BIOGENIX

POLICY PROCEDURE OF COVID-19 SAMPLE RECEVING AND IN ACTIVATION

	NAME	DESIGNATION	SIGNATURE	DATE
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1. REVISION HISTORY

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

2. REVIEW HISTORY

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1	1.0				

3. POLICY STATEMENT

3.1 The process of COVID sample receiving and inactivation can affect the suitability of specimens for analysis. The policy is implemented as per the following procedure.

4. PURPOSE

4.1 This procedure is in accordance with ISO15189:2012 clause 5.4.6. Biogenix follows this policy and procedure of COVID sample receiving and inactivation.

4.2 To assure that the samples which are collected in Biogenix phlebotomy room or coming from the outsides centers /clinics /labs, reach the laboratory by following proper conditions.

4.3 Samples are received by authorized person

4.4 The identity of the person receiving the sample is recorded.

4.5 All samples are entered in the LIS.

5. SCOPE

5.1 The scope this procedure extends to COVID sample receiving and inactivation.

5.2 Target Audience: BIOGENIX Laboratory staff

6. DEFINITIONS

6.1 **Customer:** Self patient/referred patient/ referral clinician

6.2 **Receiving:** be given, be presented with, collect, accept.

6.3 **Processing:** Preparing the specimen for analysis

7. ACRONYMS

7.1 N.A.

8. RESPONSIBILITIES

8.1 It is the responsibility of the technical staff receiving the sample to properly examine their acceptability according to the established criteria and prepare them for processing.

9. PROCEDURE

9.1 **General Precautions**

9.1.1 Treat all specimens as possibly infective.
9.1.2 Wear laboratory coat
9.1.3 Gloves should be worn when handling all specimens
9.1.4 Gloves should be changed when contaminated and hands should be washed after removal of gloves.
9.1.5 Facial protection devices should be used when there is a possibility of specimen splashing.
9.1.6 Laboratory surface (benches) should always be clean
9.1.7 Care with bio hazard waste (specific garbage can, bag and label).
9.1.8 Sharps should be disposed in their special containers.
9.1.9 Work area is divided into red and green zones by applying colored tapes to the edges of them. Gloves should be worn while working in the red zone and vice versa in the green zone.

9.2 **Specimen Receiving**

9.2.1 Upon arrival of specimen to the laboratory, the information on the specimen label should be matched with the same information on the requisition form. (ID sticker, if there is discrepancy the specimen and request will be rejected and informed to lab coordinator to communicate the rejection with the requesting facility).
9.2.2 Specimen will be accessioned in the LIS using barcode.
9.2.3 Check the specimen: its volume, anticoagulant used, no leakage …etc.
9.2.4 After positive verification, identification and accessioning the specimens are accepted for analysis and distributed to different laboratory sections.
9.2.5 They are rechecked once again for the tests ordered before analysis.

9.3 **Specimen Inactivation**

9.3.1 Nasopharyngeal Swabs

9.3.1.1 Sample inactivation in the oven at 70 degrees for 1 hour
9.3.1.2 After keeping the samples in the Oven for inactivation fill the COVID-19 Sample Inactivation Record.
9.3.1.3 After taking out the samples from oven fill the Sample Information Verification Record
9.3.1.4 Samples are then barcoded and batched
9.3.1.5 After inactivation completes fill the Matching Serial No. Details record sheets.
9.3.1.6 Prepare the sample to keep in pass box for Extraction room along with Record of Inactivated Sample Handover to Extraction Room

9.4 **Storage and Stability:**

If samples are not processed the same time

9.4.1 Negative Samples are stored at -20 to -80 for 1 week
9.4.2 Positive samples are stored at -80 for 6 months

10. CROSS REFERENCE

10.1 ISO 15189 :2012 Medical laboratories – Requirements for Quality and Competence
10.2 Sample Acceptance and Rejection Criteria
10.3 KaiBiLi Extended ViralTrans Kit Insert, HANGZHOU GENESIS

11. RELEVANT DOCUMENTS & RECORDS

11.1 Policy and Procedure of PPE
11.2 BG/REC/SAMP/003 Sample Rejection Log sheet
11.3 BG/REC/SAMP/006 COVID-19 Sample Inactivation Record
11.4 BG/REC/SAMP/004 Sample Information Verification Record
11.5 BG/REC/SAMP/005 Matching Serial, No Details record sheets
11.6 BG/REC/SAMP/007 Record of Inactivated Sample Handover to Extraction Room