maintenance and calibration plans for the laboratory's equipment?			
2.4	Are calibration materials stored, as required by the manufacturer?			
2.4a	Are calibration materials properly labeled, indicating content and calibration value?			
2.5	Are refrigerators, freezers present?			
2.5a	Are Preventative Maintenance activities performed/documented?			
2.5b	Are temperature readings taken and documented? If "Yes", report the frequency			
2.5c	Have tolerance limits been established/documented for temperature readings?			
2.5d	Is there documentation of corrective actions taken, in response to out-of range values?			

S No.	Organization and Personnel	Yes	No	Remarks
2.6	Are centrifuges present?			
2.6a	Are Preventative Maintenance activities performed/documented?			
2.6b	Is calibration performed/documented for each centrifuge? report the frequency			
2.7	Are pipettes present?			
2.7a	Are calibration procedures performed for all pipettes? If "Yes", report the frequency			
2.8	Are thermometers present?			
2.8a	Is a known standard thermometric device available (NABL certified)?			
2.8b	Have all non-certified thermometers been tested against a standard device?			
2.9	Is flow cytometry instrumentation present? If "Yes", please report the manufacturer/model			
2.9a	Are Preventative Maintenance activities performed/documented?			
2.9b	Are calibration procedures performed, as described by the manufacturer?			
2.10	Are balances present?			
2.10a	Are calibration procedures performed, as described by the manufacturer?			
2.11	Is ELISA testing equipment present?			
2.11a	Are Preventative Maintenance activities performed/documented?			
2.11b	Are calibration procedures performed, as described by the manufacturer?			
2.12	Supervisor or designee has reviewed and signed maintenance, repair, and calibration records monthly?			
2.13	Are there records to verify that a back-up generator system is in place and operational?			
2.14	Have there been any recent changes in the facilities or the equipment? (Major repairs, new equipment, etc.)			
2.15	Are there back up procedures for equipment failure.			
III	**Test Procedures**			
3.1	A. Is there a list of all testing activities performed in the laboratory?			
3.2	Are there SOPs for each			
3.3	Is there a written document control plan that addresses topics such as procedural relevance, authorization process, annual reviews, and discontinuation of procedures?			
3.3a	Are the laboratory's SOPs reviewed for accuracy and relevance on an annual basis?			
3.3b	Does the laboratory have a system of documenting that all personnel are knowledgeable of the contents of the laboratory's SOPs?			

S No.	Organization and Personnel	Yes	No	Remarks
3.3c	Are the laboratory's SOPs available in the work area?			
3.3d	Are old versions (retired) of SOPs identified as retired and archived in the laboratory?			
3.4	Is there a list of assay turnaround times present?			
3.5	Does the laboratory have a policy for employees to communicate concerns, regarding testing quality or laboratory safety to management?			
IV	**Quality Control**			
4.1	Is there a written Quality Control program that clearly defines procedures for monitoring analytic performance, including establishment of tolerance limits, number and frequency of control tests, corrective action based on Quality Control data, and related information?			
4.2	Are logs present, documenting control results assayed with each test, as described in the specific assay procedure?			
4.2a	Does the technologist performing the QC initial the logs?			
4.3	Are appropriate charts utilized to document QC data (i.e. Levey Jennings charts)?			
4.3a	Has a supervisor/designee reviewed and signed Levey Jennings charts? (If "Yes", note the frequency)			
4.4	Has a supervisor/designee reviewed and signed all QC logs? (If "Yes", note the frequency			
4.4a	Are all QC documents available for the past two years?			
4.5	For quantitative tests, are control materials at more than one level used?			
4.6	For qualitative tests, is a positive and negative control included with each run?			
4.7	Quality Control Failure/Corrective Action			
4.7a	Is there a Corrective Action Log present, documenting resolution of QC failures?			
4.7b	Has a supervisor/designee reviewed and signed the Corrective Action Log? If "Yes", note the frequency			
4.8	QC Materials			
4.8a	Are all Quality Control materials dated within the manufacturer's assigned expiration dates?			
4.8b	Are all Quality Control materials properly stored, as required by the manufacturer?			
4.8c	If calibrators are used as controls, are they from a different lot number than those used to calibrate the method?			
V	**Reagent/Testing Kits**			
5.1	Are all reagents/testing kits within the manufacturer's assigned expiration dates?			
5.2	Are all reagents/testing kits properly stored, as described by the manufacturer?			

S No.	Organization and Personnel	Yes	No	Remarks
5.3	Are all reagents/solutions properly labeled, to indicate identity, lot number, storage requirement, date prepared/reconstituted, and expiration date?			
5.4	Is there an inventory control system in operation?			
5.5	Is there a system for forecasting needs for supplies and reagents?			
5.6	Is first expiry first out practiced?			
VI	**Records and Reports**			
6.1	Are copies of network lab-specific manuals, protocols, and appendices available?			
6.2	Specimen Tracking Forms/Requisitions Are forms readily available for at least two years?			
6.2a	Are the forms retrievable for the entire protocol?			
6.3	Is specimen chain of custody adequately documented?			
6.4	Is there a list of places laboratory results are reported?			
6.5	Where appropriate, are analytic results reported with accompanying reference intervals?			
6.6	Do the laboratory reports identify the laboratory performing the testing?			
6.7	Does the laboratory archive result data (result printouts, etc.)? If "Yes" how long data is archived.			
6.8	Are the archived records accessible to only authorized personnel?			
VII.	**Physical Facilities**			
7.1	Is there adequate, conveniently located space so the quality of work and safety of personnel are not compromised? (Is the client area and testing area distinctly separated?)			
7.2	Are the ventilation and humidity adequately controlled in all Areas?			
7.3	Are ambient room temperature readings taken and documented?			
7.3a	Have tolerance limits been established/documented for ambient room temperature?			
VIII.	**Specimen Transport and Management**			
8.1	Is a manual containing instructions for specimen collection in the laboratory and areas dedicated for specimen collection?			
8.2	Is there a documented policy/procedure for identifying and assessing the quality of specimens received in the laboratory?			
8.3	Specimen Transport			
8.3a	Is there a policy/procedure in place for transporting specimens (transported in a sturdy, non-breakable, closable container labeled "biohazard")?			
8.3b	Does the document address transport within the facility?			
8.3c	Does the document address transportation between off-site clinics and the laboratory?			

S No.	Organization and Personnel	Yes	No	Remarks
IX	**Personnel Safety**			
9.1	Safety-Related Incidents			
9.1a	Is there documentation of all safety-related incidents signed monthly by laboratory director or designee?			
9.1b	Has an evaluation of these incidents been incorporated into the laboratory's Quality Management program, to avoid recurrence?			
9.2	Are laboratory personnel offered appropriate immunization?			
9.3	Are post exposure prophylaxis policies and procedures posted and implemented after possible and known exposure?			
9.4	Material Safety Data Sheets (MSDS)			
9.4a	Are MSDS on file?			
9.4b	Are MSDS readily available to all laboratory personnel?			
9.5	Is there documented participation of laboratory personnel in a safety training program? If "Yes", list that provides the training and what is the frequency of the training?			
9.6	Safety Policies			
9.6a	Is a written Standard Precautions Policy available?			
9.6b	Is a written Chemical Hygiene/Hazardous Materials Plan available?			
9.6c	Is there a written policy for the handling and disposal of bio hazardous materials and regulated medical waste?			
9.6d	Are safety policies and procedures readily available to all staff?			
9.6e	Is there evidence of at least annual review of safety policies and procedures by the laboratory director/designee?			
9.7	Is safety equipment such as eyewashes, safety showers, fire extinguishers, fire blankets, and sharps containers present in the laboratory			
9.8	Personal Protective Equipment (PPE)			
9.8a	Is Personal Protective Equipment (gloves, gowns, masks, eye protectors, etc.) available to and utilized by laboratory staff?			
9.8b	Is Personal Protective Equipment maintained in a sanitary and reliable condition in all technical work areas, in which blood and body substances are handled, and in circumstances during which exposure is likely to occur?			
X	**Quality Assurance**			
10.1	Does the laboratory have a Quality Assurance/Quality Management program?			
10.2	Does the program follow a documented operational plan, designed to monitor, assess, and (when indicated) correct problems identified in pre-analytic, analytic, and post-analytic systems as well as general laboratory systems?			
10.3	Are key indicators of quality monitored and evaluated, to detect problems and opportunities for improvement?			
10.4	Are appropriate corrective action and/or preventive actions taken, when opportunities for improvement are identified?			

