NIAID/DAIDS CRSS Team

PPD

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: PBMC

Audit Date(s):

Final Report Issued:

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Laboratory Audit Report for PBMC Processing

Laboratory Report Summary

Study Site Name/Number/Location	
Visit Date(s)	
Audit Requestor	
Laboratory Auditor	
Principal Investigator	
Laboratory Name	
Laboratory Type	
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

PBMC Processing	Yes ☐	No ☐	Comments ☐
PBMC Counting	Yes ☐	No ☐	Comments ☐
Serum/Plasma Processing	Yes ☐	No ☐	Comments ☐
Specimen Storage	Yes ☐	No ☐	Comments ☐
Specimen Shipping	Yes ☐	No ☐	Comments ☐
Other	Yes ☐	No ☐	Comments ☐

Comments:

I. External Quality Assurance (EQA)

1.	Does the laboratory participate in any external proficiency programs for DAIDS-supported protocol-related PBMC processing? (If "Yes," list all EQA providers.)	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, survey provider result and report, raw result data, and indication of who performed the processing and/or testing)?	Yes ☐ No ☐ Comments ☐
4.	Are EQA specimens processed 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.	Are PBMCs isolated by laboratory personnel assessed by the EQA program on a rotational basis?	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 involved with protocol-related activities?	Yes ☐ No ☐ Comments ☐
5.	Are training records available for all laboratory personnel involved with processing and/or 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 versus 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? (If "Yes," report the methods utilized to assess competency 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, processing and/or testing quality, or safety concerns to laboratory management?**	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Is there a mechanism for the leadership of the laboratory and the clinic to discuss laboratory performance?**	Yes ☐ No ☐ Comments ☐

Comments:

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

Comments:

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

Comments:

B. 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:

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

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

Comments:

E.	**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:

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

Comments:

G.	**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. Laboratory Data Management System (LDMS)

A.	**Does this laboratory facility contain an LDMS? (If "Yes", provide the LDMS ID in the Comments Section; If "No," disregard the rest of Section IV and explain how specimen storage/shipping data are maintained.)**	Yes ☐ No ☐ Comments ☐

Comments:

B.	**LDMS Reports Verified by the Auditor**	
1.	Primary Specimens Received Report	Yes ☐ No ☐ Comments ☐
2.	Storage Detail Report	Yes ☐ No ☐ Comments ☐
3.	Shipped Specimen Report–Detail	Yes ☐ No ☐ Comments ☐

Comments:

C.	**Specimen Verification**	
1.	Can the participant identification (PID), date, protocol, derivative, and additive for specimens be verified with the LDMS?	Yes ☐ No ☐ Comments ☐
2	Does the LDMS accurately reflect the number, type, and volume of all specimen aliquots as well as their storage location and shipping record?	Yes ☐ No ☐ Comments ☐
3.	Can the physical presence of specimens be verified with the LDMS Storage Detail Report?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Is the current LDMS manual available in the laboratory?**	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Backup**	
1.	Is the LDMS backed up daily?	Yes ☐ No ☐ Comments ☐
2.	Is the LDMS backup device stored in a different location than the LDMS computer?	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Is the LDMS connected to a backup power source?**	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Do laboratory SOPs include implementation and compliance with DAIDS-network mandates regarding LDMS usage?**	Yes ☐ No ☐ Comments ☐

Comments:

V. 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 laboratory management? (If "Yes," indicate the frequency.)	Yes ☐ No ☐ Comments ☐
7.	Does the laboratory have an internal auditing program?	Yes ☐ No ☐ Comments ☐

Comments:

VI. 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:

VII. Equipment

A.	**Is all equipment used for DAIDS protocol-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 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 liquid 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 calibration procedures performed as described by the manufacturer?	Yes ☐ No ☐ Comments ☐
b.	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 ☐
c.	Is an alarm system with oxygen setpoints available? (If "Yes," report the frequency of alarm testing.)	Yes ☐ No ☐ Comments ☐
e.	Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Comments:

5.	Are centrifuges 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.	Is calibration of speed, time, and temperature (if applicable) performed and documented for each centrifuge? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐

Comments:

6.	Are biosafety cabinets/hoods 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.	Has each cabinet/hood been certified? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐
d.	Are pressure readings 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:

7. Are pipettors present? (If "No," skip to Question 8.)	Yes ☐ No ☐ Comments ☐
a. Are calibration/verification procedures performed for all pipettors? (If "Yes," report the frequency.)	Yes ☐ No ☐ Comments ☐

Comments:

8. Are thermometers present? (If "No," skip to Question 9.)	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 "No" to 11.a. and "Yes" to 11.b., describe the procedure performed.)	Yes ☐ No ☐ Comments ☐

Comments:

9. Are scales and/or balances present? (If "No," skip to Question 10.)	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:

10. Are microscopes present? (If "No," skip to Question 11.)	Yes ☐ No ☐ Comments ☐
a. Are daily and annual PM activities/services performed and documented?	Yes ☐ No ☐ Comments ☐

Comments:

11. Are timers present? (If "No," skip to Question 12.)	Yes ☐ No ☐ Comments ☐
a. Are calibration procedures performed and documented?	Yes ☐ No ☐ Comments ☐

Comments:

12. Is a hemocytometer present? (If "No," skip to Question 13.)	Yes ☐ No ☐ Comments ☐
a. Has the laboratory demonstrated and documented the ability to perform reliable counts for the manual cell counting method used in the laboratory?	Yes ☐ No ☐ Comments ☐
Comments:	

13.	Is an automated cell counting method and instrument in use in the laboratory? (If "No," skip to Question 14.)	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 the laboratory verified or established and documented analytic accuracy and precision of the automated cell counting method?	Yes ☐ No ☐ Comments ☐
d.	Has the laboratory verified or established and documented an analytic measurement range (linearity)?	Yes ☐ No ☐ Comments ☐
e.	Is the instrument calibrated? (If "Yes," report the frequency. If "No," skip to Question 13h.)	Yes ☐ No ☐ Comments ☐
f.	Are calibration materials stored as required by the manufacturer?	Yes ☐ No ☐ Comments ☐
g.	Are calibration materials properly labeled indicating content and calibration value?	Yes ☐ No ☐ Comments ☐
h.	Is a backup method available for automated cell counting?	Yes ☐ No ☐ Comments ☐
i.	Are there periodic comparison checks between the primary and backup methods?	Yes ☐ No ☐ Comments ☐

Comments:

14.	Is equipment for PBMC rate control freezing present?	Yes ☐ No ☐ Comments ☐
a.	Are PM activities/services performed and documented by laboratory personnel?	Yes ☐ No ☐ Comments ☐

Comments:

15.	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 freezer, refrigerator, 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:

VIII. Test and Control

A.	**Automated Cell Counting Method Quality Control (QC)**	
1.	Does the laboratory use an automated cell counting method? (If "No," skip to Section B.)	Yes ☐ No ☐ Comments ☐
2.	Are QC materials dated within the manufacturer's assigned expiration dates?	Yes ☐ No ☐ Comments ☐
3.	Are QC materials properly stored as required by the manufacturer?	Yes ☐ No ☐ Comments ☐
4.	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 ☐
5.	Are control materials used at more than one level? (If "Yes," indicate the number of levels used.)	Yes ☐ No ☐ Comments ☐
6.	Are controls tested in the same manner as patient samples?	Yes ☐ No ☐ Comments ☐
7.	Is a log present documenting control results? (If "No," skip to Question 9.)	Yes ☐ No ☐ Comments ☐
8.	Does the technologist performing the QC initial and date the log?	Yes ☐ No ☐ Comments ☐
9.	Are appropriate charts utilized to document QC data (e.g., Levey-Jennings charts)? (If "No," skip to Question 11.)	Yes ☐ No ☐ Comments ☐
10.	Has laboratory management reviewed and signed the charts? (If "Yes," note the frequency.)	Yes ☐ No ☐ Comments ☐
11.	Are QC records available for the past 2 years and retrievable within 24 hours?	Yes ☐ No ☐ Comments ☐

Comments:

B.	**Manual Cell Counting QC**	
1.	Does the laboratory perform manual cell counts? (If "No," skip to Section C.)	Yes ☐ No ☐ Comments ☐

2.	Has the laboratory established limits to determine whether the cell counts between squares are comparable?	Yes ☐ No ☐ Comments ☐
3.	Are cell counts verified by another technologist periodically? (If "Yes," note the frequency.)	Yes ☐ No ☐ Comments ☐

Comments:

C.	**QC Failure/Corrective Action**	
1.	Is there documentation of corrective actions taken in response to QC failures? (If "No," skip to Section D.)	Yes ☐ No ☐ Comments ☐
2.	Has laboratory management reviewed and signed the records for QC failures? (If "Yes," note the frequency.)	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Reagents and Solutions**	
1.	Is adequate labelling information of reagents and solutions available, that indicates traceability to the identity, lot number, storage requirements, preparer as well as preparation/reconstitution, and expiration dates?	Yes ☐ No ☐ Comments ☐
2.	Are all reagents and solutions properly stored as required by the manufacturer?	Yes ☐ No ☐ Comments ☐
3.	Are all reagents and solutions used within their listed expiration date?	Yes ☐ No ☐ Comments ☐
4.	Are documented procedures used to check or monitor the integrity of new lots of reagents prior to being placed into service? (If "Yes," describe.)	Yes ☐ No ☐ Comments ☐
5.	Are manufacturers' Certificates of Analysis and package inserts present for specimen processing reagents (e.g., FBS, DMSO, HBSS, PBS, RPMI 1640, Ficoll, Histopaque, and Accuspin)?	Yes ☐ No ☐ Comments ☐

Comments:

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

Comments:

IX. 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.	**Is there a written policy/procedure for updating network documents to ensure that the most recent issue is in circulation?**	Yes ☐ No ☐ Comments ☐

Comments:

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

Comments:

D.	**Does the laboratory archive specimen tracking/requisition forms and result data (result printouts, processing worksheets, 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 Section X.)**	Yes ☐ No ☐ Comments ☐

Comments:

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

Comments:

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

Comments:

X. Laboratory Capacity

1.	How many participants are processed for PBMC isolation/storage per week?	(Enter number here.)
2.	How many shipments does the laboratory send per week?	(Enter number here.)
3.	Does the laboratory support multiple clinics? (If "Yes," indicate the number of clinics.)	Yes ☐ No ☐ Comments ☐
4.	Does the clinic coordinate the protocol workload with the laboratory in advance?	Yes ☐ No ☐ Comments ☐

Comments:

XI. Specimen Transport and Management

A.	**Are there documented guidelines for specimen collection in the laboratory and areas dedicated for specimen collection?**	Yes ☐ No ☐ Comments ☐

Comments:

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

Comments:

C.	**Are specimen rejection criteria established? (If "Yes," describe how the specimen rejection is communicated to the clinic personnel.)**	Yes ☐ No ☐ Comments ☐

Comments:

D.	**Specimen Transport**	
1.	Is there a documented policy/procedure in place for transporting samples (e.g., transported in a sturdy, non-breakable, closable container labeled with the international symbol for biohazard)?	Yes ☐ No ☐ Comments ☐
2.	Is there a documented policy/procedure available addressing transportation within the facility?	Yes ☐ No ☐ Comments ☐
3.	Is there a documented policy/procedure available addressing transportation between off-site clinics and the laboratory?	Yes ☐ No ☐ Comments ☐

Comments:

E.	**PBMC Processing Times**	
1.	Is the laboratory located in proximity to the clinic to support processing within time constraints?	Yes ☐ No ☐ Comments ☐
2.	Are there scheduled times for specimen transport from the clinic to the laboratory? (If "Yes," note the frequency.)	Yes ☐ No ☐ Comments ☐
3.	Has the laboratory established time limits for processing PBMC specimens?	Yes ☐ No ☐ Comments ☐

Comments:

F.	**PBMC Handling**	
1.	Are PBMCs handled in a manner to prevent thawing or warming from their frozen status during relocation? (If "Yes," explain the procedures for maintenance of the cold chain.)	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Outgoing Shipments QC**	
1.	Are samples checked against the prepared shipping manifest prior to shipment?	Yes ☐ No ☐ Comments ☐

Comments:

H.	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 in place for shipping samples 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 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) orMaterial 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 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 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.	Are training and competency evaluations documented for the personnel performing the procedure?	Yes ☐ No ☐ Comments ☐
2.	Is SOP user knowledge documented?	Yes ☐ No ☐ Comments ☐

Comments:

B.	Pre-Test Specimen Handling	
1.	Are specimens submitted for processing as required by the SOP?	Yes ☐ No ☐ Comments ☐
2.	Does the specimen receiving procedure preserve the chain of custody for the samples?	Yes ☐ No ☐ Comments ☐
3.	Are specimens submitted within the timeframe required for processing?	Yes ☐ No ☐ Comments ☐
4.	Are specimens maintained at appropriate conditions (e.g., temperature) until processing can be performed?	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 processing can be performed?	Yes ☐ No ☐ Comments ☐
3.	Are reagents adequately labeled with information traceable to their identity, lot number, storage requirements, preparer, as well as preparation/reconstitution and expiration dates?	Yes ☐ No ☐ Comments ☐

Comments:

D.	**PBMC Processing**	
1.	Are specimens processed within the timeframe as defined in the SOP?	Yes ☐ No ☐ Comments ☐
2.	Are appropriate conditions maintained to perform the PBMC processing (e.g., a sterile, biohazard containment)?	Yes ☐ No ☐ Comments ☐
3.	Are tubes pre-labeled prior to processing? (If "Yes," comment on how far in advance labeling occurs.)	Yes ☐ No ☐ Comments ☐
4.	Are tubes labeled appropriately with sufficient identification to prevent mix-up?	Yes ☐ No ☐ Comments ☐
5.	Is appropriate equipment (e.g., pipettors or a vortex mixer) available at the start of the procedure to avoid delay?	Yes ☐ No ☐ Comments ☐
6.	Are reagents and samples added in the appropriate order and at appropriate times?	Yes ☐ No ☐ Comments ☐
7.	Is the laboratory personnel able to demonstrate proper use of the label-making software?	Yes ☐ No ☐ Comments ☐
8.	Is processing performed according to the SOP?	Yes ☐ No ☐ Comments ☐

Comments:

E.	**Analysis Phase**	
1.	Are cells counted as required by the SOP? (If “Yes,” provide the method of cell counting.)	Yes ☐ No ☐ Comments ☐

Comments:

F.	**Manual Counting Methods**	
Are manual counting methods used during analysis? (If “No,” skip to Section G.)		Yes ☐ No ☐ Comments ☐
1.	Is viability performed during the cell counting procedure?	Yes ☐ No ☐ Comments ☐
2.	Which squares are counted on the hemocytometer?	Inner square: ☐ Outer square: ☐
3.	How many squares are counted in order to calculate the cell count?	(Enter number here.)

4.	Does the final dilution of specimen result in an adequate number of cells counted in each square? (List the acceptable range documented by the laboratory and note the results obtained.)	Yes ☐ No ☐ Comments ☐
5.	Are cell numbers between individual squares comparable? (If “Yes,” describe how this is determined.)	Yes ☐ No ☐ Comments ☐
6.	Are counts verified? (If “Yes,” describe the method used.)	Yes ☐ No ☐ Comments ☐
7.	Is cell yield documented for specimens? (If “Yes,” describe the method used.)	Yes ☐ No ☐ Comments ☐

Comments:

G.	**Automated Counting Methods**	
Are automated counting methods used during analysis? (If "No," skip to Section H.)		Yes ☐ No ☐ Comments ☐
1.	Is the analyzer set up as required by the SOP?	Yes ☐ No ☐ Comments ☐
2.	Are appropriate controls available and tested?	Yes ☐ No ☐ Comments ☐
3.	Does the dilution of specimen result in an adequate number of cells counted by the analyzer? (List the acceptable range documented by the laboratory and note the results obtained.)	Yes ☐ No ☐ Comments ☐
4.	Is cell yield documented for specimens? (If "Yes," describe the method used.)	Yes ☐ No ☐ Comments ☐

Comments:

H.	**Freezing Samples**	
1.	Is a freezing device/container used?	Yes ☐ No ☐ Comments ☐
2.	If freezing containers are used, are they equilibrated at the appropriate temperature?	Yes ☐ No ☐ Comments ☐
3.	Are cryovials labeled before freezing media is added to the PBMC pellet?	Yes ☐ No ☐ Comments ☐
4.	Is freezing media pre-chilled, added to the PBMC pellet, and aliquoted as described in the SOP?	Yes ☐ No ☐ Comments ☐
5.	Are PBMC aliquots moved into the freezing chamber/freezer within the timeframe defined in the SOP?	Yes ☐ No ☐ Comments ☐
6.	Is the duration of processing documented?	Yes ☐ No ☐ Comments ☐
7.	If a timeframe is defined in the SOP, are specimens with out-of-range times documented and corrective action taken?	Yes ☐ No ☐ Comments ☐

Comments:

I.	**Calculations and Result Reporting**	
1.	Are manual calculations performed? (If "No," skip to Question 3.)	Yes ☐ No ☐ Comments ☐
2.	Is the derivation of the final result 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 ☐

Comments:

J.	**Transfer/Retrieval of Frozen Specimens**	
1.	Are specimens handled in a manner to prevent thawing or warming from their frozen status during relocation?	Yes ☐ No ☐ Comments ☐
2.	Are the physical storage positions of the specimens verified against their LDMS-assigned locations during transfer? (If "Yes," provide details.)	Yes ☐ No ☐ Comments ☐

Comments: