96444.1362 Criteria for rejection for samples and Laboratory Request Forms

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Author
P. Manuel-Odoño

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Comments for version 2.0
Revised and adjusted.
Transferred to a new template to adapt medialab

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
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1.0	Retired	Initial version	07/10/2021	16/09/2022	27/02/2023

Linked Documents

- 96444.227 Sample Rejection Form
- 96444.1479 Sample Rejection Criteria and Corrective Actions

Criteria for rejection of Samples and/or Laboratory Request Forms

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Author:

Manuel-Odoño, Pauline

Authorizer:

Fleming, Chérina

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Par 6 Procedure; delete Exceptions (page 6)	31-03-2016
Change layout in the new procedure template	16-09-2022
Revised Purpose and procedure	16-09-2022
Final revision	21-02-2023

Criteria for rejection of Samples and/or Laboratory Request Forms

1 Table of Contents

Criteria for rejection of Samples and/or Laboratory Request Forms

2 Subject

This document describes the procedure for rejecting samples and laboratory forms within St. Maarten laboratory Services NV (SLS)

3 Definition and common terms

aPTT	activated Partial Thromboplastin Time
DOB	Date of Birth
ESR	Erythrocytes Sedimentation Rate
ID	Identification
IRAS	Irregular Antibodies
PSA	Prostate Specific Antigen
PT	Prothrombin Time
RBC	Red Blood Cell
SLS NV	St. Maarten Laboratory Services NV
SMMC	St. Maarten Medical Center
WB	Whole Blood
WBC	White Blood Cell

4 Purpose

The purpose of this document is to put in place a policy for accepting samples for standardization.
This policy should be adhered to by SLS clients and should be screened properly by SLS staff.

5 Principle and method of the procedure

All samples shall be accompanied with a laboratory request form. The request forms are received in all SLS front offices including the SLS Main building, STAT Lab (SMMC), and in all other Phlebotomy posts. Request forms should be screened properly in the front office before registration in the LIS system and before sample collection. The patient requires three or more independent unique identifiers in their lab request form (e.g., DOB, Last name, First name, Insurance number, ID number, etc.)

All accepted lab forms are registered and followed by sample collection. Samples are sent to the Distribution center (or STAT Lab if samples are from SMMC). This is the initial checkpoint for the accepted samples/lab forms, whether these were properly obtained and transported under the correct conditions and within the correct time frame.

5.1 Criteria for rejection

All specimens need 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.

5.1.1 General specimen and request data

5.1.1.1 Sample that are improperly labeled

- No label or no name/DOB/last name
- Specimen where the name or DOB DO NOT match the corresponding lab request form

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- Specimen with insufficient patient information

5.1.1.2 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)

5.1.1.3 Inappropriate specimen 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
- No valid ID/Insurance

5.1.2 Department specific details and criteria

5.1.2.1 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 correct temperature
- Samples not analyzed within the specified maximal allowable time (e.g., ESR samples > 4hrs)
- Urine specimens left at room temperature > 2hrs
- Coagulation samples > 4hrs (for aPTT) or > 24hrs for PT

5.1.2.2 Hematology Department

- ESR tube > 4hrs
- Manual diff only in samples < 8hrs
- Coagulation: aPTT < 4hrs old and PT < 24hrs old at 4°C
- Clots which will affect normal distribution of cells or false-low platelet counts
- Inadequate fill for coagulation tubes – ratio of WB: citrate should be 9:1
- Coombs Indirect and IRAS: IRAS is only valid for 72hrs
- Urine analysis: > 2hrs storage at room temperature
- Urine analysis: > 4hrs at 4°C for urine sediment: WBC and/or RBC count decay rapidly

5.1.2.3 Clinical Chemistry Department

This is test specific:

Icteric, lipemic or hemolyzed samples

- Samples containing fibrin strands
- Serum not separated from clot on time

5.1.2.4 Microbiology Department

- Urine specimens contaminated with fecal material

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5.1.2.5 Environmental and 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

5.1.3 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 out a rejection form and 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 96444.1479 Sample Rejection Criteria and Corrective Actions

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 96444.1479 Sample Rejection Criteria and Corrective Actions

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6 Responsibilities

- PPA worker and technicians are responsible to:
  - Apply this acceptance and rejection criteria according to 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

7 Comments/Remarks/Limitations

For special and emergency cases where it is difficult to apply the rejection criteria, please contact your supervisor or the laboratory specialist.

8 Accompanying form/document

- 96444.1479 Sample Rejection Criteria and Corrective Actions
- 96444.227 Sample Rejection form

9 References

- ISO 15189:2012 Section 5.4.4 Primary sample collection and handling, 5.4.6 Sample reception, 5.4.7 Pre-examination handling, preparation, and storage
- ISO 17025:2017 Handling of test or calibration items