S No.	Organization and Personnel	Yes	No	Remarks
10.5	Are specimens maintained at appropriate conditions (e.g. temperature), until testing can be performed?			
10.6	Are reagents prepared, in accordance with the SOP?			
10.7	Are reagents maintained at appropriate conditions, until testing can be performed?			
10.8	Are tubes/plates labeled appropriately with sufficient identification, to prevent mix-up?			
10.9	Are appropriate conditions maintained to perform the assay			
10.10	Are reagents and specimens added in the appropriate order, and at appropriate times?			
10.11	Are appropriate controls (positive and negative) available and tested?			
10.12	Are specimens maintained under appropriate conditions until analysis?			
10.13	Are appropriate controls and, when applicable, calibrators available and tested?			
10.14	Are specimens analyzed, as defined by the SOP?			
10.15	Are results verified by alternate personnel? And are results reported as defined in the SOP?			
XI	**Documents**			
11.1	Is there a standard format for written procedures?			
11.2	Is there an approval system for written procedures?			
11.3	How are revised procedures handled?			
11.4	Does the quality assurance plan include documentation of problems and corrective action taken?			
11.5	Is there a written quality control plan for the laboratory that includes control material to be used and frequency of use?			
11.6	Are there guidelines for collection, labeling, preservation and handling?			
XII	**EQAS**			
12.1	Does the laboratory participate in proficiency programs for each of the analytes tested? Which programs? Frequency?			
12.2	How is the proficiency specimens handled?			
12.3	Who tests the proficiency specimens?			
12.4	Who reviews the proficiency results?			
12.5	What action is taken if results are not within guidelines given?			
XIII	**Personnel**			
13.1	Are all posts filled. If not which and why			
13.2	Are all personnel files/records maintained			
13.3	How are new personnel trained? Records?			
13.4	How are existing personnel trained on new equipment or procedures?			
13.5	Are there CE/refresher trainings for staff			

S No.	Organization and Personnel	Yes	No	Remarks
13.6	How is the technical competency of the laboratory staff monitored?			
13.7	Are department meetings held? Frequency? Who chairs? Records?			
XIV	**Specimen Management**			
14.1	What procedures are in place to prevent mislabeling or mishandling?			
14.2	Is there a unique identification for each patient specimen?			
14.3	Are there guidelines for acceptation and rejection of specimens?			
14.4	How is a rejected specimen handled?			
14.5	How are the specimens checked for correct labeling?			
14.6	How the specimens are stored pending testing?			
14.6a	Are specimens stored in a manner that assures specimen integrity prior to testing?			
14.7	What checks are used to make sure a test request is not missed? Ensure ordered test is performed			
14.8	Is there a policy for retaining tested specimens?			
14.9	How are specimens handled for long term storage?			

Summary of Assessment Findings: .....
.....

Noted Challenges: .....
.....

Noted Commendations: .....
.....

Recommendations: .....
.....

Action Plan with Responsible person/s and Time Frame:

1. .....
2. .....
3. .....

Name, Designation and Signature of Assessor: .....
.....

QSP on Personnel Management:

The following headings are suggested:

XYZ Laboratory Quality System Procedure (Level II document)	Document no.: LAB.5.1	Version no.:
Personnel Management -LAB.5.1	Effective date:	Page: 1 of _
Authority for issue :		

0 Introduction

0.1 Scope and purpose
0.2 Responsibilities
0.3 Background
0.4 References
0.5 Definitions
0.6 Related documents (supporting documents)

1.0 Procedure

1.1 Recruitment and Selection
1.2 Job Descriptions (Roles and Responsibilities)
1.3 Induction / Orientation of New Personnel to the Laboratory
1.4 Training
1.5 Assessment of Competence
1.6 Continuing education and professional development
1.7 Performance Evaluation/Review
1.8 Meetings and Communication
1.9 Ethics

2.0 Personnel records

3.0 Attachments/Annexures

4.0 Document and Change History

Example of an SOP "Writing an SOP"

Logo	Name of the Laboratory:	Version no.:
SOP no.:	Title: SOP WRITING	Page: 1 of 4
Effective Date:	Issuing authority:	

1.0 PURPOSE AND SCOPE

This Procedure details the method to be followed when developing, reviewing, approving, authorizing and issuing Standard Operating Procedures (SOPs) within the various sections of laboratory which is to operate in compliance with the Principles of Good Clinical Laboratory Practice (GCLP).

This Standard Operating Procedure (SOP) details the method to be followed when preparing, distributing, using, and reviewing, all XYZ Laboratory SOPs.

This sop is applicable to all XYZ laboratory specific operating procedures.

2.0 DIFINITIONS AND ABBREVIATIONS

(International Conference on Harmonization –Good Clinical Practice, ICH-GCP)
A Standard Operating Procedure is a detailed, written instruction to achieve uniformity of the performance of a specific routine function. These documents are issued to cover standard laboratory practice and also to cover routine procedures on given specific projects.

3.0 RESPONSIBILITY

3.1 It is the responsibility of the Author of the SOP to prepare a clear and concise procedure, which complies with the requirements of GCLP. The SOP should fully describe the roles and responsibilities of individuals, materials and methods to be used and a description of data recording and data retention requirements.

3.2 It is the responsibility of the laboratory staff to be aware of and adhere to the contents of applicable SOPs. It is the responsibility of XYZ Lab staff to bring the following to the attention of the Lab Director/Quality Manager:

3.2.1 Procedures for which a Standard Operating Procedure is required
3.2.2 Existing SOPs in need of revision
3.2.3 Any deviation from SOPs
3.2.4 Feedback regarding current SOPs.
3.3 The responsibilities of the Lab Director/Quality Manager include:
3.3.1 Ensuring that SOPs are prepared to cover the work, equipment and procedures of the Department

3.3.2 SOP's are regularly reviewed, updated when necessary and re-issued in a timely manner.

3.3.3 Distribution of hard copies of the SOPs to the laboratory staff performing the procedures and ensure that SOPs are immediately available in the areas where the activity covered by the SOP is performed.

3.3.4 Ensuring that SOPs are followed once issued.

3.3.5 Monitoring SOP deviation

3.3.6 Ensuring historical file of all SOPs is held in the Archive.

4.0 PROCEDURE

4.1 Format and Numbering

4.1.1 Each page of SOP should have a Header and footer as shown in this SOP

4.1.2 The version number will be written on the SOP header and commence at 1 for the original issue of an SOP and will increase by point one for each subsequent re-issue.

4.1.3 A unique identification number will be allocated to each new SOP. This will be alphanumeric and comprise of a combination of the QSE/Clause acronym and the SOP number.

4.1.4 The SOP number will be assigned by referring to the SOP index page. The same Number will be continued for SOPs that have been revised. New SOPs will be assigned the next number in the index sequence.

4.1.5 To facilitate the maintenance of the historical file of SOPs, a number must not be re-allocated to an SOP with a different title, even if the original SOP is withdrawn.

4.2 Content

4.2.1 The initial part of the SOP text will give an introduction, with any relevant background information and should include reference to the scope of the SOP.

4.2.2 Subsequent sections of the SOP will detail the definition (if applicable), and procedures.

4.2.3 Responsibilities of lab staff conducting the procedures will be identified by job function.

4.2.4 The SOP if necessary should include procedural checks or quality controls for the activity in question.

4.2.5 Procedures will be described in sufficient detail to ensure reproducibility of performance by any suitable trained member of staff, but should avoid being as specific as to become restrictive.

4.2.6 Once prepared, the draft SOP will be distributed for comments to the Lab -In-Charge and any others as appropriate.

4.3 Approval

4.3.1 When all valid comments have been incorporated, the SOP will become a final draft.

4.3.2 The individual responsible for preparation of the SOP will sign and date the footer of the final draft of a paper copy of the SOP and send it to the Lab-In Charge for review.

4.3.3 After reviewing the final draft of SOP, the Lab-In-Charge/Designee will approve the SOP and then the Director/ Designee will sign the footer.

4.3.4 The SOP will now be final.

4.4 Distribution of SOPs

4.4.1 All SOPs are confidential documents and authorization to distribute SOPs to external

parties must be obtained in written permission from the Lab Director.

4.4.2 SOPs will be distributed in different sections of laboratory.

4.4.3 SOP Document control log will be maintained (Appendix B).

4.4.4 The Master copy of SOP Control Log will be maintained by the Quality Manager.

4.4.5 The Control logs of the relevant SOPs of each department will also be maintained by the Quality Manager with a copy in each department

4.5 Access to SOP.

4.5.1 Lab -In-Charge, Q Manager and their staff will have access to lab SOPs in both paper and electronic format. So that SOPs are immediately available in the areas where the activity covered by the SOP is performed.

4.5.2 Lab staff should ensure that the version of the SOP they are using is the most up-to-date version before use.

4.6 SOP Training and Adherence

All staff members should read all the concerned SOPs and should be trained in using them. SOP training log (Appendix C) should be maintained for the same. All the staff members should strictly follow the SOPs while performing the concerned procedures.

4.7 Deviation to SOPs

4.7.1 Each staff member is responsible for promptly reporting to the Lab -In-Charge any areas where deviation from the SOPs is occurring or likely to occur.

4.7.2 If a situation is encountered that necessitates a (significant) deviation from an SOP, the details must be documented and reported to the Lab -In-Charge with a full explanation including the reason for the deviation, the action taken, and the outcome. After being reviewed this document will be retained in the archive.

