NIAID HIV and Other Infectious Diseases Clinical Research Support Services (CRSS)
Contract No. HHSN272201700078C

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NIAID/DAIDS CRSS Team
PPD

Laboratory Audit Visit of

Harmonized ID (HID)	Laboratory Name - Address

Conducted by PPD

Audit Type: Central

Audit Date(s):

Final Report Issued:

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Central Laboratory Report

Laboratory Report Summary

Laboratory Name/Location	
Visit Date(s)	
Audit Requestor	
Laboratory Auditor	
Principal Investigator	
Laboratory Management	
Quality Assurance Unit Manager	
Safety Officer	
Date(s) Last Audited	
Biosafety Level of Laboratory	
Protocol(s) Supported by DAIDS	
DAIDS Network/Non-Network Affiliation(s)	

Comments:

Laboratory Activities

Describe all laboratory testing activities below.

Comments:

Does the laboratory utilize any non-FDA-approved or modified FDA-approved methods? (If "Yes," list the assays.)	Yes ☐ No ☐ Comments ☐

Comments:

I. External Quality Assurance (EQA)

1. Does the laboratory participate in any external proficiency programs for DAIDS-supported protocol-related assays? (If "Yes," list all EQA providers. If "No," list the analytes not covered.)	Yes ☐ No ☐ Comments ☐

2.	Does the laboratory have a written policy to address the following aspects of EQA: specimen handling and analysis, results review, and troubleshooting for unsatisfactory performance?	Yes ☐ No ☐ Comments ☐
3.	Is EQA documentation present and organized (e.g., Investigation Reports, SMILE Review, survey provider result and report, raw result data, attestation page, or other indication of who performed the processing and/or testing)?	Yes ☐ No ☐ Comments ☐
4.	Are EQA specimens tested in the same manner as participant specimens?	Yes ☐ No ☐ Comments ☐
5.	Is there documented review by laboratory management of all EQA results?	Yes ☐ No ☐ Comments ☐
6.	Is EQA specimen testing rotated among personnel who routinely test participant samples?	Yes ☐ No ☐ Comments ☐

Comments

II. Organization and Personnel

A.	**Is an organizational chart inclusive of all laboratory personnel involved with DAIDS-supported protocol-related activities present?**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Is there a policy/process for determining authorized designees? (If "Yes," please describe.)**	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Personnel Records**	
1.	Are personnel records kept? (If "Yes," describe how these records are organized and securely stored.)	Yes ☐ No ☐ Comments ☐
2.	Is a job description/delegation of duties documentation present for all laboratory personnel involved with protocol-related activities?	Yes ☐ No ☐ Comments ☐
3.	For each laboratory position involved with protocol-related activities, is there a documented profile that lists requirements such as education, experience, and certification/license requirements?	Yes ☐ No ☐ Comments ☐
4.	Are education records maintained for all laboratory personnel, including the Principal Investigator, involved with protocol-related activities?	Yes ☐ No ☐ Comments ☐
5.	Are assay-specific training records available for all laboratory personnel involved with testing activities?	Yes ☐ No ☐ Comments ☐

6.	Have all personnel involved in processing and/or testing of DAIDS-supported protocol specimens completed DAIDS Good Clinical Laboratory Practice training? (If "No," indicate the total number of trained vs untrained personnel).	Yes ☐ No ☐ Comments ☐
7.	Is documentation maintained, indicating the laboratory has assessed the competency of each employee to perform his/her assigned duties in accordance to the requirements for waived and non-waived testing? (If "Yes," report the methods utilized to assess competency [including color blindness and/or color vision deficiency testing where applicable] and the frequency of evaluation.)	Yes ☐ No ☐ Comments ☐
8.	Are personnel identification lists (signature/initial/code) present to verify responsible personnel?	Yes ☐ No ☐ Comments ☐
9.	Has the laboratory defined and established a process for auditing personnel records?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Has the laboratory been certified by any regulatory/accrediting agency? (If "Yes," list the agency and date[s] of certification.)**	Yes ☐ No ☐ Comments ☐

