JHP Laboratories

Title: **Specimen Processing** Document: SPEC-P-02				
Applies to: **JHP Laboratory Technicians**	Version: 1.0	Supersedes: N/A	Effective Date: 28-May-12	
	Name	**Signature**	**Title**	**Date**
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Revision History

Revision	Date	Author	Change Reference	Reason for Change

GENERAL

This procedure describes the processing procedure to be followed at the Johns Hopkins Project Laboratory.

PRINCIPLE

JHP Laboratory is involved in numerous scientific research projects and is responsible for the processing and storage of specimens provided by participants of these projects. To ensure the validity of any results obtained from these specimens, it is essential that each specimen be handled, processed and stored appropriately.

Refer to the site-specific protocol if any questions arise.

BIO-HAZARD SAFETY

1. Lab coats and gloves are required for this procedure. If removing of specimen tube top is required use of eye protection is recommended.
2. Universal Precautions are to be followed. Refer to Laboratory Safety – General (SAFE-6) for more information.

MATERIALS REQUIRED

1. Cryovials
2. Pipettes
3. Markers/pens with permanent ink
4. Processing of Specimens for Testing at JHP Laboratory (Appendix I)
5. Specimen Discrepancy/Rejection Log (Appendix I, SPEC-P-01 Specimen Reception)

INSTRUMENTS

1. Centrifuge (see appropriate SOP for maintenance).

PROCEDURE

Specimen Processing Area

1. Specimens, Laboratory Test Request Form (LTRF) and LDMS Specimen Tracking Sheet (if protocol specimen) will be received from specimen reception.
2. Verify the samples received from specimen reception by comparing the specimen label(s) with the LTRF and LDMS Specimen Tracking Sheet (if protocol specimen).
   a. Verify the information on LTRF matches the specimen and LDMS tracking sheet.
      – PID, gender, date of birth
      – Collection date and time, initials of phlebotomist
   b. Verify the number of each specimen type that was received is the same as what was documented on the LTRF and/or LDMS Tracking Sheet.
   c. If any discrepancies are found, the appropriate staff must be notified (clinic staff, QA/QC manager, etc.).
   d. Complete the Specimen Discrepancy / Rejection Log (Appendix I, SPEC-P-01 Specimen Reception) if discrepancies are detected **even** if they have been resolved.
3. Specimens will be processed within the required stability time.
   a. See Appendix I for processing requirements of routine specimens.
   b. See the study specific protocol SOPs for study-specific processing requirements for archive samples.

4. When labeling aliquots, verify labeling information placed on the aliquots matches the information on the primary tube label and the LTRF.
5. Specimens will be put into the appropriate departmental rack, except:
   a. Wet Mounts: Due to the short turn-around-time required, specimens for wet mounts will be announced to the appropriate tech and placed in the microscopy area.
   b. STATs: Due to the implied emergency status, samples indicated as STATs will be taken to the tech working in the department and identified as a STAT.

Testing Departments

1. Techs will periodically check the pending list that is generated by Laboratory Information System (LIS) and pick up specimens from the department racks in CPD.
2. Before the lab closes for the day or prior to a department tech leaving for the day, they need to review the LIS pending list and pick up any remaining specimens in the racks.
3. For Departments that batch their testing, a pending list will be printed prior to testing.
4. Specimens for viral load will be placed in the appropriate storage box(es) in the appropriate sequence.

PROCEDURAL NOTES

1. See SPEC-S-01 Specimen Rejection for criteria and procedure.
2. See the specific protocol SOP for study-specific processing requirements for archival specimen (aliquot volumes, number of aliquots, etc.).
3. See GENL-Q-06 Testing at Backup Laboratory for required actions and documentation.
4. Specimens for PBMCs will be recorded on the PBMC Processing Worksheet (Appendix I, SPEC-P-03 PBMC Processing).

Processing and Storage of Specimens for Testing at JHP Laboratory

Test	Specimen	Collection to Receipt Time	Processing								Notes
			Centrifuge		Aliquot(s)		Pre-Testing Storage Temperature (Limits)				
			Speed (x g)	Time (min)	Number	Volume	18-25°C	2-8°C	-20°C	-70°C	
Chemistry, General	Serum	< 1 hour	800-1500	15	1	1 mL	8 hr.	48 hr.	Indef.		Separate from cells w/in 2 hours of collection
CK (creatine kinase)	Serum	< 1 hour	800-1500	15	1	1 mL	4 hr.	12 hr.	3 days		Separate from cells w/in 2 hours of collection
LD-L(LDH)	Serum	< 1 hour	800-1500	15	1	1 mL	8 hr.				Separate from cells w/in 2 hours of collection
Lipase	Serum	< 1 hour	800-1500	15	1	1 mL	4 hr.	48 hr.	Indef.		Separate from cells w/in 2 hours of collection
Lactate	Serum	10 min. on ice	800-1500	15	1	1 mL	STAT				Separate from cells w/in 15 minutes of collection
HIV-1 RNA	Plasma	5 hours**	800-1600	20	2	1 mL		5 days		Indef.	**Separate plasma from whole blood within 6 hours of collection; HPTN and ACTG allow up to 48 hours but prefer 6 hours.
Abbott Determine Rapid HIV	Serum, plasma	ASAP	800-1500	15	1	1 mL		7 days	Indef.		
	Whole blood	ASAP					24 hrs.	7 days			
OraQuick Advanced Rapid HIV	Plasma	ASAP	800-1500	15	1	1 mL		7 days			
	Whole blood	ASAP					5 days				
Serology	Serum, plasma	ASAP	800-1500	15	1	1 mL		7 days	Indef.		
Pregnancy Test	Urine	ASAP					8 hrs.	48 hrs.	Indef.		

Test	Specimen	Collection to Receipt	Pre-Testing Storage Temperature (Limits)		
			18-25°C	2-8°C	-20°C
HIV-1 DNA	Whole blood	ASAP	4 days	4 days	
	Dried blood spot	ASAP	Indef.		
CD4/CD8	EDTA whole blood	ASAP	48 hr.		
Wet Mount	Vaginal Swab/Saline	10 min.	30 min.		

Test	Specimen	Collection to Receipt	Pre-Testing Storage Temperature (Limits)		
			18-25°C	2-8°C	-20°C
GC/CT GeneXpert	Urine	ASAP		7 days	2 months
	Swab	ASAP	6 days	6 days	
OSOM Rapid Trich	Swab	ASAP	24 hr.	36 hr.	
CBC	EDTA whole blood	ASAP	24 hr.		

Review of Standard Operating Procedure for

Title: Specimen Processing

SOP: SPEC-P-02 Version: 1.0 Eff. Date: 28-May-12

Training date (if applicable): _____ Trainer: _____

By signing below, I hereby state that I have read the SOP listed above and have asked questions when I didn't understand it. I now fully understand the new and/or modified SOP and all appendices and will perform the procedure as stated in the SOP.

If applicable, the training date and trainer's initials are documented on the form.

Date	Print Name	Position	Signature