






BIOGENIX

POLICY PROCEDURE FOR SAMPLE LABELLING

	NAME	DESIGNATION	SIGNATURE	DATE
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SAMPLE LABELLING PROCEDURE

CODE: BG/PP/SAMP/002

VERSION: 1.0

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**DATE OF EFFECTIVITY:
01/07/2020**

NEW REVIEW DATE: 30/06/2022

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1. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				





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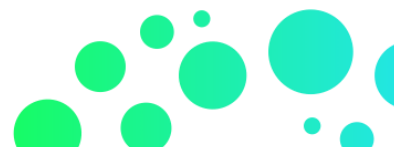
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3. POLICY STATEMENT

- 3.1 Proper labeling is very important to avoid sampling error, after proper identification of patients.

4. PURPOSE

- 4.1 The purpose of this policy is to describe proper labeling of collection tubes and containers, and information that should be included in the label.
- 4.2 This procedure is in accordance with clause no. 5.4.4.3. of ISO 15189 Medical laboratory- Requirements for Quality and Competence

5. SCOPE

- 5.1 All the procedures involved in labeling of the specimen for positive patient identification.
- 5.2 Target Audience: All BIOGENIX Laboratory staff

6. DEFINITIONS

- 6.1 N/A

7. ACRONYMS

- 7.1 N/A

8. RESPONSIBILITIES

- 8.1 9.1. BIOGENIX Management
- 8.2 9.2. BIOGENIX Laboratory staff and team leaders

9. PROCEDURE

- 9.1 **Patient Registration based on Self / External Doctors:**
 - 9.1.1 Reception team carry's out day-to-day responsibilities associated with the receiving of self-patients. Patient registration is taken care by Reception staff. The patient fills registration form and through this





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patient permanent identification number is generated and registration process starts from here.

9.1.2 The Reception staff accepts the "Request Form" from referral physician/patients.

9.1.3 Patient comes to Laboratory for testing along with a Request Form if the patient doesn't have request form, the same is generated by the reception staff and the patient is requested to sign.

9.1.4 In any ways no sample are processed without registering in LIS.

9.1.5 Patient fills the Consent forms at the time of registration;

9.1.6 Patient's demographic details and tests requested are entered in the LIS.

9.1.7 A permanent identification number of the patient is generated.

9.1.8 A barcode is generated.

9.1.9 The label i.e. barcoded sticker has the following information:

9.1.9.1 Barcode number

9.1.9.2 Patient's Name

9.1.9.3 Patient's age

9.1.9.4 Permanent identification number

9.1.9.5 Date and time

9.1.10 All urgent requests are identified with "U" in LDM and any Urgent stamp the Request Form so that it can be differentiated from routine samples and processed on priority basis.

9.2 For Specimens which are received from outside clinics or laboratories.

9.2.1 Upon arrival of specimen to the laboratory (for outside sample), the information on the specimen label is matched by laboratory technical staff, with the information on the requisition form./portal (ID sticker, if there is discrepancy, the specimen and request are rejected).

9.2.2 Check the specimen: its volume, anticoagulant used, leakage ...etc

9.2.3 The staff who receives the samples check the samples for the number of tubes and volume of sample. Staff then write on the request form all the information and do signatures

9.2.4 For some special tests Patients family history, travel and exposure history, communicable diseases and other clinically relevant information are provided.

9.2.5 After identification the specimens are accepted for analysis, request is handed over to the reception for registration.

9.2.6 The samples that are received from outside are labeled in a way that original identification is visible so that an unequivocal link with the patients from whom they are collected.

9.2.7 Each patient is given a unique identification number.

9.2.8 All the demographic details are entered by Lab. Reception staff in LIS.



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- 9.2.9 All samples are labeled with the barcoded stickers generated by laboratory reception.
- 9.2.10 Samples are labeled in such a way that they are unequivocally traceable, to an identified site or patient.
- 9.3 **Once the barcode is generated it is attached to all the samples of concerned patient.**
- 9.4 **Amendments made to Test Request:**
 - 9.4.1 Any additions or deletions to the test requests are informed to the Laboratory Director, Laboratory Coordinator, laboratory staff and reception staff and also informed to referral doctor when relevant and is documented.
- 9.5 **Test request is approved after considering the following:**
 - 9.5.1 Whether the test and test method requested is within the scope of testing of the laboratory.
 - 9.5.2 Test method requested capable of meeting customer requirements wherever applicable.
 - 9.5.3 Laboratory capacity to release the report at requested time by the patient/clinic.
 - 9.5.4 Patient preparation criteria are followed.
 - 9.5.5 All the samples which are received from outside is received by laboratory technical staff. Date and time of sample receiving and how many types of samples and tubes are received and who received the sample all information is documented.
 - 9.5.6 The laboratory staff who is receiving the samples check the samples as per criteria mention in Procedure for Sample acceptance.
 - 9.5.7 Samples are transported to the laboratory as per the sample transport procedure.
 - 9.5.8 Amendments to the test requests can be accepted after commencement of work & any such amendment is not considered as new requisition until the final test report is printed.

10. CROSS REFERENCE

- 10.1 ISO 15189:2012 Medical laboratories Requirements for quality and competence for clinical laboratories.
- 10.2 HAAD standard for clinical laboratory.

11. RELEVANT DOCUMENTS & RECORDS





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11.1

N/A

