




BIOGENIX

POLICY PROCEDURE FOR SAMPLE REJECTION

NAME		DESIGNATION	SIGNATURE	DATE
Prepared by	Ms. Preety Raheja	Quality Manager		30/06/2020
Reviewed by	Dr Bhagyashree Thakre	Deputy Lab Director		01/07/2020
Reviewed & Approved by	Dr Sally Abdulla Ibrahim	Lab Director		01/07/2020



POLICY PROCEDURE FOR SAMPLE REJECTION

Document Control: BG/PP/SAMP/010

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 01/07/2020

PAGE: 2 of 7

NEW REVIEW DATE: 30/06/2022

TABLE OF CONTENT

TABLE OF CONTENT	2
1 REVISION HISTORY	3
2 REVIEW HISTORY	4
3 POLICY STATEMENT	5
4 PURPOSE	5
5 SCOPE	5
6 DEFINITIONS	5
7 ACRONYMS	5
8 RESPONSIBILITIES	5
9 PROCEDURE	6
10 CROSS REFERENCE	7
11 RELEVANT DOCUMENTS & RECORDS	7



Document Control: BG/PP/SAMP/010

DATE OF EFFECTIVITY: 01/07/2020

NEW REVIEW DATE: 30/06/2022

[illegible]



Document Control: BG/PP/SAMP/010

DATE OF EFFECTIVITY: 01/07/2020

NEW REVIEW DATE: 30/06/2022

[illegible]



POLICY PROCEDURE FOR SAMPLE REJECTION

Document Control: BG/PP/SAMP/010

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 01/07/2020

PAGE: 5 of 7

NEW REVIEW DATE: 30/06/2022

3 POLICY STATEMENT

This policy defines the criteria for acceptance and rejection of samples in Biogenix laboratory and will be implemented as per the following procedure.

4 PURPOSE

4.1. To ensure accuracy of patient results by establishing criteria for rejection of specimens that is not suitable for analysis. This procedure is in accordance with ISO15189:2012 Medical laboratories requirement for quality and competence, clause 5.4.2. (j) and 5.4.6.

4.2. Biogenix laboratory follows this procedure for sample acceptance and rejection.

5 SCOPE

- 5.1. Specimen acceptance criteria apply in general to all specimens collected or received by Laboratory.
- 5.2. Target Audience: All BIOGENIX Laboratory staff

6 DEFINITIONS

- 6.1. Temperature Data logger: is an electronic device that records temperature over time.
- 6.2. Sample: Biological Sample

7 ACRONYMS

- 7.1. N.A.

8 RESPONSIBILITIES

- 8.1. It is the responsibility of the medical facilities to assign qualified professionals to collect the samples.
- 8.2. It is the responsibility of the medical facility to store the samples following correct environmental condition during and after collection.
- 8.3. It is the responsibility of the medical facility to safely and immediately transport the collected samples into cool boxes or transport boxes filled with ice. Transport boxes should be attached with data logger to check the temperature of the samples by laboratory personnel upon receiving them.
- 8.4. It is the responsibility of the medical facility to maintain the integrity of the sample until being received at the laboratory reception.



POLICY PROCEDURE FOR SAMPLE REJECTION

Document Control: BG/PP/SAMP/010

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 01/07/2020

PAGE: 6 of 7

NEW REVIEW DATE: 30/06/2022

- 8.5. It is the responsibility of the laboratory technologists receiving the samples to inspect their suitability for testing.
- 8.6. It is the responsibility of the laboratory technologists to relay the data of rejected samples to laboratory coordinators, who should in turn inform the sending medical facility.

9 PROCEDURE

9.1. General Precautions

- 9.1.1. Treat all specimens as possibly infective.
- 9.1.2. Wear the required PPE for the Sample Collection Room as described in the PPE Policy

9.2. Criteria of Rejecting Samples

- 9.2.1. No proper patient identification.
- 9.2.2. Un labelled sample
- 9.2.3. Sample without request form
- 9.2.4. Improper filled request form.
- 9.2.5. Discrepancy between the specimen and request form ID stickers.
- 9.2.6. Incorrect sample type.
- 9.2.7. Incorrect sample container
- 9.2.8. Insufficient quantity.
- 9.2.9. Not covered by the insurance
- 9.2.10. Blood level doesn't reach the mark on the anticoagulant tube.
- 9.2.11. Incorrect preparation of the patient
- 9.2.12. Finding a clot in an anticoagulant tube
- 9.2.13. Leaking specimens
- 9.2.14. Improper storage (temperature not maintained) or delay in delivering the sample
- 9.2.15. Hemolysed samples
- 9.2.16. Contamination of the specimen with other substances e.g. urine or stool
- 9.2.17. Incorrect time of specimen collection.
- 9.2.18. Outdated equipment e.g. expired tubes, containers or transport media.

9.3. Action to be taken if sample is rejected:

- 9.3.1. Determine the origin of the discrepancy (phlebotomist, nurse, etc.)
- 9.3.2. Contact the appropriate physician /charge nurse and inform them of the discrepancy.
- 9.3.3. Requesting clinic or physician is informed.
- 9.3.4. Request appropriate measures to be taken (re-draw, submit proper request form, claim form etc.)
- 9.3.5. If the rejected sample was sent from an outside clinic, the lab.staff sends an illustration indicating which tube to be used for the test.
- 9.3.6. If needed, the lab demonstrates to nurse the phlebotomy procedures.
- 9.3.7. If an entirely new specimen is required, the original request is returned to be sent again with the new specimen



POLICY PROCEDURE FOR SAMPLE REJECTION

Document Control: BG/PP/SAMP/010

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 01/07/2020

PAGE: 7 of 7

NEW REVIEW DATE: 30/06/2022

- 9.3.8. If a second specimen of a different type is necessary to complete a requisition, the laboratory staff notifies the appropriate nurse that a specimen is missing. The test is then deleted from the request. The person notified and the reason for the deletion is noted on the request form/ LIS. The deleted test is re-ordered when the new specimen arrives.
- 9.3.9. If a requisition does not match the specimen (for example: 24 hours urine specimen with random urine request), the nurse responsible for generating the request is contacted. Patient must re-collect or make appropriate corrections (by coming to the laboratory) as deemed necessary by the laboratory staff.
- 9.3.10. If the patient specimen is rejected and cannot be re-drawn, an attempt is made to contact the ordering physician and inform him/her of the circumstances. This is to be noted on the requisition form.
- 9.3.11. In case the specimen and request were accepted by the laboratory reception without noticing that it should have been rejected for example hemolyzed sample was found after centrifugation, the technical staff informs the laboratory coordinator immediately to correct and contact the patient or sending clinic.
- 9.3.12. Sample Rejection Log (BG/REC/PHLEB/003) is filled by Laboratory technical staff.

10 CROSS REFERENCE

- 10.1. ISO15189:2012 Medical Laboratories Requirement for Quality and competence.
- 10.2. HAAD Clinical Laboratory standards, Version1.0, (PP9.4)

11 RELEVANT DOCUMENTS & RECORDS

- 11.1. BG/REC/SAMP/003 Sample Rejection Form