Regulatory/Accrediting Agency	Date(s) of Certification

E.	**Does the laboratory have a policy that prohibits retaliation against personnel who communicate study integrity, testing quality, and/or safety concerns to laboratory management?**	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Did the laboratory change location since the last audit visit?**	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Have any new laboratory employees been hired since the last audit? (If "Yes," document the changes in personnel and management positions.)**	Yes ☐ No ☐ Comments ☐

Comments:

III. Testing Facility Operation

A.	**Is there a list of all DAIDS-supported testing activities performed in the laboratory?**	Yes ☐ No ☐ Comments ☐

Comments:

B. Are turnaround times (TATs) present for all DAIDS-supported assays?	Yes ☐ No ☐ Comments ☐

Comments:

C. Is a master list of currently used SOPs maintained by the laboratory?	Yes ☐ No ☐ Comments ☐

Comments:

D. Standard Operating Procedures (List at least one example from each laboratory category)

Written Procedure Name	Review completed by laboratory management within two-year interval?	Laboratory management signature present?
1.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
2.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
3.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
4.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
5.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
6.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
7.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
8.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
9.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
10.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐

Comments:

E. Is there a written document control plan that addresses topics such as procedural relevance, authorization process, reviews, revisions and discontinuation of procedures?	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Are laboratory SOPs reviewed for accuracy and relevance within two-year intervals?**	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Does the laboratory have a system of documenting that all personnel are knowledgeable of the contents of the laboratory's SOPs?**	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Are the laboratory SOPs available in the work area?**	Yes ☐ No ☐ Comments ☐

Comments:

I.	**Are superseded SOP versions identified as retired and archived in the laboratory? (If "Yes," explain the archiving process and provide the retention time.)**	Yes ☐ No ☐ Comments ☐

Comments:

IV. Test Method Validation and Verification

A.	**Has the laboratory documented analytic accuracy qualification, verification and/or validation studies as applicable for all methods or equipment? (If "No," list the missing elements.)**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Has the laboratory documented analytic precision qualification, verification and/or validation studies as applicable for all methods or equipment? (If "No," list the missing elements.)**	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Has the laboratory documented linearity (including analytic measurement range and clinical reportable range) qualification, verification and/or validation studies as applicable for all methods or equipment? (If "No," list the missing elements.)**	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Has the laboratory verified or established and documented the analytic sensitivity (lower detection limit) of each non-FDA-approved or modified FDA-approved test? (If "No," list the missing elements.)**	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Has the laboratory verified or established and documented analytic interferences for each non-FDA-approved or modified FDA-approved test? (If "No," list the missing elements.)**	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Has the laboratory verified or established and documented normal responses for <u>each</u> test?**	Yes ☐ No ☐ Comments ☐

Comments:

V. Laboratory Information Systems (LIS)

A.	**Is an LIS utilized in this laboratory? (If "No," skip to Section VI.)**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**LIS**	
1.	Are documented validation data present for the LIS?	Yes ☐ No ☐ Comments ☐
2.	Can accurate and complete copies be generated by the LIS?	Yes ☐ No ☐ Comments ☐
3.	Are computer time-stamped audit trails used by the LIS?	Yes ☐ No ☐ Comments ☐
4.	Is system access limited to authorized individuals?	Yes ☐ No ☐ Comments ☐
5.	Is there a written SOP for the operation of the LIS?	Yes ☐ No ☐ Comments ☐
6.	Is there a backup system for the LIS? (If "Yes," describe how data are stored.)	Yes ☐ No ☐ Comments ☐
7.	Is there a documented procedure that is followed in the event of LIS downtime?	Yes ☐ No ☐ Comments ☐
8.	Where applicable, is there ongoing validation of interface systems? (If yes, specify frequency.)	Yes ☐ No ☐ Comments ☐
9.	Are measures in place to ensure secure and confidential storage and transfer of participant data, including (if applicable) written procedures addressing data transfer?	Yes ☐ No ☐ Comments ☐
10.	Are calculated values reported with participant results reviewed every two years or when a system change is made that may affect the calculations?	Yes ☐ No ☐ Comments ☐

Comments:

VI. Quality Management

1.	Does the laboratory have a quality assurance/quality management program? (If "No," skip to Question 3.)	Yes ☐ No ☐ Comments ☐
2.	Does the program include a documented operational plan to promptly record and investigate, correct (as appropriate), and trend nonconformities or other problems identified in pre-analytic, analytic, post-analytic, and general laboratory systems?	Yes ☐ No ☐ Comments ☐
3.	Are key indicators of quality monitored and evaluated to detect problems and opportunities for improvement? (If "Yes," list the indicators.)	Yes ☐ No ☐ Comments ☐
4.	Are appropriate corrective actions and/or preventive actions (CAPAs) taken when opportunities for improvement are identified?	Yes ☐ No ☐ Comments ☐
5.	Is there evidence that CAPAs are monitored through resolution?	Yes ☐ No ☐ Comments ☐
6.	Is quality management documentation surrounding key indicators of quality and CAPAs reviewed by the laboratory management? (If "Yes," indicate the frequency.)	Yes ☐ No ☐ Comments ☐
7.	Does the laboratory have an internal auditing program?	Yes ☐ No ☐ Comments ☐

Comments:

VII. Physical Facilities

1.	Is there a documented policy/procedure in place for access control into the laboratory?	Yes ☐ No ☐ Comments ☐
2.	Are the ventilation (and humidity, where applicable,) adequately controlled in all areas?	Yes ☐ No ☐ Comments ☐
3.	Are ambient room temperature readings and humidity, where applicable taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
4.	Have tolerance limits been established and documented for ambient room temperature and humidity, where applicable? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
5.	Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐
6.	Is there adequate, conveniently located space so the quality of work and safety of personnel are not compromised?	Yes ☐ No ☐ Comments ☐
7.	Is there adequate space for records and specimen storage?	Yes ☐ No ☐ Comments ☐

Comments:

VIII. Equipment

A. Is all equipment used for DAIDS-related laboratory activities listed on an inventory document?	Yes ☐ No ☐ Comments ☐

Comments:

B. Is all out-of-service/not-in-use equipment clearly identified as such?	Yes ☐ No ☐ Comments ☐

Comments:

C. Are there documented Preventive Maintenance (PM) and calibration plans for all laboratory equipment indicated?	Yes ☐ No ☐ Comments ☐

Comments:

D. Has any DAIDS-related equipment been replaced, added, or removed since the last audit? (If "Yes," list the equipment.)	Yes ☐ No ☐ Comments ☐

Comments:

E. Laboratory Equipment

Verify the following as it applies to equipment used for study-specific laboratory activities: (List the manufacturer and model of the equipment, where applicable.)

1. Are freezers present? (If "No," skip to Question 2.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are temperature readings taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Have tolerance limits been established and documented for temperature readings? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

2. Are refrigerators present? (If "No," skip to Question 3.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐

c. Are temperature readings taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Have tolerance limits been established and documented for temperature readings? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

3. Are liquid nitrogen freezers present? (If "No," skip to Question 5.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are liquid nitrogen levels taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Have tolerance limits been established and documented for nitrogen levels? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

4. Is oxygen monitoring equipment present in areas where liquid nitrogen is used? (If "No," skip to Question 5.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented?	Yes ☐ No ☐ Comments ☐
b. Are calibration procedures performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐
c. Are oxygen levels taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Have tolerance limits been established and documented for oxygen levels? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

5. Are incubators present? (If "No," skip to Question 6.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are temperature readings, and CO_2 and humidity levels (if applicable) taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐

d. Have tolerance limits been established and documented for temperature readings, and CO_2 and humidity levels, where applicable? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

6. Are water baths present? (If "No," skip to Question 7.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are temperature readings taken and documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Have tolerance limits been established and documented for temperature readings? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

7. Are centrifuges present? (If "No," skip to Question 8.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Is calibration of speed, time, and temperature (if applicable) performed and documented for each centrifuge? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐

Comments:

8. Are biosafety cabinets/hoods present? (If "No," skip to Question 9.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Has each cabinet/hood been certified? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d. Are pressure or air flow rate readings documented? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
e. Have tolerance limits been established and documented for pressure or air flow rate readings? (If "Yes," list the limits.)	Yes ☐ No ☐ Comments ☐

Comments:

9.	Are autoclaves present? (If "No," skip to Question 10.)	Yes ☐ No ☐ Comments ☐
a.	Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b.	Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c.	Are checks to verify effective autoclave sterilization, including use of heat-sensitive tape and biological indicators, performed and documented? (If “Yes,” indicate the frequency).	Yes ☐ No ☐ Comments ☐

Comments:

10.	Is flow cytometry instrumentation present? (If "No," skip to Question 11.)	Yes ☐ No ☐ Comments ☐
a.	Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b.	Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c.	Are calibration procedures performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐

Comments:

11.	Is PCR/molecular testing equipment present? (If "No," skip to Question 12.)	Yes ☐ No ☐ Comments ☐
a.	Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b.	Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c.	Are calibration procedures performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐

Comments:

12.	Are pipettors present? (If "No," skip to Question 13.)	Yes ☐ No ☐ Comments ☐
a.	Are calibration/verification procedures performed for all pipettors? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐

Comments:

13.	Are thermometers present? (If "No," skip to Question 14.)	Yes ☐ No ☐ Comments ☐
a.	Is a known standard thermometric device available (e.g., NIST certified)?	Yes ☐ No ☐ Comments ☐

b. Have all non-certified thermometers been tested against a standard device? (If "Yes", describe the procedure performed.)	Yes ☐ No ☐ Comments ☐

Comments:

14. Are scales and/or balances present? (If "No," skip to Question 15.)	Yes ☐ No ☐ Comments ☐
a. Are accuracy checks performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐
b. Are service and calibration procedures performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐

Comments:

15. Is an ELISA plate reader/washer present? (If "No," skip to Question 16.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are calibration procedures performed as described by the manufacturer? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐

Comments:

16. Are cell counters present? (If "No," skip to Question 17.)	Yes ☐ No ☐ Comments ☐
a. Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐
b. Are PM activities/services performed and documented by outside vendors and/or company technical representatives?	Yes ☐ No ☐ Comments ☐
c. Are calibration procedures performed as described by the manufacturer? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐

Comments:

17. Are microscopes present? (If "No," skip to Question 18.)	Yes ☐ No ☐ Comments ☐
a. Are daily and annual PM activities/services performed and documented?	Yes ☐ No ☐ Comments ☐

Comments:

18. Are timers present? (If "No," skip to Question 19.)	Yes ☐ No ☐ Comments ☐
a. Are calibration procedures performed and documented?	Yes ☐ No ☐ Comments ☐

Comments:

19.	Is additional equipment used for protocol-related assays present? (If "Yes," report on PM and calibration activities where applicable.)	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Temperature Monitoring**	
1.	Is there a written policy/procedure in place, explaining how temperatures are monitored during the absence of laboratory personnel?	Yes ☐ No ☐ Comments ☐
2.	Is a computerized alarm system with setpoint temperature ranges utilized for continuous monitoring of temperature-sensitive equipment and ambient room temperature? (If "Yes," report the frequency of alarm testing; if "No," specify the system used for continuous temperature monitoring.)	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Is there an SOP in place that describes backup power resources? (If yes, specify how backup power equipment is maintained, e.g., logs or SOPs that detail the frequency of maintenance.)**	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Are maintenance, repair, and calibration records reviewed and signed monthly by laboratory management?**	Yes ☐ No ☐ Comments ☐

Comments:

IX. Test and Control

A. Qualitative/Quantitative Assays

Name of Assay	QC Levels/Replicates	QC Frequency

1.	Is there a written Quality Control (QC) program that clearly defines procedures for monitoring analytic performance, including establishment of tolerance limits, number and frequency of control tests, corrective action based on QC data, and related information?	Yes ☐ No ☐ Comments ☐
2.	Are records present documenting control results assayed with each test as described in the specific assay procedure? (If no QC records are present, skip to Question 5.)	Yes ☐ No ☐ Comments ☐