4.8 Archive

4.8.1 The Master Copy of the SOP, the one with the original signatures, is the copy, which include a full and complete set of SOPs covering all aspects of work should be sent to the Archive. It is this copy, which is retained as the historical copy of all SOPs.

4.8.2 A historical file of all versions of SOPs must be archived in a secure facility. Historical archived SOPs must never be destroyed.

4.8.3 The QM will make sure that all the relevant copies of the archived SOPs will be removed from the respective departments before issuing an upgraded version of the SOP.

4.9 SOP Review

4.9.1 All existing SOP's will be reviewed annually in the month of _____. To determine the continued relevance of the stated procedures. This interval will be annually and any changes/additions required before the annual review will be implemented as amendments/addendum to the SOPs and will be documented in the SOP Amendment sheet (Appendix D)

4.9.2 Comments from applicable lab staff will be sought as appropriate during review. The outcome of an SOP review will result in one of three possible actions:

The SOP does not require any change.

The SOP requires changing and is to be re-issued.

The SOP is redundant and can be withdrawn.

4.9.3 Following the review if no change has taken place in the SOP then the annual review page (Appendix E) in the SOP will be signed by the Approver of the SOP and copies of the log distributed to the appropriate work areas.

4.9.4 If following the review it is decided to update an SOP, the appropriate changes which will include the amendments/addendums will be incorporated and the SOP re-issued following the same approval process as defined earlier. The SOP version number will be updated and increased by one point one to reflect the re-issue.

4.9.5 If following the review it is decided that the SOP is no longer required then it should be withdrawn from issue.

4.9.6 The Contents List for the SOP index will be updated to reflect this change.

5. PROCEDURE FOR AMENDMENT:

5.5.1 The amendment will be made by the authorized person (author of the SOP /Head of the department/designee).It will be made on the electronic copy of the amendment sheet. The authorized person will sign the sheet. Xerox copies will be distributed to the relevant work areas. The original copy will be retained with the original SOP with the QM.

5.5.2 If there are more than one amendment the version of the amendment sheet will increase by point one only.

5.5.3 Along with the amendment sheet a new page incorporating the changes should be added to the SOP. A line should be drawn across the original page and CANCELLED should be written on it.

5.5.4 The new page along with the amendment should be stapled on the cancelled page.

5.5.5 This amendments/addendum will be incorporated in the next version of SOP during the annual review.

5.5.5 Please ensure the documentation of the reading and understanding of the amendment sheet by resigning on the SOP Training log.

6 REFERENCES

ISO 15189:2012

NABL 112

7 APPENDICES AND FORMS

Appendix A: SOP Template

Appendix B: SOP Training Log

Appendix C: Annual Review of SOP

Appendix D: SOP Control Log

Appendix E: SOP Amendment sheet

8 VALIDITY STATEMENT

SOP TEMPLATE

Name and Logo of Health facility and laboratory		
SOP NO.:	TITLE	VERSION NO
	Effective Date:	Page: 1 of
Issuing authority:		

1.0 PURPOSE AND SCOPE of EXAMINATION
2.0 DEFINITIONS AND ABBREVIATIONS
3.0 RESPONSIBILITY
4.0 PROCEDURE
4.1 Principle and Method of the Procedure used for Examination
4.2 Patient Preparation
4.3 Primary Specimen Collection; Specimen Rejection Criteria
4.4 Type of Specimen; Container and Additives; Transportation; Stability and Temperature
4.5 Required Equipment; Name, location
4.6 Required Reagents
4.7 Environmental and Safety Controls
4.8 Calibration procedures (Metrological Traceability)
4.9 Quality Control procedures
4.10 Procedural Steps
4.11 Principle of procedure for calculating results including where relevant the UM of measured quantity values
4.12 Performance Characteristics
4.12.1 Accuracy
4.12.2 Precision
4.12.3 Analytical Measurement Range (AMR)
4.12.4 Clinical Reportable Range (CRR)
4.12.5 Sensitivity
4.12.6 Specificity
4.12.7 Interference
4.13 Result and Laboratory Clinical Interpretation
4.14 Limitations and Potential Sources of Variation
4.15 Biological Reference Intervals or Clinical decision values
5.0 REFERENCES
6.0 APPENDICES AND RECORDING FORMS
7.0 VALIDITY STATEMENT

SOP TRAINING LOG

Department: .....

SOP: .....

Date	Name	Signature

ANNUAL REVIEW

XYZ Laboratory

SOP #..... Name: .....

Prepared by	Date Adopted	Supersedes Procedure #

ANNUAL REVIEW

	Signature/title	Date
REVIEWED	_____	_____
REVIEWED	_____	_____
REVIEWED	_____	_____
REVIEWED	_____	_____
REVIEWED	_____	_____

DOCUMENT (SOP) CONTROL LOG

Lab SOP No.	Title	Current Version	Original Effective/ Date	Reviewed / Revision effective date	Issuing authority	No. of copies	Distributed to

SOP AMENDMENT SHEET

S. No.	Page No.	Date of Amendment	Amendment made	Reason	Signature of Author	Signature of Approver
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2						
3						
4						
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7						
8						
9						
10						

REFRIGERATORS AND FREEZERS

(Temperature Controlled Units TCU)

Refrigerators store reagents, kits and quality control materials to ensure shelf life and stability. Freezers store specimens collected for EQA purposes prior to transport to a reference laboratory. Quality control specimens may also be stored in a freezer. The following general advice may be helpful for maintenance:

- Refrigerator / Freezers must be placed so that sufficient air can pass the condenser (at the back of the refrigerator) for exchange of heat and also to facilitate cleaning of the condenser.
- The TCU must be connected directly to the electrical outlet. It must never be connected to an overloaded electrical outlet or one with voltage deficiencies. The use of electrical extensions must be avoided.
- Installing the unit under direct sunlight or near a heat source such as radiators or heaters is to be avoided. It must be remembered that the greater the difference in temperature between the environment and the condenser, the more efficient will be the heat transference.
- The door must seal perfectly to prevent warm outside air from entering the cool chamber.
- The inside and outside of the TCU must be periodically cleaned.
- Do not store food items or beverages in laboratory refrigerator or freezer

Refrigerator/Freezer Routine Maintenance
Frequency: Every quarter

Cleaning the interior: Verify that the refrigerator's inner shelves are clean. Before cleaning, any material which can interfere must be removed from the refrigerator. Move the empty shelves towards the front. Dampen a piece of cloth with a mild detergent and apply by rubbing surfaces gently. Dry and place in their original position. Avoid using steel wool or other abrasive materials for cleaning the shelves.

The door gasket verification: The door gasket is a component which must stay in a good condition for the unit to work correctly. To verify its condition, one must proceed according to the following steps: I). Open the door. Ii). Insert a strip of paper of about 5 cm in width between the door gasket and the edge of the refrigerator's body where the gasket is housed. 3. Close the door. 4. Pull the paper gently from the exterior. The paper must put up resistance when being moved outwards. If the paper can be moved without resistance, the gasket must be substituted. Perform this procedure on 10 cm of gasket at a time around the entire gasket housing.

A door gasket in bad condition produces various problems in the functioning of cooling units: (I). it allows humidity to enter which condenses and freezes inside the evaporator.(ii) it increases the time needed by the compressor for maintaining the selected temperature.(iii) it affects the

storage temperature (iv) it increases the operational costs. Frequency: Every six months

Cleaning the Condenser: The electrical feed cable must be is disconnected. Verify the position of the condenser. Remove the dust and grime deposited on the surface of the condenser. If the condenser is not clean, this will interfere with the heat transference process and the refrigerator could "heat" or function at temperatures different than selected.

Defrosting: Many modern freezers have automatic cycles for defrosting the evaporator in order to avoid frost accumulation. Some models do not have defrosting cycles and the process is done manually on a scheduled basis. Defrosting must be done through the night during which time the contents must be transferred to another refrigerator.

Incubators

- The incubator should have a fan to maintain uniform temperature.
- Incubators are used for bacterial culture by laboratories working in microbiology.
- The incubator must maintain a constant temperature of 37ºC± 1ºC.
- Temperature should be daily recorded in incubators.
- Like all laboratory instruments, incubators must be cleaned and disinfected routinely at short intervals (at least every fortnight) and after spilling of infectious material.
- The actual temperature must correspond to the thermometer control when te instrument is used.
- Calibration: use a pre-calibrated thermometer to ensure accuracy of temperature checks.

Temperature controlled equipment such as refrigerators, freezers, incubators etc. influence integrity of specimens and reagents and thus likelihood of consistently producing accurate results over time. Their temperature must be monitored by using temperature monitoring units (TMU) /Temperature measuring devices, including thermometers and electronic monitoring units. The TMU must be calibrated since any thermometer indicating a certain temperature, does not ensure correctness..

