

**Standard Test Procedure for Sars Covid 19  
Sample Collection and Transportation**

**1.0 Purpose and Scope:**

This STP provides the guidelines to the sample collection and technical staff, instructions for preparation of the patient for the test, sample collection techniques, separation if any and transportation of samples to SagePath Labs (SPL) Private Limited for testing.

**2.0 Responsibility:**

**2.1** It is the responsibility of all Customers/Clients (Hospitals, Nursing Homes, Diagnostic and Pathological Labs, Clinicians and Clinics) to follow the procedures given in the manual during sample collection and transportation.

**2.2** It is the responsibility of the Laboratory staff members to ensure that the samples are received as per the given requirement.

**2.3** It is the responsibility of the Head of Sales and Sales team to implement the same.

**3.0 General Consideration :**

**3.1** Laboratory tests results contribute relevant information about a patient's health. Correct diagnosis relies on the accuracy of test results. Correct and adequate patient preparation, specimen collection, and specimen handling are essential prerequisites for accurate test results. The accuracy of test results is dependent on the integrity of specimens.

**4.0 EQUIPMENT AND PREPARATION**

**4.1** Viral transport medium (VTM)

**4.2** Nasopharyngeal Swabs

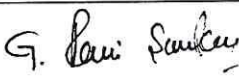
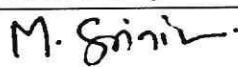

**4.3** Oropharyngeal Swabs

**4.4** Test Requisition form

**4.5** Personal protective equipment (PPE)

**5.0 Universal Safety Precautions:**

**5.1** Before beginning the procedure, the requisition form should be filled properly with patient details, travel history, contact history, and contact number of patient and the doctor.

Prepared by: Dr.G.Ravi sankar	Reviewed by: Mr.M.Srinivas	Approved by: Dr.Raturaj
		
Issue No: 1.0	Issue Date: 01.06.2021	Page 0 of 6
Amend. No.: 00	Last Amend. Date: 00	

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**Standard Test Procedure  
For Sars Covid 19 Sample Collection**

**5.2** The novel coronavirus testing specimens shall be collected by qualified technicians who have received biosafety training (who have passed the training) and are equipped with the corresponding laboratory skills. Personal protective equipment (PPE) requirements for sampling personnel are: N95 masks or masks with higher filtration efficiency, goggles, protective clothing, double-layer latex gloves and waterproof boot covers; the outer layer of the latex gloves shall be changed in a timely manner should sampling personnel touch patients' blood, body fluids, secretions etc.

**5.3** Specimens of inpatient cases shall be collected by medical staff of the hospital where they are being treated.

**6.0 Sample Collection General**

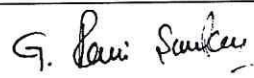
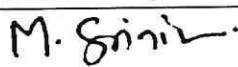
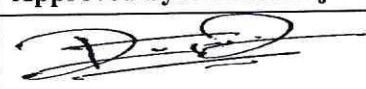
**6.1 Trained Personnel for Sample Collection:**

- 6.1.1** Ensure that the trained personnel are deputed for Patient Sample collection.
- 6.1.2** Training should be given on Phlebotomy procedures, personnel safety, handling of emergencies during specimen collection, handling and packing of specimens, handling and cleaning of biological spills.
- 6.1.3** Periodic training has to be provided to all the personnel involved in the specimen collection.

**7.0 Primary Sample Collection**

**7.1** Proper specimen collection is the most important step in the laboratory diagnosis of infectious diseases. A specimen that is not collected correctly may lead to false or inconclusive test results. The following specimen collection guidelines follow standard recommended procedures.

**7.2** For initial diagnostic testing for current SARS-CoV-2 infections, CDC recommends collecting and testing an upper respiratory specimen. Contact the testing laboratory to confirm accepted specimen types and follow the manufacturer instructions for specimen collection. Sterile swabs should be used

Prepared by: Dr.G.Ravi sankar	Reviewed by: Mr.M.Srinivas	Approved by: Dr.Ruturaj
		
Issue No: 1.0	Issue Date: 01.06.2021	Page 1 of 6
Amend. No.: 00	Last Amend. Date: 00	

**CONTROLLED COPY**

**Standard Test Procedure  
For Sars Covid 19 Sample Collection**

for the collection of upper respiratory specimens. This is important both to ensure patient safety and preserve specimen integrity. Note that nasopharyngeal and oropharyngeal specimens are not appropriate for self-collection.