3.	Are QC records initialed and dated by the testing personnel?	Yes ☐ No ☐ Comments ☐
4.	Has laboratory management reviewed and signed all QC records? (If "Yes," note the frequency.)	Yes ☐ No ☐ Comments ☐
5.	Are appropriate charts utilized to document QC data (e.g., Levey-Jennings charts)? (If "No," skip to Question 7.)	Yes ☐ No ☐ Comments ☐
6.	Has laboratory management reviewed and signed the charts? (If "Yes," note the frequency.)	Yes ☐ No ☐ Comments ☐
7.	Are QC records available for the past 2 years and retrievable within 24 hours?	Yes ☐ No ☐ Comments ☐
8.	For quantitative assays, are control materials at more than one level used?	Yes ☐ No ☐ Comments ☐
9.	For qualitative assays, is a positive and negative control tested?	Yes ☐ No ☐ Comments ☐

Comments:

B.	**QC Failure/Corrective Action**	
1.	Is there documentation of corrective actions taken in response to QC failures? (If "No," skip to Section C.)	Yes ☐ No ☐ Comments ☐
2.	Has laboratory management reviewed and signed the records for QC failures? (If "Yes," note the frequency.)	Yes ☐ No ☐ Comments ☐
3.	In the event that QC data is determined to be unacceptable due to systematic error, does the laboratory re-evaluate all study-participant test results since the last acceptable run?	Yes ☐ No ☐ Comments ☐

Comments:

C.	**QC Materials**	
1.	Are QC materials dated within the manufacturer's assigned expiration dates?	Yes ☐ No ☐ Comments ☐
2.	Are QC materials properly stored as required by the manufacturer?	Yes ☐ No ☐ Comments ☐
3.	Is adequate labelling information of QC materials available, that indicates traceability to the identity, lot number, storage requirements, preparer as well as preparation/reconstitution, and expiration dates?	Yes ☐ No ☐ Comments ☐
4.	Are calibrators used as controls? (If "No," skip to Section D.)	Yes ☐ No ☐ Comments ☐
5.	Are the calibrators from a different lot number than those used to calibrate the method?	Yes ☐ No ☐ Comments ☐

Comments:

D.	Calibration Materials	
1.	Are calibration materials utilized by the laboratory? (If "No," skip to Section E.)	Yes ☐ No ☐ Comments ☐
2.	Are all calibration materials dated within the manufacturer's assigned expiration dates?	Yes ☐ No ☐ Comments ☐
3.	Are all calibration materials properly stored as required by the manufacturer?	Yes ☐ No ☐ Comments ☐
4.	Is adequate labelling information of calibration materials available, that indicates traceability to the identity, lot number, storage requirements, preparer as well as preparation/reconstitution, and expiration dates?	Yes ☐ No ☐ Comments ☐

Comments:

E.	Reagent/Testing Kits/Solutions	
1.	Are all reagent/testing kits/solutions dated within the manufacturer's assigned expiration dates?	Yes ☐ No ☐ Comments ☐
2.	Are all reagents/testing kits/solutions properly stored as required by the manufacturer?	Yes ☐ No ☐ Comments ☐
3.	Is adequate labelling information of reagents/testing kits/solutions available, that indicates traceability to the identity, lot number, storage requirements, preparer as well as preparation/reconstitution, and expiration dates?	Yes ☐ No ☐ Comments ☐

Comments:

F.	Water Quality	
1.	Does the laboratory require specific water types for certain testing procedures? (If "Yes," describe. If "No," skip to Section G.)	Yes ☐ No ☐ Comments ☐
2.	Is there a documented policy that defines standards and frequency of water testing? (If "Yes," include the testing frequency.)	Yes ☐ No ☐ Comments ☐
3.	Are Certificates of Analysis maintained for commercially bottled purified water?	Yes ☐ No ☐ Comments ☐