The comparison method is recommended for the in-house calibration of thermometers: A certified traceably calibrated reference thermometer and the thermometer/thermocouple to be calibrated are immersed in a suitable, stirred liquid bath (organic liquid – glycerin /ethanol, deionized/distilled water,), and the readings of the thermometers are compared. The choice of calibration temperatures should cover the range which is used in the temperature measurement. A minimum of four temperature readings are taken at specified intervals for each position (recommended time intervals are 30, 45, 60 and 75 minutes). The temperature should be monitored in various locations to include top, middle and bottom shelves. It is important to ensure that the sensing head of the thermometer to be calibrated and the actuating element of the reference thermometer are at the same temperature. A correction factor may be used to compensate for any difference between readings of both thermometers if applicable.

A label denoting, the serial number of thermometer, date of calibration and correction factor if necessary is placed around the top of the corresponding thermometer. The calibration interval of TMU is at a minimum every 6 months.

Daily function checks:

A one page form may be affixed to all temperature controlled equipment. The recording format must indicate the unique ID of the TCU and location, TMU and calibration date and correction factor if any, the time, day, month and year, the acceptable temperature range and the identity

of personnel performing the activity and supervising the activity. The temperature is monitored with calibrated recording devices with the doors shut. Each day and sometimes more than once per day, a staff member should check the temperature of the equipment and record the results in the form in the "current" column in the numbered row corresponding to the date. At the end of the month the form is replaced. The completed form is stored as a quality record

Criteria for acceptance: Temperature controlled equipment should operate between ranges of temperatures specified for equipment, specimens and reagents. Setting the limits and specifications of temperature for refrigerators and freezers involves understanding the necessary operating temperatures and maintaining them as a set of requirement for the operating ranges of the refrigerator or freezer.

Recommended temperature range for different equipment and materials:

Categories of stored material	Temperature Range
-70 °C freezer	
Frozen plasma PCR	Cooler than -65°C
Frozen lymphocytes for PCR	Cooler than -65°C
-20° C freezer	
Frozen plasma for panel	Cooler than -15°C
Lab specimens being stored	Cooler than -15°C
4° C Refrigerator (self-contained and walk in type)	
Lab specimens to be or being tested	2° to 8°C
Lab reagents and Test kits	2° to 8°C
Incubators	
Set point = 37°C	36° to 38°C
Set point = 40°C	39° to 41°C
Set point = 45° C	44° to 46°C

Centrifuge

A centrifuge is a laboratory machine driven by a motor which spins liquid specimens at high speed. It works on the sedimentation principle, where the centripetal acceleration is used to separate substances of greater and lesser density. It comprises of a rotor that holds the tubes and rotates during operation. The rotor contains two, four, six, or many more numbered wells within which the specimens may be placed. Separation activity is a function of both centrifugal force and timing. Proper balance, lubrication and rotor function are essential for proper centrifugation to occur.

The major aspects in maintenance of different types of centrifuges used in laboratory routine are as follows:

- The centrifuges must be positioned exactly horizontally to prevent the instrument moving away from its place when out of balance during centrifugation. Check if the rubber buffers are in the buckets.
- Avoid spilling liquids on control keys. The keys must be operated with the fingertips: The operator should avoid using fingernails, as this can result in the perforation of their protective membrane.
- It is critically important that the centrifuge load is balanced at all times. Therefore, buckets loaded in matched pans and tubes should be arranged so that balanced tubes oppose each other in the centrifuge head. This is necessary to maintain the same forces of gravity in the opposite positions of the tubes. This arrangement involves placing a “dummy”, i.e., a tube filled with the appropriate volume of water corresponding to the weight of the volume, in the oppositely positioned test tube, when an odd number of specimens must be centrifuged.
- Always operate with the lids closed – operating a centrifuge without the lid closed poses an unnecessary safety hazard.
- Keep lids on tubes when spinning – do not take the tops off the tubes before spinning. Doing so will cause splashing and creating of aerosols from potentially infectious material
- Turn the speed control slowly up and down.
- Do not open the lid until the rotor has come to a complete stop
- Check for vibration – There may be several reasons why a centrifuge vibrates.
- Check for corrosion and clean and repaint if necessary.

Centrifuge: Routine Maintenance

- When cleaning the centrifuge: Clean interior daily with soap and water, wipe with a disinfectant Wipe spills using 0.1% aqueous sodium hypochlorite solution
- After use, the buckets should be inverted to drain dry.
- After cleaning, run the centrifuge at varying rpms to check the braking mechanism and ensure a smooth gradual stop.
- When noticing unusual noises or vibrations: stop operation of the centrifuge Follow manufacturer’s recommendation on activation and release of brakes. Determine the cause

of the noise or vibration. Refer to the owner's manual for possible causes aside from improper balancing. Correct immediately to prevent severe damage to the centrifuge or injury to the worker.

- Inspect for evidence of wear, cracks in fitting, corrosion, uneven wear, or signs of fatigue by checking: Head, shaft head and coupling, Rotor, Brushes and bearings, Power supply, Motor and lubricant, Gaskets, seals, mounts and lubricants and replace if necessary.
- Brushes need to be inspected every 3-6 months and replaced according to manufacturer specifications.

Centrifuge Safety

Follow these safety rules when operating a centrifuge:

- Increase the speed slowly until optimal speed is reached
- Disconnect the centrifuge from the electrical source before preventive maintenance, cleaning or inspection
- Take caution when removing spills and broken specimen tubes after a run
- If tubes are broken, keep the door closed and allow to sit undisturbed for 30 minutes before attempting to clean
- Use tweezers to remove broken glass
- Simply turning the power off does not remove power to the centrifuge.

Calibration verification of rotational speed and time

Frequency: should be performed at a minimum annually.

Examine the exactitude of the time controls. Use a calibrated timer. The time measured must not vary by more than ± 10 % of the programmed time. Verify the actual rotation speed against the selected one using a normal load. The testing is done with a calibrated tachometer or a photo tachometer. If the hatch is not transparent, the procedure indicated by the manufacturer must be followed.

Pipettes

Types of Pipettes

(I) Precision pipettes (not disposable): They dispense precise and accurate volume. Always use disposable, single-use, pipette tip

(ii) Graduated plastic bulb pipettes (Disposable): They dispense approximate volume but are easy to use

Use and Care of Pipettes

- Select the appropriate pipette for the volume required
- Ensure that the pipette, tips, and specimen are at the same temperature. When pipetting hot or cold material, the tip's temperature should be equalized to that of the solution to prevent contraction or expansion of specimen.
- Firmly attach tip
- Hold the pipette vertically when aspirating (10 deg max from vertical)
- Use the same speed for both the intake and delivery of all specimens, and use smooth depression and release of the plunger knob. Never allow the plunger to snap back.
- Always depress the plunger knob to the proper stop before insertion of the tip into the solution try to insert the tip to approximately the same depth in the specimen each time, never going deeper than 3 mm.
- Place tip just below the specimen
- Avoid air bubbles
- After each use, the mechanical pipettes must be kept in an upright position and thoroughly cleaned at periodic intervals.
- Discard contaminated tips in appropriate sharps container after completion of task
- The practice of washing and reusing disposable tips is to be discouraged, as any cleaning procedure will change the "wettability" of the plastic. In addition, drying even to only slightly elevated temperatures may be distorting the tip. This will prevent a good pneumatic seal with the pipette body and change the volume of liquid to be pipetted.

Routine Maintenance of Pipettes:

Inspection:

Frequency: Daily

Pipettes require frequent inspection in order to detect abnormal wear and tear or damage and/or to verify that they are in good working condition. Inspection must cover the following aspects:

- Verify the integrity and adjustment of the mechanisms. These must move smoothly. The piston must move smoothly.
- Confirm that the tip holder is not displaying distortions or signs of being worn out, as it is essential for the exactitude of measurements. Verify the adjustment of the tips.

- Put on a tip and fill it with distilled water. The pipette must not show any leak.

Cleaning and decontamination

- Every day, verify that the pipette is clean. If dirt is detected, it must be cleaned using a suitable solvent or a mild detergent solution. Check the manufacturer's recommendation regarding the compatibility of the pipette with solvents to select the appropriate one. In the HIV laboratory use 0.1% sodium hypochlorite freshly prepared solution
- Sterilize the pipette according to the manufacturer's indications. Some pipettes can be sterilized in an autoclave using a cycle of 121 °C for approximately 20 minutes. Some will need to be disassembled for the vapor to come into contact with their internal components. Some manufacturers recommend sterilizing the pipette using a 60 % isopropanol solution and washing the components with distilled water, drying and assembling.
- If a pipette has been used with harmful substances, it is the responsibility of the user to ensure that it is completely decontaminated before it is used in other procedures or removed from the laboratory.

Servicing of pipettes by an external agency:

Frequency: six monthly

A pipette used daily must be submitted to the following procedures for guaranteeing its correct functioning:

- Disassemble the pipette. Follow the procedure described by the manufacturer in the user manual
- Clean the O rings, the plunger and the inside of the cylinder before lubricating. If the internal components were contaminated accidentally, all the surfaces should be cleaned with a mild detergent and then with distilled water. If the O rings or gaskets need to be changed, replacement parts with the same characteristics as the original should be used.
- Lubricate the plunger and piston with silicone grease especially developed for pipettes. Always use the lubricant recommended by the manufacturer. Remove any excessive lubricant with absorbent paper.
- Assemble following the reverse process to that of disassembly.
- Calibrate the pipette before use.

Single channel and multichannel pipettes

To adhere to quality control measure, mechanical pipettes must be calibrated to ensure accuracy and precision.

Accuracy relates to the closeness with which the dispensed volume approximates the volume set on the pipette (how close is the volume delivered to volume expected).

Precision demonstrates the reproducibly of repetitive measurement and is usually reported as the standard deviation and / or the coefficient of variation.

Reliability is a general term referring to the combined accuracy and precision. A pipette is highly

reliable if it is both accurate and precise.

Calibration of pipettes

Pipettes are precise and important basic instruments of the laboratory, and as such, need to be calibrated at least every 3-6 months.

Calibration using gravimetric method: The procedure is based on measuring the volume of a water specimen from the mass of water dispensed by the pipette and dividing that mass by the water density. In practice, a group of measurements is done, to which corrections are applied to compensate for any variation due to nonstandard temperature and atmospheric pressure and to any significant evaporation during test.

To calibrate a pipette using the gravimetric method, a high precision analytic balance and distilled water are needed. It is to be noted that, 1 ml of distilled water weights 1 g, but this measurement is dependent on temperature. Because the volume of a particular piece of glassware varies with temperature calibration procedures must be conducted at a particular temperature, between 20oC and 25oC.

The pipette must be adjusted (calibrated) so that the dial on the pipette that indicates the volume dispensed is in accordance with the weight of the fluid dispensed by the pipette. Using distilled water and setting the temperature between 20-25oC, aspirate a volume of water and after weighing it, adjust the volume delivered by the pipette (see manufacturer's instructions for internal adjustments) until the expected weight equals the volume delivered. This should be performed using a repeated series of reverse dispensing.

It is imperative that a perfectly calibrated balance is required to calibrate pipettes by the weighing method and that the balance must have strict and high confidence limits around the volume required.

The procedure explained is valid for air displacement pipettes. It includes the following steps:

1. Install a new tip on the pipette.
2. Pipette distilled water and empty into the waste container. Repeat at least 5 times in order to stabilize the humidity of the air inside the pipette.
3. Add water to the weighing receptacle until the level of liquid reaches at least 3 mm.
4. Register the temperature of the water, environmental pressure and relative humidity.
5. Cover the weighing receptacle, if this applies.
6. Register the weight shown on the balance or press tab so that the reading is zero
7. Fill the pipette with water from the storage container and dispense it into the weighing receptacle expelling all the water. This is done in the same way pipettes are used on a daily basis technique).
8. Register the new weight detected by the balance.
9. Repeat steps 7 and 8 nine (9) additional times, recording the weight registered by the balance at the end of each cycle.

10. Register the temperature of the liquid inside the weighing receptacle at the end of the tenth cycle and measure the time elapsed since the measurements started.
11. Evaluate if evaporation has been significant (this is critical when working with pipettes of very small volumes). If this is the case, an additional period of time [Ta] equal to the time used during the ten measurements must be allowed to elapse, and when completed, a new reading has to be carried out.
12. The mass of water lost by evaporation in the additional time [Ta] is divided by the total number of specimens analyzed (ten). This will give an indication of the average mass of liquid lost due to evaporation per cycle. This figure must be added to each of the mass readings.

Calculations - Proceed as follows:

1. Calculate the mass of water dispensed by the pipette in each cycle. Subtract the reading registered at the end of the previous cycle to the reading registered in the current cycle. Repeat for all measurements. If appropriate, add the average mass corresponding to the calculated evaporation per cycle.
2. Convert each mass value to a volume at 20 °C, dividing the mass by the density of water adjusted to the mentioned temperature.

$$V_i = \frac{M_i}{D}$$

3. Calculate the average of the volumes calculated instep 2. (The sum of volumes, divided by the number of specimens). Apply the adjustments per phenomenon such as the air pressure onto the mass (flotation). To accomplish this, multiply each mass by a correction factor [Z].

$$X = \sum \frac{V_i}{n} \times Z$$

4. Calculate the standard deviation of the specimen.

$$SD = \sqrt{\frac{1}{n-1}} \times \sum_{i=1}^{n} (X_i - X_{AV})^2$$

5. Calculate the coefficient of variation.

$$CV(\%) \frac{S}{X_{AV}} \times 100$$

6. A table containing a summary of the mathematical formulae mentioned is shown next.

Table of mathematical formulae

$X = \sum \frac{V_i}{n} \times Z$	$CV(\%) \frac{S}{X_{AV}} \times 100$
$SD = \sqrt{\frac{1}{n-1}} \times \sum_{i=1}^{n} (X_i - X_{AV})^2$	$D\% = \frac{X_{AV} - X_{Nom}}{X_{nom}}$
$E_s = X - V_n$	$V_i = \frac{M_i}{D}$
Conventions: X=average volume SD=standard deviation Z=adjustment factor in $(\mu l/mg)^2$	CV(%)=variation coefficient D(%)=error

Source: *WHO Maintenance Manual for Laboratory Equipment 2nd Edition*

For adjustable devices check volume delivered at several settings.

Acceptance criteria (%Accuracy =+/- 2%, 98%-102% and % CV=<2 %)

The acceptance or rejection processes include.

- To check the accuracy of the pipette, calculate the average from 10 readings of weighing and compare the average to the reference range provided by the manufacturer. For example for a 100-1000 ml pipette that has been calibrated at the 100 ml level, the average should fall within 100 ± 8.0 ml
- To check the precision of the pipette, calculate the standard deviation (SD) from the 10 readings and compare the SD to the reference SD provided by the manufacture. For example for a 100-1000 ml pipette that has been calibrated at the 100 ml level, the SD should be 3.0 or less.
- Verify calculated results are within limits

Range	Max/Min	Accuracy
10 µl	+ 1.0 µl	10%
100 µl	+ 10.0 µ l	10%
200 µl	+ 20.0 µ l	10 %

- Decontaminate pipette and scale after use.

- If the measurements are acceptable, the pipette should be identified as being appropriate for use this often is achieved by placing a confirmation sticker on the pipette displaying the valid calibration period. However, there also must be a written record of the date of calibration and the results for each pipette.
- If the pipette fails calibration (the accuracy and / or the precision are outside the permitted range) remove from service until appropriate adjustment can be made .The manufacturer must be consulted.

Electronic Balance

It is characterized as an instrument of high precision functions by comparing known weight masses with that of a substance of unknown weight. This type of balance generally has a capacity of up to 200 grams. Analytical balances can weigh ten thousandths of a gram (0.0001 g) or 100 thousandths of a gram (0.00001 g). In the metrological classification of electronic balances, only two parameters are of importance:
(i) the maximum load [Max.]
(ii) The value of the digital division [d]

It is necessary to have a set of certified masses. The set is generally composed of simple pieces of 1, 2, 5, 10, 20, and 50 g, 100, 200 and 500 g and fractional pieces of 2, 5, 10, 20 and 50 mg, 100, 200 and 500 mg.

An area free of vibrations is the best environment for a weigh balance (vibration has effect on balance for measurement 0.01 g or less, place the balance on a vibration free surface). The surface on which the balance is mounted should be level and balance feet should be adjusted, using the spirit-level device to show when the balance is level. Temperature fluctuations should not be large (ideally the ambient temperature should be stable to within ± 3°C. Temperature fluctuations can cause gradients in the balance mechanism). Air draughts from doors, windows, and passer-by should be minimized. Magnetic fields should be avoided as they may cause permanent changes in the response of the balance. Direct sunlight should be avoided.

Operating an electronic analytical balance

- Allow the balance to equilibrate with the environment where it is installed.
- Allow the balance to warm-up before initiating activities.
- Verify that the balance is calibrated.
- Make sure the balance is level
- Adjust the balance to zero (the pan should be clean and doors shut to avoid air currents)
- Tare the weighing container or weigh the empty container
- Place the specimen on the weighing pan and read the value for the measurement
- Remove the specimen; clean the balance and area around it.
- In general, the manufacturer or the specialized installation representative carries out the maintenance of the balances, according to procedures which vary depending on the type and model.

