

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

Title: Specimen Collection, Packaging and Transport Guidelines for 2019 Novel Coronavirus (2019-nCoV)	SOP number: ICMR-NIV/2019-nCoV/Specimens_01 Prepared by: Dr. Y.K. Gurav Date: 19/01/2020 Reviewed by: Dr. V. Potdar Date: 20/01/2020 Approved by: Dr. P. Abraham Date: 20/01/2020
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Scope:

To be used by the Government health authorities/ hospitals/ clinicians/ laboratories planning to collect appropriate clinical samples as indicated for diagnosis of 2019-nCoV.

Purpose:

This document describes the information for collection, packaging and transport of clinical specimens to Influenza group at ICMR-National Institute of Virology (NIV), Pune, Maharashtra for diagnosis of 2019 Novel Coronavirus (2019-nCoV)

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.
- 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 (ICMR-NIV, Pune) by following standard triple packaging.

Selection of patient:

Any person who presents with Severe Acute Respiratory Illness (SARI) AND any one of the following i.e. a history of travel from Wuhan, China in 14 days prior to symptoms onset; disease in healthcare worker working in an environment of SARI patients; unusual or unexpected clinical course, especially sudden deterioration despite appropriate treatment; should be urgently investigated. Updated case definition need to be followed as per MOHFW, Govt of India which is available on the website www.mohfw.gov.in

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 flocked 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	≤24 hours: 4 °C >24 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.*

Specimen labelling and processing:

- Personal protective equipment (apron, hand gloves, face shield, N95 Masks etc.) need to be used and all biosafety precautions should be followed so as to protect individuals and the environment.
- Proper labelling (name/age/gender/specimen ID) need to be done on specimen container and other details of sender (name/address/phone number) on the outer container by mentioning “To be tested for 2019-nCoV”
- For any queries, the nodal officer from ICMR-NIV Pune (Dr Yogesh K. Gurav, Scientist E) may be contacted (Phone 020-26006290/ 26006390; Email: gurav.yk@gmail.com/gurav.yk@gov.in) and need to be informed in advance before sending specimens to ICMR-NIV, Pune.

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Requirements for Clinical Samples Collection, Packaging and Transport			
<p>1. Sample vials and Virus Transport Medium (VTM)</p> 	<p>2. Adsorbent material (cotton, tissue paper), paraffin, seizer, cello tape</p> 	<p>3. A leak-proof secondary container (e.g., ziplock pouch, cryobox, 50 mL centrifuge tube, plastic container)</p> 	
<p>4. Hard-frozen Gel Packs</p> 		<p>5. A suitable outer container (e.g., thermocol box, ice-box, hard-board box) (minimum dimensions: 10 x 10 x 10 cm)</p> 	
Procedure for Specimen Packaging and Transport			
<p>1. Use PPE while handling specimen</p> 	<p>2. Seal the neck of the sample vials using parafilm</p> 	<p>3. Cover the sample vials using absorbent material</p> 	<p>4. Arrange primary container (vial) in secondary container</p> 
<p>5. Placing the centrifuge tube inside a zip-lock pouch</p> 	<p>6. Placing the zip-lock pouch inside a sturdy plastic container and seal the neck of the container</p> 	<p>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</p>	<p>7. Using a thermocol box as an outer container and placing the secondary container within it, surrounded by hard-frozen gel packs</p> 
<p>7. Using a hard card-board box as an outer container and placing the secondary container and the gel packs</p> 	<p>8. Placing the completed Specimen Referral Form (available on www.niv.co.in) and request letter inside a leak-proof, zip-lock pouch</p> 	<p>9. Securing the zip-lock pouch with the Specimen Referral Form on the outer container</p> 	<p>10. Attaching the labels:</p> <ul style="list-style-type: none"> • Senders' address, contact number; Consignee's address /contact number; • Biological substance- Category B; • 'UN 3373'; Orientation label, Handle with care 
<p>Documents to accompany:</p> <p>1) Packaging list/proforma Invoice 2) Air way bill (for air transport) (to be prepared by sender or shipper) 3) Value equivalence document (for road/rail/sea 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 10 cm (length x width x height)]</p>			
<p>Routing of samples:</p> <ul style="list-style-type: none"> • 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: 4110001). • For shipment-related queries/information, kindly contact Dr Sumit Bhadwaj (Scientist B, Influenza Group) on email: sumitduttbhadwaj@gmail.com, phone 020-26006290/26006390 			