**7.3** Testing lower respiratory tract specimens is also an option. For patients who develop a productive cough, sputum can be collected and tested for SARS-CoV-2 when available. However, the induction of sputum is not recommended due to the possibility of aerosol production during the procedure. Under certain clinical circumstances (e.g., for those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage specimen can be collected and tested as a lower respiratory tract specimen.

**7.4 Upper respiratory tract**

**7.4.1** Nasopharyngeal specimen (NP) collection /Oropharyngeal (OP) (throat) specimen collection (performed by a trained healthcare provider, only).

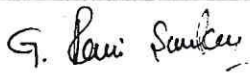
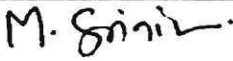

**7.4.2** Use only synthetic fiber swabs with thin plastic or wire shafts that have been designed for sampling the nasopharyngeal mucosa. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and may inhibit molecular tests.

**7.4.3** both NP and OP specimens are collected, combine them in a single tube to maximize test sensitivity and limit use of testing resources.

**7.4.4 Instructions for collecting an Nasopharyngeal specimen (performed by a trained healthcare provider):**

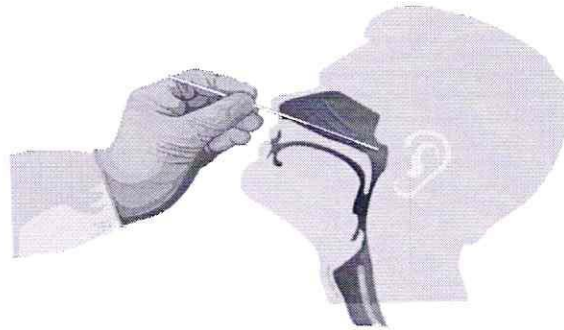
**7.4.4.1** Tilt patient's head back 70 degrees.

**7.4.4.2** Gently and slowly insert a minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.

Prepared by: Dr.G.Ravi sankar	Reviewed by: Mr.M.Srinivas	Approved by: Dr.Raturaj
		
Issue No: 1.0	Issue Date: 01.06.2021	Page 2 of 6
Amend. No.: 00	Last Amend. Date: 00	

**CONTROLLED COPY**

**Standard Test Procedure  
For Sars Covid 19 Sample Collection**



**7.4.4.3** Gently rub and roll the swab.

**7.4.4.4** Leave swab in place for several seconds to absorb secretions.

**7.4.4.5** Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab tip is saturated with fluid from the first collection.

**7.4.4.6** If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

**7.4.4.7** Place swab, tip first, into the Viral Transport Medium tube provided.

**7.4.5 Instructions for collecting an OP specimen (performed by a trained healthcare provider):**

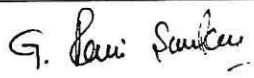
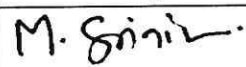
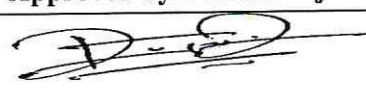
**7.4.5.1** Insert swab into the posterior pharynx and tonsillar areas.

**7.4.5.2** Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

**7.4.5.3** Place swab, tip first, into the Viral Transport Medium tube provided.

**7.5 Lower respiratory tract**

**7.5.1 Bronchoalveolar lavage, tracheal aspirate, pleural fluid, lung biopsy (generally performed by a physician in the hospital setting)**

Prepared by: Dr.G.Ravi sankar	Reviewed by: Mr.M.Srinivas	Approved by: Dr.Ruturaj
		
Issue No: 1.0	Issue Date: 01.06.2021	Page 3 of 6
Amend. No.: 00	Last Amend. Date: 00	

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**Standard Test Procedure  
For Sars Covid 19 Sample Collection**

**7.5.1.1** Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

**7.5.1.2** Due to the increased technical skill and equipment needs, collection of specimens other than sputum from the lower respiratory tract may be limited to patients presenting with more severe disease, including people admitted to the hospital and/or fatal cases.