Routine maintenance

The balance is characterized as an instrument of high precision. For this reason, the operator is only responsible for minimal maintenance limited to the following:

Daily Activities

- Clean the weighing plate so that it is kept free of dust. Cleaning is done by using a piece of clean cloth which may be dampened with distilled water. If there is a stain, a mild detergent can be applied. A paintbrush with soft bristles can be used to remove particles or dust deposited on the weight plate.
- Clean the weighing chamber, externally and internally. Verify that the glass is free from dust.
- Verify that the adjustment mechanisms on the front door of the weighing chamber works adequately. Always use a clean, pre-weighed container for weighing (glass container or weighing paper if possible). Note that plastic can become electromagnetically charged and is not recommended for weighing powdered or granulated chemicals.
- Any spill must be cleaned immediately to avoid corrosion or contamination. Use 70% ethanol to disinfect the pan of the balance.
- Never lubricate a balance unless the manufacturer has expressly indicated it. Any substance interfering with the mechanism of the balance retards its response or definitely alters the measurement process.

The OIML (International Organization of Legal Metrology) has defined and classified the mass standards and test weights used in the calibration of weighing machines. The series of mass standards are identified in accuracy order (beginning from most accurate), with the letter codes E1, E2, F1, F2, M1, and M2.The verification procedure of a weighing instrument usually includes checking of the structure and proper functioning of the device as well as checking resolution, repeatability, loading curve, zero point and effects of angular loading. A one year verification period is recommended. Partial verifications, such as repeatability checks, and one-point checks, are recommended to be performed more frequently zero checks before each weighing. Any calibration process must be done using standard weights. The standard weights must be selected based on the balance's capacity.

Table of standard weights' use according to the balance's capacity

Capacity	Resolution							
	100 g	10 g	1 g	100 mg	10 mg	1 mg	0.1 mg	0.01 mg
Up to 200 g	-	-	-	M1	M1	F2	F1	F2

Annexure 4.5

Table of OIML reference weights classification

Class	Description	Tolerance	Uncertainty allowed	Frequency of recalibration
E1	Stainless steel weights without marks or adjusting cavity.	± 0.5 ppm per kg	± 1/3 of the tolerance	2 years
E2	Stainless steel weights without marks or adjusting cavity.	± 1.5 ppm per kg	± 1/3 of the tolerance	2 years
F1	Stainless steel weights with screw button for protecting the adjusting cavity	± 5 ppm per kg	± 1/5 of the tolerance	1 year
F2	Bronze plated weights.	± 15 ppm per kg	± 1/5 of the tolerance	1 year
M1	Bronze weights (that do not corrode or become stained) or of cast iron weights with a high quality paint finish	± 50 ppm per kg	± 1/5 of the tolerance	1 year
M2	Bronze or cast iron weights (commercial weights).	± 200 ppm per kg	± 1/5 of the tolerance	1 year

Source: *WHO Maintenance Manual for Laboratory Equipment 2nd Edition*

ELISA System

Photometer instruments such as ELISA readers require calibration to ensure accuracy and linearity of their readings. This is usually accomplished using special calibration plates, available from the manufacturer. The plates consist of different wells, each capable of producing a different O.D. reading. Observed readings are compared to theoretical values and evaluated using confidence limits. Likewise, automated diluters must be calibrated. This is usually accomplished by diluting a standard color solution and reading O.D. spectrophotometrically. Results must be within 10% of the expected limits. The manufacturer of any automated instrument can be contacted for details of these procedures. The annual maintenance contract should include the above mentioned check-ups and laboratory in charge should ensure the implementations.

Function checks

It is essential that laboratory personnel know and document that all equipment is in good condition each day of use. This can be accomplished by undertaking function checks, often referred to as calibration and validation.

Calibration: that process which is applied quantitative measuring or metering of equipment to assure its accurate operation throughout its measuring limits.

Validation: the steps taken to confirm and record the proper operation of equipment at a given point of time in the range in which tests are performed.

ELISA Reader

Regular maintenance of the ELISA machine should be carried out according to the manufacturer's instructions and may vary between brands. The machine itself should not be opened. The filters must be protected from moisture and fungal growth. Keep silica gel packet in the filter box.

Plate washer

Plate washers are critical in ELISA assay performance. The washer works on a simple principle and comprises of wash fluid, waste fluid reservoirs, pressure and vacuum pumps, a dispense manifold and a plate carrier.

The wash fluid is pressurized and a valve opens and allows the fluid through a manifold and into assay micro wells. The waste fluid under vacuum is aspirated back through the manifold to the waste container. A number of cycles of dispense and aspiration comprises the washing of a plate. At the end of the wash procedure the wells are empty of the fluid.

After use care

- Fill the rinse bottle with about 500 ml of distilled water
- Dispose of the unused wash buffer. Rinse with distilled water, a couple of times and leave about 500ml in the wash bottle. Fix the cap tightly.
- After using the washer switch off power.

Microliter plate reader

Maintenance: The routine maintenance that is required for a microliter plate reader is detailed in the operating manuals that are provided by the manufacturer. In general, maintenance should include cleaning of the optical system and the plate carrier system and monitoring lamps, fuses and paper printer rolls, lubrication of moving parts may be indicated. It is always a good idea to have extra excitation light bulbs, printer, paper etc. for when they are needed. Each reader's operational manual should be reviewed and the instruction followed to keep the instrument maintained properly.

Verification: Between calibrations, the reader can be verified that it is working appropriately by testing a verification plate that can be purchased from appropriate suppliers. These plates are used to verify the correct performance of microliter plate readers with respect to their measurements. Generally, verification plates are composed of neutral density filters with nominal absorbance's that can be used to calibrate the reader at a number of wavelengths. Verification plates should be traceable to international reference material and require recalibration at least every 24 month by an accredited calibrations laboratory, sometimes, these verifications plates may be supplied with the reader, but more often must be purchased or provided by the manufacturer or servicing organization.

Calibration: Microliter plate readers should be calibrated annually to check

1) Alignment
2) Accuracy
3) Precision
4) Turnaround
5) Linearity

Common Supplies in a HIV Testing Laboratory

PPE

- Gloves
  - Latex gloves
  - Heavy duty gloves
  - Plastic gloves
  - Cryo gloves
- Disposable Masks
- Laboratory Coats
- Disposable Aprons
- Covered footwear
- Safety goggles

Consumables

- Micropipette tips
- Evacuated blood collection tube (eg. BD Vacutainer).
- Evacuated blood collection tube needles
- Pronto holder
- Storage vials
- Vial box
- Filter paper
- Color coded waste disposal bags
- Color coded waste disposal containers
- Sharps container
- Absorbent cotton
- Tourniquet

Equipment

- Needle destroyer
- Centrifuge
- Micropipettes
- Incubator
- ELISA Washer
- ELISA Reader
- Refrigerator
- Deep freezer
- Safety related equipment
- Eye wash station/bottle

- Spill kits
- First Aid kit
- PEP
- Fire Extinguisher

Reagents

- Sodium hypochlorite
- Distilled Water
- Spirit
- Alcohol Hand Rub
- Phenolic disinfectants

Stock register for ICTC

Name of the Tests/ Consumable: .....

Date	Opening stock	Number of tests received this month	Batch/Lot number	Expiry date	Number of test performed	Number of controls	Wastage (if any)	Closing stock	Number requested	Date of placing request	Signature

Annexure:5.3

Receiving Inspection Checklist

Consignment: .....
Receipt Inspection Performed By: .....
Receipt Inspection Date: ..... Invoice Number: .....
Consignment Arrival Date: .....

Attach a copy of the invoice and order request with checklist.

	Yes	No
The correct items were received		
No items are missing		
Quantity of items received matches quantity indicated on invoice		
Quantity of items received matches quantity requested by laboratory		
Manufacturer's expiry date is acceptable		
Items transported at the correct shipping temperature		
Cold packs are cold (refrigerated items) or frozen or partially thawed (frozen items).		
Seal of the consignment is intact		
Items are not crushed, broken or leaking		
Any broken/ leaking item has been handled safely and disposed of properly		
Inventory records are updated		
Expiry Date written in bold on consignment (where applicable) A copy of the invoice and order request is retained in the laboratory		
Shipment is unpacked and properly integrated with existing inventory		

- The order is complete and acceptable ☐ Y ☐ N
- If Not accepted, fill in the following:

Reason for Non acceptance	Tick appropriately
Wrong Item	
Wrong Quantity	
Item Not Requested by Laboratory	
Damaged Item	
Close to Expiry date	
Temperature of receipt not acceptable	

Formula for dilution of Stock solution of Sodium Hypochlorite to working concentration of Sodium Hypochlorite

$$\text{Amount of stock Required} = \frac{\text{Working Conc. Required}}{\text{Stock Conc.}} \times \text{Working solution Volume Required}$$

Water Required = Working solution Volume Required – Amount Stock Required

Preparation of different concentration of Sodium Hypochlorite Solution.

Required Strength (Available solution of chlorine)	Stock/commercially available Sodium Hypochlorite		
	4 %(40g/L); dilute	5 %(50g/L); dilute	6%(60g/L); dilute
0.1%(1 g/L)	1:39*	1:49	1:59
0.5%(5 g/L)	1:7	1:9	1:11
1%(10 g/L)	1:3	1:4	1:5

**parts of stock solution: parts of water*

0.1% Working Solution from **4%** Stock Solution of **Sodium Hypochlorite**

Required Volume of Working Solution(ml)	Quantity of Sodium Hypochlorite (ml)	Quantity of Water
250 ml	6.25 ml	243.75 ml
500 ml	12.5 ml	487.5 ml
1000 ml	25 ml	975 ml
2000 ml	50 ml	1950 ml

0.5% Working Solution from **4%** Stock Solution of **Sodium Hypochlorite**

Required Volume of Working Solution(ml)	Quantity of Sodium Hypochlorite (ml)	Quantity of Water
250 ml	31.25 ml	218.75
500 ml	62.5 ml	437.5 ml
1000 ml	125 ml	875 ml
2000 ml	250 ml	1750 ml

Annexure 7.1

1% Working Solution from **4%** Stock Solution of **Sodium Hypochlorite**

Required Volume of Working Solution(ml)	Quantity of Sodium Hypochlorite (ml)	Quantity of Water
250 ml	62.5 ml	187.5 ml
500 ml	125 ml	375 ml
1000 ml	250 ml	750 ml
2000 ml	500 ml	1500 ml

NOTE: Kindly see the concentration of commercially available Stock solution before Dilution

0.1% Working Solution from **5%** Stock Solution of **Sodium Hypochlorite**

Required Volume of Working Solution(ml)	Quantity of Sodium Hypochlorite (ml)	Quantity of Water
250 ml	5 ml	245 ml
500 ml	10 ml	490 ml
1000 ml	20 ml	980 ml
2000 ml	40 ml	1960 ml

0.5% Working Solution from **5%** Stock Solution of **Sodium Hypochlorite**

Required Volume of Working Solution(ml)	Quantity of Sodium Hypochlorite (ml)	Quantity of Water
250 ml	25 ml	225 ml
500 ml	50 ml	450 ml
1000 ml	100 ml	900 ml
2000 ml	200 ml	1800 ml

1% Working Solution from **5%** Stock Solution of **Sodium Hypochlorite**

Required Volume of Working Solution(ml)	Quantity of Sodium Hypochlorite (ml)	Quantity of Water
250 ml	50 ml	200 ml
500 ml	100 ml	400 ml
1000 ml	200 ml	800 ml
2000 ml	400 ml	1600 ml

NOTE: Kindly see the concentration of commercially available Stock solution before Dilution

0.1% Working Solution from **6%** Stock Solution of **Sodium Hypochlorite**

Required Volume of Working Solution(ml)	Quantity of Sodium Hypochlorite (ml)	Quantity of Water
250 ml	4.2 ml	245.8 ml
500 ml	8.3 ml	491.7
1000 ml	16.7 ml	983.3
2000 ml	33.3 ml	1966.7 ml

0.5% Working Solution from **6%** Stock Solution of **Sodium Hypochlorite**

Required Volume of Working Solution(ml)	Quantity of Sodium Hypochlorite (ml)	Quantity of Water
250 ml	20.8 ml	229.2 ml
500 ml	41.7 ml	458.3 ml
1000 ml	83.3 ml	916.7 ml
2000 ml	166.7 ml	1833.3 ml

1% Working Solution from **6%** Stock Solution of **Sodium Hypochlorite**

Required Volume of Working Solution(ml)	Quantity of Sodium Hypochlorite (ml)	Quantity of Water
250 ml	41.7 ml	208.3 ml
500 ml	83.3 ml	416.7 ml
1000 ml	166.7 ml	833.3 ml
2000 ml	333.3 ml	1666.7 ml

NOTE: Kindly see the concentration of commercially available Stock solution before Dilution

Annexure 7.2

Specimen Laboratory Safety Audit

Laboratory Safety Audit

Date: .....

Instructions: .....

.....

Indicate Y (Yes), N (No), or N/A (not applicable)

I General (Indicate Y (Yes), N (No), or N/A (not applicable))

1. Design of the lab and workflow patterns minimise the chance of accidents.
2. Lab has adequate space, counters, shelves and storage to prevent accidents.
3. Lab is properly ventilate and lit up
4. Staff does not eat, drink, smoke or apply make up in the laboratory.
5. Storage of foods or drinks in lab refrigerators/freezers prohibited, signage provided on each, inspected periodically for compliance
6. Biosafety hoods if needed available
7. Are biological safety cabinets certified annually?
8. Has a designated Safety Officer been appointed to oversee laboratory safety issues?
9. Safety manual with a safety and health policy available reviewed and signed by all lab staff.
10. Do employees receive safety training at the time of hire and annually thereafter?
11. Annual review of staff for compliance with all safety regulations, updated written information received and records of same
12. Periodic inspections conducted to ensure compliance with all safety recommendations (including fire drills) and findings discussed with all employees
13. Is there a current listing posted of emergency contacts with phone numbers?
14. Are blood-borne pathogen and chemical spill kits maintained in accessible locations?
15. Are first Aid kits located in accessible locations
16. Is there signage indicating the location of these first aid and spill kits?
17. Safety equipment checked periodically and maintained in good working condition and records kept
18. Adequate safety information displayed in the laboratory
19. Are noise levels below 75 decibels?
20. Do employees understand what to do if they sustain an exposure to blood and body fluids?
21. Is annual safety training provided to all employees and attendance documented?
22. Have all employees been offered hepatitis B vaccine and has this information been documented?
23. Are biological and chemical fume hoods certified annually?
24. When hoods are in use, are supplies and equipment kept at least four inches away from the hood face?
25. Adequate PEP signage and PEP available round the clock (immediate consultation and treatment)

26. Transport of specimens in compliance with safety regulations

II HOUSEKEEPING (Indicate Y (Yes), N (No), or N/A (not applicable))

1. Designated "clean" and "dirty" areas in the laboratory
2. Individuals trained in good cleaning practices in all work areas
3. Are all work areas, benches, floors, shelves and storage areas maintained in a neat and orderly manner? (free of clutter)
4. Are all work surfaces decontaminated with an appropriate disinfectant at the end of each work shift and when grossly contaminated with blood and body fluids?
5. Sinks, faucets, handles, telephones and other clean areas are cleaned daily
6. Is broken glass picked up by tongs or forceps and disposed of in an appropriate container?
7. Do spill clean-up procedures include soaking up the spill with absorbent material such as paper towels, decontaminating the area with an appropriate disinfectant, and disposing of the contaminated materials appropriately?
8. Are heavy objects stored on lower shelving?
9. Are aisles free of trash and other debris?
10. Are biohazard receptacles for blood or other potential infectious materials separate from regular trash?
11. Are these containers in good condition?
12. Is trash removed at least daily?
13. Are main access hall corridors at least 48 inches wide?
14. Are floors wet mopped daily?
15. Are floors cleaned and wax stripped regularly to prevent paraffin build-up?
16. Are certain computers and telephones designated as clean/dirty?
17. Have you looked in each and every cabinet for unlabelled containers and labelled them correctly?
18. Are loads in centrifuges balanced?
19. Are tops of centrifuges locked down when in use?
20. Is chipped or cracked glassware disposed of in a rigid container?
21. Is the refrigerator for food clean and defrosted?
22. Is the microwave oven clean?
23. Are workstations disinfected with an appropriate disinfectant at the end of each shift?

III PERSONAL PROTECTIVE EQUIPMENT (Indicate Y (Yes), N (No), or N/A (not applicable))

1. Has a personal protective equipment assessment been completed and documented?
2. Staff trained on correct use and removal of PPE
3. Staff always use PPE and safety equipment provided
4. Do employees wear safety glasses with side shields (or goggles) in case of splash hazards?
5. Do employees wear nonslip type shoes , Do shoes cover the entire foot
6. Do employees wear lab coats or cover gowns with long sleeves, knitted cuffs, and closed in the front while in the work area?

7. If these coats/gowns are reusable, are they laundered by a hospital or outside laundry service?
8. Do employees remove their lab coats/gowns when leaving the laboratory environment?
9. Do employees wear appropriate gloves when performing laboratory testing or phlebotomy?
10. Are gloves available in appropriate sizes for all workers at risk for exposure?
11. Are gloves removed when leaving the laboratory environment?

