Criteria for rejection of samples and/or laboratory request forms

Distribution List:
Name or Location:
Quality Officer
Clinical Chemistry Department SMMC
Clinical Chemistry Department Main Building
Front office of all phlebotomy centrums (Main Building, SMMC, Betty Estate, Dutch Quarter, Colebay)
<table>
<thead>
<tr>
<th>Changes to previous versions</th>
<th>Date of Change</th>
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<tbody>
<tr>
<td>Change layout in the new procedure layout</td>
<td>31-03-2016</td>
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<tr>
<td>Par 2 Title: Principle (page 5)</td>
<td>31-03-2016</td>
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<td>Par 2 Delete first sentence and add more information (page 5)</td>
<td>31-03-2016</td>
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<tr>
<td>Delete par 4 Background and 5 Occupational Safety Environmental Aspects (page 5)</td>
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General Information

No part of this document shall be altered without the prior authorization of competent authority (either the department supervisor, Clinical Biochemist or Microbiologist). Any suggestions for change shall be written on a separate A-4 paper and submitted to their respective department supervisor and such suggestions for modifications can only be approved by the Clinical Biochemist / Medical Microbiologists. The new version will then be transferred to the Quality Officer to adapt the SOP and generate a new version.
1 Subject
This document describes the procedure for rejecting samples/laboratory forms within the SLS NV.

2 Principle
The result of any laboratory test is only as good as the specimen received by the laboratory. This protocol gives the appropriate action to be followed when specimens with incomplete or questionable identification, incorrect preservatives or external contamination are received by the laboratory. Each individual department within the laboratory may have additional listing of rejection depending on the specific testing criteria.

3 Definitions and common terms
aPTT activated Partial Thromboplastin Time
BRMO Bijzonder Resistente Micro Organisme
CSF Cerebral Spinal Fluid
DOB Date of Birth
ESBL Extended Spectrum Beta-Lactamase
ESR Erythrocytes Sedimentation Rate
ID Identification
IRAS Irregular Antibodies
MRSA Methicillin Resistant Staphylococcus Aureus
PSA Prostate Specific Antigen
PT Prothrombin Time
RBC Red Blood Cell
SAF Sodium Acetate Formalin
SLS NV St. Maarten Laboratory Services NV
SMMC St. Maarten Medical Center
WB Whole Blood
WBC White Blood Cell

4 Procedure
All (patient) samples shall be accompanied by a laboratory request form. These are received either at the distribution center in the main building of SLS NV or at the internal reception located at the SMMC. This is the initial checkpoint where the received samples are the correct ones, whether these were properly obtained and transported under the correct conditions and within the correct time frame. Furthermore, the laboratory forms are checked for completion. The patient requires three or more independent unique identifiers (such as DOB, family, first names, insurance or ID number, etc.).
4.1 Criteria for rejection

Specimens needs to be screened for acceptable/unacceptable conditions. All deficiencies or discrepancies will be corrected before the specimens are sent to the analytical section for processing. The requesting provider must be notified of rejected specimens and those needing resubmission.

4.1.1 General specimen and request data

4.1.1.1 Sample that are improperly labeled
- No label or no name/DOB/last name
- Specimen where the name/DOB DO NOT match the corresponding lab request form
- Specimens with insufficient patient information

4.1.1.2 Improper collection
- Specimen collected in inappropriate preservative/anticoagulant
- Quantity is not sufficient for the required tests
- The ratio between the whole blood and anticoagulant is inadequate which will affect the test result (e.g. ratio citrate/whole blood for coagulation tests)

4.1.1.3 Inappropriate specimens or forms
- Specimen collected from intravenous tubing or lock that has not been flushed
- Specimens drawn from areas that have lymphatic drainage
- Samples obtained from areas with badly damaged skin
- Specimens that have visual clots
- Specimens collected in the wrong (improper) container
- Grossly contaminated laboratory request forms

4.1.2 Department specific details and criteria

4.1.2.1 Delay in transit and/or improper storage/transportation conditions
- Serum specimens which have not been separated in a timely fashion from the clot (e.g. free PSA test)
- Samples not properly stored at the right temperature
- Samples not analyzed within the specified maximal allowable time (e.g. ESR samples > 4 hrs)
- Urine specimens left at room temperature > 2hrs
- Coagulation samples > 4 hrs (for aPTT) or > 24 hrs for PT

4.1.2.2 Hematology Department
- ESR tube > 4 hrs
- Manual diff only in samples < 8 hrs
- Coagulation: aPTT < 4 hrs old and PT < 24 hrs old at 4C
- Clots which will affect normal distribution of cells or false-low platelet counts
- Inadequate fill for coagulation tubes: ratio WB/citrate should be 8:1
- Coombs Indirect and IRAS: IRAS is only valid for 72 hrs
- Urine analysis: > 2hrs storage at room temperature
4.1.2.3 Clinical Chemistry Department
This is test specific:
- Icterus, lipemia or hemolysis
- Samples containing fibrin strands
- Serum not separated from clot on time

4.1.2.4 Microbiology Department
- Urine specimens contaminated with fecal material.

4.1.2.5 Water department
- Overfilled sample container
- Sample transportation not at the adequate temperature (on ice, temperature 10°C)
- Microbiological examination samples not in sterilized, non-reactive glass or plastic bottles
- Samples not properly collected
- Submission samples for analysis time greater than:
  - Legionella > 24 hours
  - Clostridia > 24 hours
  - Pseudomonas Aeruginosa > 24 hours
  - Plate count > 12 hours
  - Fecal Streptococcus > 6 hours
  - Enterococcus > 6 hours
  - E. Coli > 6 hours

4.1.3 Corrective actions
Upon receipt of an unacceptable sample and/or request form, the ordering physician or department ward or responsible nurse or contact person from the referring laboratory will be notified. In case of contaminated samples, no testing will be performed and a new sample will be requested. The laboratory personnel will fill and rejection form and also register the non-conformity in a logbook.

To determine the corrective actions applying to the criteria for the general specimen and request data, follow table 1: Corrective Actions for Rejection criteria of general specimen and request data on SLS.GEN.FOR.020 Corrective actions for rejection criteria.

To Determine the corrective actions applying to the criteria for the Department specific details and criteria, follow Table 2: Corrective Actions for Rejection criteria of department specific details on SLS.GEN.FOR.020 Corrective actions for rejection criteria.

5 Responsibilities
PPA worker and technicians are responsible to:
- Apply this acceptance and rejection criteria according this SOP
- Apply the corrective actions accordingly
- Inform the requester when there is a form and/or sample rejection
- Fill in a rejection form
- Document all rejections and/or non-conformities in a logbook

Quality Officer is responsible to:
- Compile on a monthly all rejections and register non-conformities
- Produce at a regular interval reports of the registrations

Management Team is responsible to:
- Design and execute the corrective plans to limits non-conformities

6 Comments
None

7 Accompanying form
- SLS.GEN.FOR.020 Corrective actions for rejection criteria form
- SLS.GEN.FOR.021 Laboratory request form and/or Sample rejection form
- Logbook for laboratory request form and/or sample rejection

8 Literature
ISO 15189:2012 Medical Laboratories-Requirements for quality and competence