Policy Statement	Saint Agnes Hospital Core Laboratory will reject specimens submitted for testing that are considered sub-optimal. Additionally, with the aid of delta checks the Core Laboratory provides accurate test results throughout all stages of patient care.
Definition and Purpose	To provide guidance to determine if samples are unacceptable specimens and action required for results producing delta checks.
Scope	This policy applies to all patient samples received by Saint Agnes Hospital Laboratory and/or any affiliated laboratories.
Responsibility	All above personnel are responsible for following this procedure without exception. Specimen processing and testing personnel are responsible for evaluating the specimens and taking proper steps including notifying the designated Charge or Lead Technologist if appropriate.

I. Unacceptable Specimens

Specimens are unacceptable for testing if improperly collected or labeled. They will be cancelled and reordered. These types of samples include, but are not limited to, the following:

1) **Adulterated:** Adulteration or contamination can occur if care is not taken when collecting the specimen. Blood, urine and other body fluids can be contaminated in many ways, for example with IV fluid, saline or water. IV solutions will most likely adulterate blood collected above an IV line. Urine that is not refrigerated will allow for bacterial growth.

2) **Hemolyzed:** Hemolysis refers to the destruction of red blood cells. This leads to the release of hemoglobin, potassium and other cell contents from within the red blood cells into the blood plasma or serum of a patient specimen. The release of these molecules may cause unpredictable alterations in various analytes. In situations where hemolysis is present, the color of the plasma or serum can appear light pink to red, brown or even dark purple. Hemolytic color may be altered or not be apparent if the blood is icteric, lipemic or contains dyes or medicinal colorants. *In vitro* hemolysis may be avoided by appropriate blood collection techniques. Most cases of *in vitro* hemolysis occur at the point of collection.

3) **Clotted:** Clotted specimens occur when collected blood is improperly mixed with the anti-coagulant in the collection tube. Clotted specimens submitted for assays requiring whole blood cannot be analyzed because they cause invalid results and clog laboratory instruments.

4) **QNS:** When an inadequate amount of a specimen is collected for specific testing, it is rejected as "QNS" (Quantity Not Sufficient.) This indicates that the volume is insufficient for that particular testing procedure. Minimum specimen volumes are determined by equipment manufacturers, reference laboratories and medically accepted laboratory practices. Frequently a specimen that is QNS will not yield any results. QNS may also indicate that the ratio of whole blood to anticoagulant is inappropriate.

5) **Lipemia:** A lipemic sample is defined as moderately milky or turbid. A sample can be airfuged and then run on the instruments with the coded comment LIPC. (Samples that have a requested Lipid Profile cannot be performed on samples that are airfuged. Samples must be recollected.)

6) **Unlabeled or Mislabeled specimens**

II. Delta Checks

The primary purpose for delta checks is to detect pre-analytical blood specimen mislabeling or adulteration. Additionally, when clinicians see delta flags in the EMR this can signal clinically important changes that may require changes in treatment that can affect patient care.

1) **Hematology:**

- **Platelet -** When a patient has a decrease in the platelet count which generates a delta check, the specimen will be checked for a clot. An internal comment (see comment section) should be attached to the PLT result. This will be in the form of a canned comment "CLNOCLT". Adult **inpatients** that have a decrease in the platelet count to a result <100 **and** that is less than half the value of a previously normal platelet count during the current admission, must have a smear reviewed to rule out platelet clumping. If there is no clumping detected, a redraw should be requested to confirm the platelet count. If a clot is detected, the sample should be cancelled and recollected. If a delta is caused by an increase in the platelet count, no further action is required.