IV DOCUMENTATION (Indicate Y (Yes), N (No), or N/A (not applicable))

1. Do you have copies of the Safety Manual
2. Are safety training records on all employees kept five years?
3. Are medical records on all employees kept for the duration of employment
4. Records of accidents/incidents , their evaluation and CAPA

V BLOOD-BORNE PATHOGENS (Indicate Y (Yes), N (No), or N/A (not applicable))

1. Is the blood-borne pathogen written program available, current, and has it been reviewed within the last year?
2. Are employees trained and understand what Standard Precautions and follow them (formerly Universal Precautions/Body Substance Isolation) means?
3. Are lab coats and gloves removed before leaving the work area?
4. Are hands washed before leaving the work area?
5. Are sharps containers available and used?
6. Are sharps containers disposed of when three-fourths full?
7. Is mouth pipetting prohibited?
8. Do employees store food in a refrigerator specifically for food and not for specimens?
9. Is this refrigerator labelled “For Food Only?”
10. Do employees refrain from eating, drinking, smoking, applying cosmetics and lip balm, or manipulating contact lenses in the work area?
11. Have employees responsible for shipping diagnostic and infectious specimens been trained in accordance with the IATA regulations?
12. Hazardous material always carried in appropriate safety carriers

INFECTIOUS MATERIALS (Indicate Y (Yes), N (No), or N/A (not applicable))

1. Are specimens received in a safe condition?
2. Are records kept of incoming materials?
3. Are specimens unpacked in biological safety cabinets with care and attention to possible breakage and leakage? breakage and leakage?
4. Are gloves and other protective clothing worn for unpacking specimens?
5. Are personnel trained to ship infectious substances according to current national and/or international regulations?
6. Are work benches kept clean and tidy?
7. Are discarded infectious materials removed daily or more often and disposed of safely?

8. Are all members of the staff aware of procedures for dealing with breakage and spillage of cultures and infectious materials?
9. Is the performance of sterilizers checked by the appropriate chemical, physical and biological indicators?
10. Is there a procedure for decontaminating centrifuges regularly?
11. Are sealed buckets provided for centrifuges?
12. Are appropriate disinfectants being used? Are they used correctly?

VI CHEMICAL HYGIENE (Indicate Y (Yes), N (No), or N/A (not applicable))

1. Is the Chemical Hygiene Plan available, current, and reviewed within the last year?
2. Do employees know where the Material Safety Data Sheets (MSDS) are located?
3. Do employees know how to use the MSDS to look up spills and first aid for a chemical they use?
4. Are old MSDS archived for 5 years
5. Has the chemical inventory been performed and updated in the last 12 months?
6. Is there a list of carcinogens, mutagens, and teratogens?
7. Has the chemical risk assessment been updated in the last year?
8. Are all manufactured chemical containers labelled with the appropriate chemical identity and hazard warning information?
9. Do transfer containers of chemicals properly labelled with an HMIS label or plain label with the name of the chemical, concentration, route of entry, health hazard, physical hazard, target organs affected, lab name, lot number, and expiration date?
10. Are incompatible chemicals effectively separated when stored or handled? (E.g. acids and bases stored separately; fuels and oxidisers stored separately. Reference MSDS)
11. Are flammable or toxic chemicals kept in closed containers when not in use?
12. Are chemicals stored away from heat, sunlight, or reactive substances?
13. Are chemicals not currently being used placed in the appropriate storage cabinet?
14. Are working supplies of chemicals limited to one gallon per 100 square feet?
15. Are Class I flammable liquids that are refrigerated stored in devices listed as approved for Class I storage?
16. Are peroxide formers used only in approved laboratory hoods?
17. Do employees understand how to properly store chemicals?
18. Is environmental monitoring performed and documented where appropriate?
19. Are chemical spill kits/materials maintained and available for use?
20. Are chemical spill kits identified by proper signage?
21. Have employees been trained in spill clean-up procedures including mercury and formaldehyde, if applicable?

Laboratory equipment (Indicate Y (Yes), N (No), or N/A (not applicable))

1. Is all equipment certified safe for use?
2. Are procedures available for decontaminating equipment regularly and prior to

maintenance?
3. Are biological safety cabinets and fume cupboards regularly tested and serviced?
4. Are autoclaves and other pressure vessels regularly inspected?
5. Are centrifuge buckets and rotors regularly inspected?
6. Are HEPA filters regularly changed?
7. Are pipettes used instead of hypodermic needles?
8. Is cracked and chipped glassware always discarded and not reused?
9. Are there safe receptacles for broken glass?
10. Are plastics used instead of glass where feasible?
11. Are sharps disposal containers available and being used?

VII COMPRESSED GAS (Indicate Y (Yes), N (No), or N/A (not applicable))

1. All electrical equipment checked for proper operation by appropriate person
2. Are all compressed gas cylinders chained to the wall or otherwise secured in a nontip base?
3. Are empty gas cylinders marked with the word "EMPTY?"
4. Are cylinders transported via hand truck or other stabilizing device?
5. Are cylinders legibly marked to clearly identify the gas in the cylinders?
6. Are cylinders equipped with a pressure regulator designed and marked for its maximum pressure?
7. Is the regulator system equipped with two gauges to show both the cylinder pressure and the outlet pressure?
8. Do cylinders have a manual shutoff valve?
9. Are valve protectors placed on cylinders when they are not in use or connected for use?
10. Is smoking prohibited near oxygen storage areas?

VIII ELECTRICAL (Indicate Y (Yes), N (No), or N/A (not applicable))

1. All electrical equipment checked for proper operation by an appropriate person
2. Is electrical equipment grounded with the use of three pronged plugs?
3. Electrical outlets and connections meet requirements and have been inspected annually for proper operation.
4. Are electrical cords free of any frayed edges?
5. Are extension cords prohibited from use?
6. Are multi-plug adapters prohibited?
7. Are receptacles properly wired?
8. Are electrical outlets located near wet locations, such as sinks, protected by a ground-fault circuit interrupter (GFCI)?
9. Are heat sources and liquid chemicals kept away from outlets, cords, and equipment as much as possible?
10. Are light fixtures in working order?
11. Have employees been trained in how to handle shock injuries?

12. Are electrical panels kept cleared within three feet in front of breaker panels?
13. Are electrical circuit breakers and panels labelled with a current listing of equipment powered by each unit?

IX EYEWASH/SHOWER (Indicate Y (Yes), N (No), or N/A (not applicable))

1. Are eyewash stations located within 100 feet of where hazardous chemicals are used?
2. Is there a sign indicating the location of the eyewash above the station?
3. Are the protective caps in place on the eyewash?
4. Is the eyewash in good working condition?
5. Are the eyewash stations checked weekly and the eye covers disinfected with 1% NaOCl?
6. Are eyewash preventive maintenance and routine checks documented?
7. Is there a sign indicating the location of the safety shower above the station?
8. Are the safety showers checked monthly?
9. Are floor drains near showers flushed monthly?
10. Are all safety checks to showers documented?

X FIRE (Indicate Y (Yes), N (No), or N/A (not applicable))

1. There is an emergency exit for fire (extra door/window)
2. Is there a fire alarm pull station located near the laboratory?
3. Can the fire alarm be heard from inside the laboratory?
4. Do fire exits have an exit sign that is illuminated by a reliable light source?
5. Are stairwells and emergency exits accessible and free of obstructions?
6. Do all employees know where the fire extinguishers are located?
7. Are all fire extinguishers easily accessible and not blocked?
8. Have all employees received fire extinguisher training including the opportunity to actually use the extinguisher in a real or simulated practice?
9. Do employees understand what type of extinguisher is needed (A, B, or C) for each class of fire?
10. Have fire extinguishers been serviced within the past year?
11. Do employees know what the acronyms RACE and PASS stand for?
12. Have quarterly fire drills been completed and documented?
13. Has each employee performed at least one full evacuation to the triage area annually?
14. Are evacuation routes posted in visible locations?
15. Does staffs know how to respond to a fire drill and what evacuation route to use?
16. Do staff know the procedure for the evacuation of disabled employees?

XI RADIATION (if applicable)

1. What type of radiation safety license does the laboratory have?
2. Who maintains the radiation badge records?
3. Has everyone involved with radiation testing been successfully trained annually on radiation safety

Xii WASTE MANAGEMENT (Indicate Y (Yes), N (No), or N/A (not applicable))

1. Is all waste disposed of properly according to national, state and local authorities?
2. Is there a waste management plan?
3. Staff trained in proper waste disposal practices.
4. PPE and immunisation of staff who handle and transport waste
5. Are there documented cradle-to-grave protocols in place where appropriate?
6. Have employees been trained to waste segregation and as to what can be discharged down the sewer?
7. Does the facility have a discharge permit or letter of acknowledgment from the wastewater treatment facility?
8. Is the laboratory discharge to the sewer routinely monitored?
9. Is waste stored less than 1 day?
10. Are incompatible wastes and/or materials separated or protected by physical means such as a wall or a cabinet?
11. Are floor drains covered to prevent a spill from entering a drain?
12. Have employees responsible for shipping hazardous waste been trained in accordance with the Department of Transportation (DOT) regulations?
13. Are waste management records (manifests, waste analysis results, inspection records, training records) retained on-site for at least five years?
14. Is there a recycling program in place that includes paper, plastic, glass, cans, alcohol, formaldehyde, solvents, etc.?

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Development of this publication was supported by cooperative agreement 5U2GPS-002030 with the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily reflect the official views of the Department of Health and Human Services and Centers for Disease Control and Prevention.

National Guidelines on Quality Management Systems In HIV Testing Laboratories

December 2015

National AIDS Control Organisaiton
Ministry of Health & Family Welfare, Government of India