



Documented Procedure

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Standard Operating Procedure

Specimen Collection, Packaging and Transport Guidelines for 2019 Novel Corona virus (COVID 2019)

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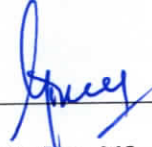
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1. Abbreviations:

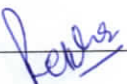

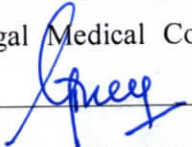
- VRDL: Viral Research and Diagnostic Laboratory
- ICMR: Indian Council of Medical Research
- NIV: National Institute of Virology
- SARI: Severe Acute Respiratory Illness
- ILI: Influenza like illness
- MoHFW: Ministry of Health and Family Welfare
- WHO: World Health Organization
- CRH: Central Referral Hospital
- VTM: Viral Transport Medium
- EDTA: Ethylenediaminetetraacetic acid
- NICED: National Institute of Cholera and Enteric Diseases

2. Scope:

To be followed by health authorities/ clinicians/ laboratories collecting the appropriate clinical samples as indicated for diagnosis of COVID-19.

3. Purpose:

This document describes the information for collection, packaging and transport of clinical specimens to VRDL centre North Bengal Medical College or NICED,

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Kolkata or ICMR-National Institute of Virology (NIV), Pune, for diagnosis of 2019 Novel Coronavirus (2019- nCoV).

4. Responsibilities:

- The clinician should decide necessity for collection of clinical specimens for laboratory testing of 2019-nCoV only after following the case definition as given by the health authorities, Government of India.

Keep updates on the case definition as it keeps changing

- Appropriate clinical sample need to be collected by laboratory personnel/ health care worker trained in specimen collection in presence of a clinician.
- By following all biosafety precautions and using personal protective equipment (PPEs), clinical samples need to be sent to the designated laboratory by following standard triple packaging.

5. Selection of patient:

- I. Symptomatic international traveler in last 14 days
- II. Symptomatic contact of lab confirmed case
- III. Symptomatic healthcare worker
- IV. Hospitalized SARI patient
- V. Asymptomatic direct and high risk contact of lab confirmed case
- VI. Asymptomatic healthcare worker in contact with confirmed case without adequate protection
- VII. Symptomatic ILI patient in hospital/ MoHFW identified clusters

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6. Specimen collection details: (Adapted from the WHO guidelines on 2019-nCoV):

Specimen type	Collection materials	Transport to laboratory	Storage till testing	Comment
Nasopharyngeal and oropharyngeal swab	Dacron or polyester flocculated swabs*	4 °C	≤5 days: 4 °C >5 days: -70 °C	The nasopharyngeal and oropharyngeal swabs should be placed in the same tube to increase the viral load.
Bronchoalveolar lavage	sterile container*	4 °C	≤48 hours: 4 °C >48 hours: -70 °C	There may be some dilution of pathogen, but still a worthwhile specimen
Tracheal aspirate, nasopharyngeal aspirate or nasal wash	sterile container*	4 °C	≤48 hours: 4 °C >48 hours: -70 °C	Not applicable
Sputum	sterile container*	4 °C	≤48 hours: 4 °C >48 hours: -70 °C	Ensure the material is from the lower respiratory tract
Tissue from biopsy or autopsy including from lung	sterile container with saline	4 °C	≤48 hours: 4 °C >48 hours: -70 °C	Autopsy sample collection preferably to be avoided
Serum (2 samples – acute and convalescent)	Serum separator tubes (adults: collect 3-5 ml whole blood)	4 °C	≤5 days: 4 °C >5 days: -70 °C	Collect paired samples: • acute – first week of illness • convalescent – 2 to 3 weeks later

*For transport of samples for viral detection, use VTM (viral transport medium) containing antifungal and antibiotic supplements. Avoid repeated freezing and thawing of specimens.

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7. Steps to follow in sample collection and packaging in CRH

1. Collect all the necessary items like VTM, EDTA and Serum separating tubes, Parafilm, Nylon swabs from the microbiology section of Central Laboratory, CRH
2. Fill the form (specimen referral form) kept at the evaluation ward clearly for each patient by the clinician.
3. Appropriate clinical sample need to be collected by health care worker trained in specimen collection in presence of a clinician.
4. One nasopharyngeal and one oropharyngeal swab is to be collected in nylon or dacron or polyester flocced swabs and immediately put both the swabs into VTM by breaking it at the breaking point present on the swab stick.
5. Whole blood sample 6-8ml is to be drawn and put 3-4 ml each in one EDTA tube (purple colored) and one serum separating tube (yellow colored).
6. Write the name, age, gender, hospital number and contact number of patient clearly on all the sample tubes before putting the sample.
7. All the tubes (VTM with the swab sticks inside it, EDTA, serum separating tube) have to be sealed with parafilm over the connection point between tube and the lid.
8. All the tubes have to be put in a closed box/ zip-lock plastic pouch and send to microbiology section of Central Laboratory, CRH.
9. Place the filled form along with the photocopy separately outside the box/zip-lock plastic pouch.

NB: Do not keep the sample containing tubes and the filled forms together.

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10. Place the samples containing box/ zip-lock pouch inside the Biosafety cabinet in the Microbiology section of Central laboratory, CRH after informing the technician on duty.

- Do not keep the sample containing tubes and the filled forms together, wet forms will not be accepted.
- Open unshielded samples and samples without patient details will not be accepted.
- Samples with incomplete forms will not be accepted.

8. Packaging

1. Packaging of the sample has to be done by the technician on duty after wearing PPE as per the risk of exposure category at microbiology section of central laboratory in the presence of laboratory In-charge.
2. Seal the neck of the sample vial using parafilm.
3. Cover the sample vials using absorbant material.
4. Arrange primary container vial in secondary container (centrifuge tube).
5. Place the centrifuge tube inside a zip-lock pouch.
6. Place the zip-lock pouch inside a sturdy plastic container and seal the neck of the container.
7. Place plastic container along with gel packs in a thermocol box or a hard card-board box or vaccine carrier or ice-box. (minimum dimensions of the outer container 10 x 10 x 10 cm Length x Breadth x Height)

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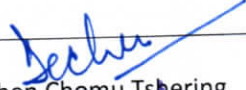

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8. Place the completed specimen referral form and request letter inside a leak proof, zip-lock pouch separately.
9. Secure the zip-lock pouch with the specimen referral form on the outer container.
10. Attach the labels:
 - Sender's address, contact number, consignee's address/contact number.
 - Biological substance- Category B
 - 'UN 3373'; Orientation label, Handle with care.
11. Scan the filled form and mail it at the given email id if the sample is going to NBMC, Siliguri: vrld.nbmc@gmail.com

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Specimen Collection, Packaging and Transport Guidelines for 2019 novel Coronavirus (2019-nCoV)

Requirements for Clinical Samples Collection, Packaging and Transport

1. Sample vials and Virus Transport Medium (VTM)	2. Adsorbent material (cotton, tissue paper), paraffin, sealers, cello tape	3. A leak-proof secondary container (e.g., ziplock pouch, cryobox, 50 mL centrifuge tube, plastic container)
4. Hard-frozen Gel Packs	5. A suitable outer container (e.g., thermocol box, ice-box, hard-board box) (minimum dimensions: 10 x 10 x 30 cm)	

Procedure for Specimen Packaging and Transport

1. Use PPE while handling specimen	2. Seal the neck of the sample vials using paraffin	3. Cover the sealed vials using absorbent material	4. Arrange primary container (vial) in secondary container
5. Placing the centrifuge tube inside a zip-lock pouch	6. Placing the zip-lock pouch inside a sturdy plastic container and seal the neck of the container	Note: Sample vials can also be placed inside a zip-lock pouch, covered in absorbent material and secured by heat-sealing or rubber bands. Then, the zip-lock pouch should be placed inside another plastic pouch and secured.	
7. Using a hard cardboard box as an outer container and placing the secondary container and the gel packs	8. Placing the completed Specimen Referral Form (available on www.icmr.in) and request letter inside a leak-proof, zip-lock pouch	9. Securing the zip-lock pouch with the Specimen Referral Form on the outer container	10. Attaching the labels: • Sender's address, contact number, Contact person's address, Contact number, Biological substance Category B; • UN 2819; Orientation label, Handle with care

Documents to accompany:
1) Packaging list/performance invoice 2) Air way bill (for air transport) (to be prepared by sender or shipper) 3) Value equivalence document (for road/sea/air transport) [Note: 1. A vaccine-carrier/ice-box can also be used as an outer container 2. The minimum dimensions of the outer container should be 10 x 10 x 30 cm (length x width x height)]

Routing of samples:
• Clinical specimens, official documents and Specimen request forms for testing of 2019-nCoV need to be sent to the ICMR-NIV address (The Director, ICMR-National Institute of Virology, 20-A, Dr Ambedkar Road, Pune, Maharashtra, Pin- 411001).
• For shipment-related queries/information, kindly contact Dr Sumit Bhardwaj (Scientist B, Influenza Group) on email: sumitduttbhardwaj@gmail.com, phone: 020-26006290/26006390

9. Reference

https://www.mohfw.gov.in/pdf/55sample%20collection_packaging%20%202019-nCoV.pdf

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