**7.5.2 Sputum (collected under the guidance of a trained healthcare professional)**

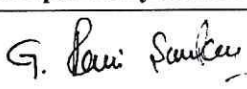
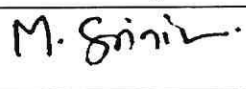
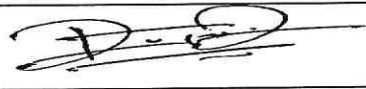
**7.5.2.1** For patients who develop a productive cough, sputum can be collected and tested when available for SARS-CoV-2. However, the induction of sputum is not recommended. Educate the patient about the difference between sputum (deep cough) and oral secretions (saliva/spit). Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap collection cup or sterile dry container.

**7.5.2.2** Note: This is an aerosol-generating procedure and likely to generate higher concentrations of infectious respiratory aerosols. Aerosol-generating procedures potentially put healthcare providers and others at an increased risk for pathogen exposure and infection. Healthcare providers should maintain proper infection control, including standard precautions, and wear an N95 or equivalent or higher-level respirator, eye protection, gloves, and a gown, when collecting specimens.

**8.0 Specimen packaging**

**8.1** Collected specimens shall be packaged separately in a biosafety cabinet of a BSL-2 laboratory.

**8.2** All specimens should be placed in an airtight freeze-tolerant sample collection tube of appropriate size, with a screw cap and a gasket inside. The sample number,

Prepared by: Dr.G.Ravi sankar	Reviewed by: Mr.M.Srinivas	Approved by: Dr.Raturaj
		
Issue No: 1.0	Issue Date: 01.06.2021	Page 4 of 6
Amend. No.: 00	Last Amend. Date: 00	

**CONTROLLED COPY**

**Standard Test Procedure  
For Sars Covid 19 Sample Collection**

category, name and sampling date should be indicated on the outside of the container.

**8.3** The labelled VTM should be placed inside the pouch and sealed with adhesive tape. If the cover is not available, a small-size zip-lock bag should be used. The packed VTM should be placed inside another zip-lock bag which acts as the second layer. Finally, the package should be inserted into a solid, unbreakable, leak-proof outer container which serves as the third layer. The VTM, zip-lock bag and the outer container should be labelled properly.

**9.0 Specimen Transportation:**

**9.1** Collected specimens should be sent to laboratories as soon as possible.

**9.2** The specimen should be transferred to the laboratory maintaining cold chain (2-4°C) throughout. The packed specimen should be placed inside the ice-box; two ice-pads should be placed on both sides of the container. The ice-box should be cleaned thoroughly outside with 1 % sodium hypochlorite and transferred to the laboratory as soon as possible with prior communication. If there is delay of more than 72 hours, sample should be stored at -70°C. Specimen data forms, letters, and other types of information that identify or describe the specimen for testing of SARS-COV-2 should be carried separately.

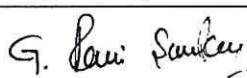
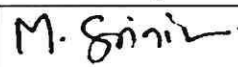
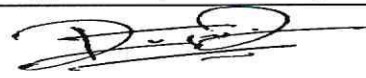
**10.0 Storing and Shipping Respiratory Specimens**

**10.1** - Store respiratory specimens at 2-8°C for up to 5 Days after collection. If a delay in testing or shipping is expected, store specimens at -70°C.

**11.0 RETENTION OF TESTED SAMPLES**

Sr. No.	Department	Sample Retention Period	Storage Temperature
1	Molecular Biology-Viral Transport Medium	48 hrs	2-8°C
2	Molecular Biology-Covid Extracted RNA	30 days	-80 °C

**12.0 References: CDC and ICMR Guidelines**

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Issue No: 1.0	Issue Date: 01.06.2021	Page 5 of 6
Amend. No.: 00	Last Amend. Date: 00	

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