Comments:

G.	Parallel Testing	
1.	Does the laboratory have a policy/procedure for parallel testing (to compare new lots to old lots for reagents and/or controls) that outlines pre-established pass/fail criteria? (If "No," skip to Section H.)	Yes ☐ No ☐ Comments ☐
2.	Does the laboratory management sign validity checks for each comparison test?	Yes ☐ No ☐ Comments ☐

Comments:

H.	**PBMC Media**	
1.	Is media utilized by the laboratory? (If "No," skip to Section I.)	Yes ☐ No ☐ Comments ☐
2.	Is a media QC log present? (If 'Yes," comment if corrective actions are present, if applicable. If "No," skip to Question 5.)	Yes ☐ No ☐ Comments ☐
3.	Are logs reviewed and signed by the laboratory management? (If "Yes," note the frequency.)	Yes ☐ No ☐ Comments ☐
4.	Is adequate labelling information of media available, that indicates traceability to the identity, lot number, storage requirements, preparer as well as preparation/reconstitution, and expiration dates?	Yes ☐ No ☐ Comments ☐

Comments:

I.	**Is there an established, documented inventory control system in operation for laboratory reagents and supplies?**	Yes ☐ No ☐ Comments ☐

Comments:

X. Records and Reports

A.	**Are copies of network laboratory-specific manuals, protocols, and appendices available and retrievable within 24 hours?**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Specimen Tracking Forms**	
1.	Are forms readily available and retrievable within 24 hours?	Yes ☐ No ☐ Comments ☐
2.	Are the forms retrievable for the entire protocol? (If "Yes," explain how archiving is accomplished and provide the retention time[s].)	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Is specimen chain of custody adequately documented?**	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Where appropriate, are analyte results reported with accompanying reference intervals and/or alert/critical values?**	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Is there a written policy/procedure that addresses the revision of laboratory reports?**	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Is a log or other appropriate record of result modifications reviewed at least monthly by laboratory management?**	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Do the laboratory reports identify the laboratory performing the testing?**	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Does the laboratory archive result data (result printouts, electronic records, etc.), QC records, package inserts, and Certificates of Analysis? (If "Yes," explain how archiving is accomplished and the duration for which data are archived. If "No," skip to Question I.)**	Yes ☐ No ☐ Comments ☐

Comments:

I.	**Are the archived records accessible only to authorized personnel?**	Yes ☐ No ☐ Comments ☐

Comments:

J.	**Are records protected from flood and fire?**	Yes ☐ No ☐ Comments ☐

Comments:

XI. Specimen Transport and Management

A.	**Is there a documented policy/procedure for identifying and assessing the quality of specimens received in the laboratory?**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Are specimen rejection criteria established? (If "Yes," describe how the specimen rejection is communicated to the repositories and laboratories)**	Yes ☐ No ☐ Comments ☐

Comments:

C.	Specimen Transport	
1.	Are systems in place to differentiate specimens that have similar identification information (e.g., serum, cells, and plasma for the same participant or specimens from more than one visit included in the same batch)?	Yes ☐ No ☐ Comments ☐
2.	For specimens submitted to the laboratory from repositories and/or remote sites, is there a documented tracking system to ensure that all specimens are actually received?	Yes ☐ No ☐ Comments ☐
3.	Is there an adequate process for correcting problems identified in specimen transport?	Yes ☐ No ☐ Comments ☐
4.	Is there a documented policy/procedure in place for transporting specimens (e.g., transported in a sturdy, non-breakable, closable container labeled with the international symbol for biohazard)?	Yes ☐ No ☐ Comments ☐
5.	Is there a documented policy/procedure available addressing transportation within the facility?	Yes ☐ No ☐ Comments ☐
6.	Is there a documented policy/procedure available addressing transportation between off-site facilities and the laboratory?	Yes ☐ No ☐ Comments ☐
7.	Are systems in place to adequately retrieve specimens from the repository and track specimens required for testing within the laboratory?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Are specimens retained for potential re-evaluation? (If "Yes," provide the retention times for all specimens.)**	Yes ☐ No ☐ Comments ☐

Comments:

E.	Shipping/IATA Certification/Training	
1.	Is there a training plan in place for shipping certification?	Yes ☐ No ☐ Comments ☐
2.	Is there documentation of persons trained for shipping?	Yes ☐ No ☐ Comments ☐
3.	Are shipping certifications renewed every 2 years?	Yes ☐ No ☐ Comments ☐
4.	Is there a policy/procedure in place for shipping specimens internationally?	Yes ☐ No ☐ Comments ☐

Comments:

XII. Personnel Safety

A.	Safety-Related Incidents	
1.	Are there procedures available for documenting or reporting safety incidents?	Yes ☐ No ☐ Comments ☐

2.	Is there documentation of all safety-related incidents? (If "No," skip to Question 4.)	Yes ☐ No ☐ Comments ☐
3.	Is the documentation reviewed and signed monthly by the laboratory management?	Yes ☐ No ☐ Comments ☐
4.	Is there a mechanism to evaluate safety incidents?	Yes ☐ No ☐ Comments ☐
5.	Is prophylaxis treatment available (e.g., hepatitis B vaccinations and post-pathogen exposure options)?	Yes ☐ No ☐ Comments ☐
6.	Does a physician provide a documented review of all exposure events?	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Safety Data Sheets (SDS) or Material Safety Data Sheets (MSDS)**	
1.	Are SDS or MSDS on file or available online? (If "No," skip to Section C.)	Yes ☐ No ☐ Comments ☐
2.	Are SDS or MSDS readily available to all laboratory personnel?	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Is there an initial and ongoing safety training program with documented participation of all laboratory personnel? (If "Yes," briefly describe the training and list the provider as well as the frequency of training.)**	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Safety Policies**	
1.	Is a written Standard Precautions Policy available?	Yes ☐ No ☐ Comments ☐
2.	Is a written Chemical Hygiene/Hazardous Materials Plan available?	Yes ☐ No ☐ Comments ☐
3.	Is there a written policy for the handling and disposal of biohazardous materials and regulated medical waste? (If "Yes," list what mechanism is used for disposing biohazardous waste.)	Yes ☐ No ☐ Comments ☐
4.	Are policies, procedures, and practices in place for use of liquid nitrogen?	Yes ☐ No ☐ Comments ☐
5.	Are policies, procedures, and practices in place for use of dry ice (solid carbon dioxide)?	Yes ☐ No ☐ Comments ☐
6.	Is an emergency preparedness policy available?	Yes ☐ No ☐ Comments ☐
7.	Are safety policies and procedures readily available to all personnel?	Yes ☐ No ☐ Comments ☐
8.	Is there evidence of review within a two-year interval of all safety policies and procedures by the laboratory management?	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Is safety equipment such as eyewashes, safety showers, fire extinguishers, sharps containers, spill kits, smoke detectors/fire alarms, hand washing sinks, and basic first aid kits present in the laboratory? (If "Yes," provide the frequency of documented functional checks for the equipment.)**	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Personal Protective Equipment (PPE)**	
1.	Is PPE (gloves, gowns, masks/respirators, eye protectors, etc.) available to laboratory personnel?	Yes ☐ No ☐ Comments ☐
2.	Is PPE correctly worn and utilized by laboratory personnel?	Yes ☐ No ☐ Comments ☐
3.	Is PPE 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?	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Emergency Evacuation**	
1.	Does the laboratory have a documented and workable evacuation plan that is available to all laboratory employees and visitors?	Yes ☐ No ☐ Comments ☐
2.	Have all laboratory employees (and visitors, if appropriate) been properly trained in the evacuation plan/policy?	Yes ☐ No ☐ Comments ☐
3.	Are annual fire drills conducted with documented participation by laboratory personnel?	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Are reviews of safe work practices performed and documented at least annually?**	Yes ☐ No ☐ Comments ☐

Comments:

XIII. Vertical Audit of SOP/Practice

Title of SOP	**Procedure Observed**	**Person Observed**

A.	**Personnel Training and Competency Verification**	
1.	Is training and competency evaluation documented for the personnel performing the test?	Yes ☐ No ☐ Comments ☐

2.	Is SOP user knowledge documented?	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Pre-Test Specimen Handling**	
1.	Are specimens submitted for testing as required by the SOP?	Yes ☐ No ☐ Comments ☐
2.	Are specimens maintained at appropriate conditions (e.g., temperature) until testing can be performed?	Yes ☐ No ☐ Comments ☐
3.	Are specimens thawed and counted as required by the SOP? (If "No," skip to Question 4.)	Yes ☐ No ☐ Comments ☐
	a. Is a hemocytometer utilized for cell counting? (If "No," note the method of cell counting and skip to Question 4.)	Yes ☐ No ☐ Comments ☐
	b. Are cells counted in duplicate to verify the hemocytometer count?	Yes ☐ No ☐ Comments ☐
4.	Are cell viability and recovery documented for specimens?	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Reagent Preparation and Storage**	
1.	Are reagents prepared in accordance with the SOP?	Yes ☐ No ☐ Comments ☐
2.	Are reagents maintained at appropriate conditions until testing can be performed?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Test Set-Up**	
1.	Are tubes/plates pre-labeled prior to testing? (If "Yes," comment on how far in advance labeling occurs.)	Yes ☐ No ☐ Comments ☐
2.	Are tubes/plates labeled appropriately with sufficient identification to prevent mix-up?	Yes ☐ No ☐ Comments ☐
3.	Is appropriate equipment (e.g., pipettors or a vortex mixer) available at the start of the procedure to avoid delay?	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Processing Phase**	
1.	Are appropriate conditions maintained to perform the assay (e.g., sterile, biohazard containment)?	Yes ☐ No ☐ Comments ☐
2.	Are reagents and samples added in the appropriate order and at appropriate times?	Yes ☐ No ☐ Comments ☐
3.	Are QC samples tested in the same manner as test samples?	Yes ☐ No ☐ Comments ☐

4.	Are incubation times required? (If "No," skip to Question 5.)	Yes ☐ No ☐ Comments ☐
	a. Is incubation performed appropriately?	Yes ☐ No ☐ Comments ☐
	b. Are incubation times documented?	Yes ☐ No ☐ Comments ☐
5.	Are additional steps followed as defined in the SOP?	Yes ☐ No ☐ Comments ☐
6.	Are specimens maintained under appropriate conditions until analysis?	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Analysis Phase**	
1.	Is an analyzer required for this phase? (If "Yes," indicate the analyzer. If "No," skip to Question 2.)	Yes ☐ No ☐ Comments ☐
	a. Is the analyzer set up as required by the SOP?	Yes ☐ No ☐ Comments ☐
2.	Are specimens analyzed by manual methods? (If "Yes," indicate the method. If "No," skip to Question 3.)	Yes ☐ No ☐ Comments ☐
3.	Are control and, where applicable, calibration results acceptable?	Yes ☐ No ☐ Comments ☐
4.	Are specimens analyzed as defined in the SOP?	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Calculations and Results Reporting**	
1.	Are manual calculations performed? (If "No," skip to Question 3.)	Yes ☐ No ☐ Comments ☐
2.	Is the derivation of the final results available?	Yes ☐ No ☐ Comments ☐
3.	Are results transmitted from the analyzer to a central LIS? (If "No," skip to Question 5.)	Yes ☐ No ☐ Comments ☐
4.	Do the results obtained by the analyzer match those in the LIS?	Yes ☐ No ☐ Comments ☐
5.	Are results verified by alternate personnel?	Yes ☐ No ☐ Comments ☐
6.	Are discrepancies or deviations recorded and reviewed?	Yes ☐ No ☐ Comments ☐
7.	Are results reported as defined in the SOP?	Yes ☐ No ☐ Comments ☐
8.	Do all procedures preserve the chain of custody?	Yes ☐ No ☐ Comments ☐

Comments: