JHP Laboratories

Title: **Specimen Rejection** Document: SPEC-S-01				
Applies to: **JHP Laboratory Staff**	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 document describes the process to follow when problems are encountered with specimens, specimen labeling and/or laboratory request forms that are received in the laboratory.

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 (GENL-SF-01) for more information.

MATERIALS REQUIRED

1. Specimen Discrepancy/Rejection Log (Appendix I, SPEC-P-01 Specimen Reception).

PROCEDURE

Specimen Rejection at Central Processing Department (CPD)

1. Specimens will be rejected if:
   a. Sample labeling does not match the information on the LTRF and/or failure to clarify with the nurse or clinician.
   b. Samples were collected in the wrong collection tube.
   c. Samples were collected in anticoagulated tubes but are clotted.
   c. The volume of the sample(s) is insufficient for the requested testing **unless** the specimen is for storage or archive.
      – If multiple tests are requested on one specimen, advise the clinic of insufficient volume and advise which tests may be performed on the specimen received. Document the outcome of the discussion on the laboratory request form.
      – If there is any question of whether a specimen for storage or archive should be saved, obtain the advice of the protocol contact person.
      – Notify the appropriate protocol contact if less than the required minimum volume will be stored.
   d. The sample is too hemolyzed; the extent of acceptable hemolysis is dependent on the testing requested. See the appropriate SOP for the testing requested.
   e. The sample container has broken or opened in transit.
   f. **Exception:** PK samples **will not be rejected** unless processing the sample poses a threat to the lab staff.
      – For example: a needle is still attached to the blood tube.
      – Any problems noted with the PK sample will be documented on the LTRF and in LDMS.
   g. **Exception:** Individual protocols may have rejection criteria which are different than those listed. You **must** check the protocol before rejecting any specimen.
2. The clinic nurse or clinician will be notified immediately of a rejected specimen and the reason for the rejection.
3. The CPD staff member will:
   a. Isolate the rejected sample(s) in a way that it will not be picked up and tested.
   b. Indicate on the LTRF which specimen(s) were rejected.

c. Complete the Specimen Discrepancy/Rejection Log (SPEC-P-01, Appendix I) with all information requested.
d. Take the completed form to the laboratory supervisor, QA/QC supervisor or the laboratory manager for review and signature ("Unacceptable specimen destruction" box).
e. Once approval for destruction is given, the specimens may be discarded as appropriate.

Specimen Rejection at the Testing Department

1. Specimens routed to the testing departments may not yield results for many reasons. For example:
   a. The sample may be found to contain clots, is hemolysed or other conditions that make it unsuitable for testing.
   b. The sample was not being tested within sample stability time due to equipment failure or reagent outages.
      – Every attempt must be made to submit specimens to the backup laboratory for testing within the specimen stability time.
      – Network/protocols must be notified prior to sending specimens to the backup laboratory.
   c. The sample was for testing in the wrong conditions (as defined in the specimen requirement section of testing SOPs).
2. The testing tech must notify the clinic as soon as possible in order for the clinic to contact the participant/patient to obtain another sample (if requested by protocol/clinician).
3. The testing tech must complete the "No Results Report" (REP-01 Reporting Test Results, Appendix V).
4. See REP-01 Report Test Results for additional information.

Review of Standard Operating Procedure for

Title: Specimen Rejection

SOP: SPEC-S-01 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