BIOGENIX

POLICY PROCEDURE OF COVID-19 SAMPLE COLLECTION, HANDLING AND TRANSPORTATION

	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
Approved by	Dr Sally Abdulla Ibrahim	Lab Director		01/07/2020

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 5
10. CROSS REFERENCE 7
11. RELEVANT DOCUMENTS & RECORDS 8

1. REVISION HISTORY

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

2. REVIEW HISTORY

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

3. POLICY STATEMENT

3.1. The Primary sample collection, handling and transportation has to be done as per the following procedure.

4. PURPOSE

4.1. This procedure is in accordance with ISO15189:2012 clause 5.4.4. and 5.4.5. Biogenix laboratory follows this procedure of COVID Sample Collection, handling and transportation to assure that the samples which are collected is coming from the outsides centers /clinicians/labs, collected, handled and transported following proper conditions.

4.2. Samples are transported to the laboratory in timely manner by taking care of environmental conditions, such as temperature, humidity, light etc.

4.3. The integrity of the sample is not to be compromised at any stage.

5. SCOPE

5.1. The scope this procedure extends to primary sample collection, handling and transportation.

5.2. Target Audience: BIOGENIX Laboratory staff

6. DEFINITIONS:

6.1. N.A.

7. ACRONYMS

7.1. **PPE:** Personal Protective Equipment

7.2. **BALF:** Broncho alveolar Lavage Fluid

8. RESPONSIBILITIES

8.1. All BIOGENIX Laboratory Staff.

9. PROCEDURE

9.1. **PATIENT INSTRUCTION:**

9.1.1 The suspected cases are told to avoid eating, drinking and aerosol inhalation and antibiotic treatment 2 hours before sampling operation.

9.2. **SAMPLE COLLECTION:**

9.2.1 Wear full PPE as per PPE procedure.

9.2.2 Consider all the patients as potentially infected

9.2.3 As soon as the patient enters the phlebotomy room, create a warm atmosphere by greeting the patient to alleviate fear.

9.2.4 Explain the procedure to be done (phlebotomy) to reassure the patient that you know what you are doing and that he/she is in good hands.

9.2.5 After accessioning print the barcode.

9.2.6 Reassure the patient that procedure will cause temporary discomfort.

9.2.7 Take care do not wet the swab before sampling with the transport medium.

9.3. **Pharyngeal swab sample collection:**

9.3.1 Use a polyester fiber head swab to gently rub the posterior pharyngeal wall (sacral or small tongue) and the bilateral tonsils on the back of the uvula, to avoid touching the tongue. Remove the rear sampling tube and break it. Soak the swab in the sampling solution with the plastic handle of the hand touching the part, and screw the cap tightly.

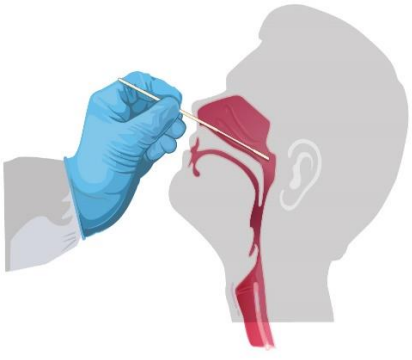
9.4. **Nasal swab sample collection:**

9.4.1 Use a polyester fiber head swab to insert the nostril in the direction of the vertical nose (face) until the finger touches the nose.

9.4.2 Keep the swab in the nose for 15-30 seconds, then gently rotate it 3 times.

9.4.3 Swabs are placed immediately into a sterile transport tube containing 2-3mL of viral transport medium (VTM)

9.4.4 Break the plastic handle of the hand contact area, soak the swab into the sampling solution, and screw the cap tightly.



Note: Use only synthetic fiber swabs with plastic or wire shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.

9.4.5 Alveolar lavage fluid sample collection: Collect fresh BALF without any pretreatment in a dry, sterile, DNA / RNase-free cryopreservation tube.

9.5. **HANDLING**

9.5.1 Label the specimen on viral transport media tube and ensure cap on tube is tightly sealed. (Do not use a pencil or pen for labeling, as they can rub off or smear. Instead, use a bar code or permanent marker).

9.5.2 Include a frozen cold pack with the specimen(s).

9.5.3 Specimens are placed into sterile viral transport media and immediately placed on refrigerant gel packs or at 4 degrees Celsius (refrigerator) for transport

9.5.4 Transport box reception in sample collection room log sheet is filled by referral clinic staff

9.6. **SAMPLE TRANSPORTATION**

9.6.1 Specimens should be transported in a timely manner.

9.6.2 All specimens (containers) should be placed and sealed in the plastic bags accompanied by the appropriate requisition form.

9.6.3 Specimen collection tubes with blood samples can also be transported using racks placed inside the specimen transport box.

9.6.4 Use specimen transport cool boxes. Samples received without proper precautions will be rejected.

9.6.5 Ship specimens for testing as soon as possible at 2-8 degrees.

9.6.6 If delivery is delayed for more than 3-4 days, specimen is kept frozen at -70 degrees Celsius (-94 degrees Fahrenheit).

Sample type	Storage conditions	Freeze-thaw, mixing conditions	Transportation conditions
Pharyngeal swabs / nasal swabs / alveolar lavage fluids	Short-term storage below -18 ℃ Long-term storage below -70 ℃	Repeated freeze-thaw	Dry ice transportation

10. CROSS REFERENCE

10.1. Genesis Kaibili Extended ViralTrans Kit insert

10.2. Safety management of nasopharyngeal specimen collection from suspected cases of coronavirus disease 2019* Yan Qian , Tieying Zeng , Hui Wang *, Min Xu , Junhua Chen , Na Hu , Daiqi Chen , Yu Liu Tongji Hospital, Tongji Medical College of Huazhong University of Science & Technology, Wuhan, Hubei, China

10.3. ISO 15189 :2012 Medical laboratories – Requirements for Quality and Competence

11. RELEVANT DOCUMENTS & RECORDS

11.1. BG/REC/MOL/003 COVID SampleTransport Package Reception Record

11.2. BG/POS/INF/004 Donning of PPE Illustration

11.3. BG/POS/INF/005 Doffing of PPE Illustration