- **Mean Cell Volume (MCV) -** MCV results showing a change of **≥5** fL from the last specimen in inpatients will be referred to the charge tech for investigation to rule out mislabeled or adulterated specimens. It will then become the Charge Techs responsibility to cancel and request a redraw based on the investigation or allow the sample to be resulted. (See Section V)

III. Unusual Results

1) **Hematology:**
   - **Adult Platelet -** Adult platelet counts with an initial result < 100 should be checked for a clot. An internal comment (see comment section) should be attached to the PLT result. This will be in the form of a canned comment "CLNOCLT".
   - **Pediatric (0-18 yrs) Platelets -** Pediatric (0-18 yrs) patients with no clot detected but with platelet counts <100, and no previous PLT result require that the specimen be cancelled and a redraw be requested to confirm the decreased platelet. If the result from the second specimen is comparable to the first specimen, the internal comment "CLREPEAT" should be attached, then the specimen can be resulted. Once the patient has been confirmed as having a low platelet count, no further redraws are needed on specimens under the same account number/admission. This process is performed to ensure that the specimen is a valid sample and has not been compromised in the pre-analytical process thereby preventing unnecessary transfusions.

2) **Chemistry:**
   - **The serum hemolysis index test** is used as a detector of hemolysis. The instrument determines a hemolytic index on most samples. If the hemolytic index is **>100** the sample is considered too hemolyzed for analysis and results should not be released, unless approved by the Charge Technologist. If the specimen is hemolyzed, this requires notification to the nurse or physician. If this is the first hemolyzed specimen for the patient, it must be cancelled and recollected. (See Section III for samples with repeated hemolysis or urgent situations.)
   - Samples with a **potassium ≤ 2.5 and calcium ≤ 6.5** should be cancelled and a new sample should be requested. Decreased potassium and calcium is an indication that a sample has been adulterated. If the repeat sample matches the original, the internal comment "CLREPEAT" should be attached, and then the specimen can be resulted.

IV. Release of Unacceptable Results in Unusual Situations

There are situations in which results from otherwise unacceptable specimens may be released by the laboratory. Use the following information to determine whether and how results will be released:

1) **Urgent patient condition:** If a physician determines that the condition of a patient is extremely urgent and the laboratory results are absolutely essential for treatment decisions, results may be released with comment CLHMD. CLHMD is entered as an external comment and should be modified to explain the situation. The clinician must be instructed to obtain an appropriate specimen as soon as possible to verify accuracy of the results.

2) **Timed and other irretrievable specimens:** The following is a list of reasons that a sample can be considered irretrievable: patient death, femoral draw, venous inaccessibility, timed specimen collections, body fluid collection. If the technologist has any questions about whether a specimen is irretrievable, consult with the Charge Tech. The comment CLHMD must be entered as an external comment. Modify the comment to fit the situation.

3) **Neonatal Patients (0-6 months) hemolyzed specimens:** Neonatal patients (0-6 months) with a hemolysis index > 100 require notification to the nurse or physician if testing including a potassium is ordered. The nurse or physician must choose to release the result or recollect the patient sample. If the individual chooses to release the results, the external comment CLBABY must be attached to the potassium result. All other assays should be released with the "Hemolyzed – see note" result in the HEMCOM field and CLHEMBABY stating that the sample is hemolyzed and to proceed with caution.

4) **Repeat hemolyzed specimens:** If a patient has an initial hemolyzed specimen, and the redraw is also hemolyzed, there are two possibilities: the patient may actually have *in vivo* hemolysis, or the specimen may have been improperly drawn a second time. Repeat hemolyzed specimen results may be released with the "Hemolyzed – see note" result in the HEMCOM field. If the HEMCOM field does not show up under the test it must ordered in Meditech. The external comment CLREDRAW should be included after contacting a physician or nurse and explaining the situation. The pertinent topics for discussion are summarized in that comment. Particularly, discuss the possibility of *in vivo* hemolysis, because this can be a life-threatening emergency. This is hemolysis that occurs within the patient's bloodstream due to a disease process. Examples include sepsis, some parasites, autoimmune hemolytic anemia, some transfusion reactions, and some genetic red blood cell disorders. Ask whether the clinician would simply prefer another redraw than accept possibly inaccurate results. This situation should be reviewed with the Charge Tech before releasing results. The test should not be verified until all information is input into the comment.

For situations that do not fit into the above scenarios or when requests are made without sufficient medical necessity, consult the pathologist on call.

V. Communication of Rejected Samples

All rejected samples must be communicated to the patient care area. Samples that are determined to be Clotted or QNS should be canceled by the lab assistant. When a sample is hemolyzed, the sample should be canceled by the lab assistant after the technologist makes sure that any additional specimens from the same collection time are acceptable. The lab assistant should follow procedure for notification to redraw the sample. When a sample is considered to be Adulterated or Mislabeled, the Charge Tech should find all samples with the same collection time. The Charge Tech should contact the patient care area and speak with the physician/nurse taking care of the patient. The sample(s) should be canceled by the Charge Tech. An ORF must be written to document all mislabeled samples.

VI. Comments

The only comments to be used for unacceptable specimens are the coded comments below. In Meditech they can be found by using the F5 lookup button and entering the first few letters of the mnemonic. To make a comment internal the @ sign should be placed at the beginning of each line to prevent comments from displaying outside the laboratory. The Meditech computer system should do this automatically. However, CLBABY, CLHMD, CLREDRAW communicate important information to the clinical team and should therefore be entered as external. Free-texting of comments is prohibited unless it is approved by the charge tech.

VII. Canned Comments

Mnemonic	Description
CLBABY	RECOLLECTED SPECIMEN REQUESTED AT DUE TO (HEMOLYSIS OR LOW PLATELET). REQUEST DENIED BY [ ] DUE TO PATIENT CIRCUMSTANCES. ABOVE RESULTS SHOULD THEREFORE BE INTERPRETED WITH CAUTION AND IN LIGHT OF THE CLINICAL SITUATION.
CLNOCLOT	NO CLOT DETECTED
CLHMD	SLIGHT, MODERATE OR MARKED HEMOLYSIS PRESENT. HEMOLYSIS MAY CAUSE UNPREDICTABLE ALTERATIONS IN ELECTROLYTES AND OTHER ANALYTES. TESTING PERFORMED AT THE REQUEST OF [ ] AND APPROVED BY DR. [ ] DUE TO SPECIAL PATIENT CIRCUMSTANCES. IF IN VIVO HEMOLYSIS IS RULED OUT CLINICALLY, TIMELY FOLLOW UP SPECIMEN WITHOUT HEMOLYSIS IS ESSENTIAL.
CLREDRAW	DISCUSSED WITH [ ] . SPECIMEN REMAINS HEMOLYZED DESPITE REDRAW; PROCEED PER PROTOCOL. HEMOLYSIS MAY CAUSE UNPREDICTABLE ALTERATIONS IN ELECTROLYTES AND OTHER ANALYTES. RECOMMEND REPEAT ATTEMPT FOR UNHEMOLYZED SPECIMEN AT A CLINICALLY APPROPRIATE INTERVAL TO VERIFY RESULTS. CLINICAL CORRELATION IS ESSENTIAL TO RULE OUT TRUE IN VIVO HEMOLYSIS, WHICH MAY BE A MEDICAL EMERGENCY (TRANSFUSION REACTION, IMMUNE HEMOLYTIC ANEMIA, TOXIC EXPOSURE, ETC).
CLHEMBABY	HEMOLYSIS MAY CAUSE UNPREDICTABLE ALTERATIONS IN ELECTROLYTES AND OTHER ANALYTES. HEMOGLOBIN RELEASED FROM LYSED RED CELLS FALSELY LOWERS BILIRUBIN MEASUREMENTS. RESULTS WERE RELEASED DUE TO SPECIAL PATIENT CIRCUMSTANCES. IF IN VIVO HEMOLYSIS IS RULED OUT CLINICALLY, TIMELY FOLLOW-UP SPECIMEN COLLECTION WITHOUT HEMOLYSIS IS ESSENTIAL.
CLREPEAT	RESULTS VERIFIED BY REPEAT
LIPC	SPECIMEN LIPEMIC, CLARIFIED BY ULTRA CENTRIFUGATION BEFORE ANALYSIS