

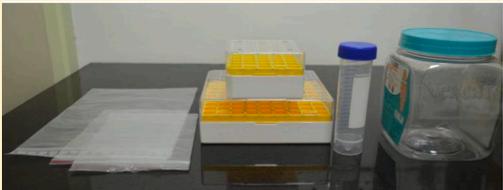
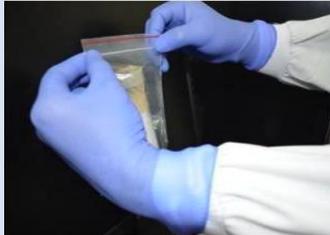


## Specimen Collection, Packaging and Transport Guidelines for 2019 novel Coronavirus (2019-nCoV)

<b>Title: Specimen Collection, Packaging and Transport Guidelines for 2019 Novel Coronavirus (2019-nCoV)</b>	SOP number: ICMR-NIV/2019-nCoV/Specimens_02 Prepared by: Dr. Y.K. Gurav      Date: 25/01/2020 Reviewed by: Dr. V. Potdar      Date: 25/01/2020 Approved by: Dr. P. Abraham      Date: 25/01/2020																																								
<b>Scope:</b> To be used by the Government health authorities/ hospitals/ clinicians/ laboratories planning to collect appropriate clinical samples as indicated for diagnosis of 2019-nCoV.																																									
<b>Purpose:</b> 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)																																									
<b>Responsibilities:</b> <ul style="list-style-type: none"> <li>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.</li> <li>Appropriate clinical sample need to be collected by laboratory personnel/ health care worker trained in specimen collection in presence of clinician.</li> <li>By following all biosafety precautions and using personal protective equipment's (PPEs), clinical samples need to be sent to designated laboratory (ICMR-NIV, Pune) by following standard triple packaging.</li> </ul>																																									
<b>Selection of patient:</b> 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 the 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 <a href="http://www.mohfw.gov.in">www.mohfw.gov.in</a>																																									
<b>Specimen collection details:</b> (Adapted from the WHO guidelines on 2019-nCoV):																																									
<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 20%;">Specimen type</th> <th style="width: 20%;">Collection materials</th> <th style="width: 10%;">Transport to laboratory</th> <th style="width: 15%;">Storage till testing</th> <th style="width: 35%;">Comment</th> </tr> </thead> <tbody> <tr> <td># Nasopharyngeal and oropharyngeal swab</td> <td>Dacron or polyester flocked swabs*</td> <td>4 °C</td> <td>≤5 days: 4 °C &gt;5 days: -70 °C</td> <td>The nasopharyngeal and oropharyngeal swabs should be placed in the same tube to increase the viral load.</td> </tr> <tr> <td>Bronchoalveolar lavage</td> <td>sterile container*</td> <td>4 °C</td> <td>≤48 hours: 4 °C &gt;48 hours: -70 °C</td> <td>There may be some dilution of pathogen, but still a worthwhile specimen</td> </tr> <tr> <td>Tracheal aspirate, nasopharyngeal aspirate or nasal wash</td> <td>sterile container*</td> <td>4 °C</td> <td>≤48 hours: 4 °C &gt;48 hours: -70 °C</td> <td>Not applicable</td> </tr> <tr> <td>Sputum</td> <td>sterile container</td> <td>4 °C</td> <td>≤48 hours: 4 °C &gt;48 hours: -70 °C</td> <td>Ensure the material is from the lower respiratory tract</td> </tr> <tr> <td>Tissue from biopsy or autopsy including from lung</td> <td>sterile container with saline</td> <td>4 °C</td> <td>≤24 hours: 4 °C &gt;24 hours: -70 °C</td> <td>Autopsy sample collection preferably to be avoided</td> </tr> <tr> <td># Serum (2 samples – acute and convalescent)</td> <td>Serum separator tubes (adults: collect 3-5 ml whole blood)</td> <td>4 °C</td> <td>≤5 days: 4 °C &gt;5 days: -70 °C</td> <td>Collect paired samples: • acute – first week of illness • convalescent – 2 to 3 weeks later</td> </tr> <tr> <td># Whole Blood (5 ml)</td> <td>Blood in EDTA Vial</td> <td>4 °C</td> <td>≤5 days: 4 °C</td> <td>Not applicable</td> </tr> </tbody> </table>		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	# Whole Blood (5 ml)	Blood in EDTA Vial	4 °C	≤5 days: 4 °C	Not applicable
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*For transport of samples for viral detection, use VTM (viral transport medium) containing antifungal and antibiotic supplements. Avoid repeated freezing and thawing of specimens. # <b>Priority specimens</b> . Other specimens need to be sent as per the clinical condition of the patient																																									
<b>Specimen labelling and processing:</b> <ul style="list-style-type: none"> <li>Personal protective equipment's (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.</li> <li>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"</li> <li>For any queries, the nodal officer from ICMR-NIV Pune (Dr Yogesh K. Gurav, Scientist E) may be contacted (Phone 020-26006290/ 26006390; Email: <a href="mailto:gurav.yk@gmail.com">gurav.yk@gmail.com</a>/<a href="mailto:gurav.yk@gov.in">gurav.yk@gov.in</a>) and need to be informed in advance before sending specimens to ICMR-NIV, Pune.</li> </ul>																																									



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

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><i><b>Note:</b> 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</i></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 <a href="http://www.niv.co.in">www.niv.co.in</a>) 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"> <li>• Senders' address, contact number; Consignee's address /contact number;</li> <li>• Biological substance-Category B;</li> <li>• 'UN 3373'; Orientation label, Handle with care</li> </ul> 
<p><b>Documents to accompany:</b></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><b>Routing of samples:</b></p> <ul style="list-style-type: none"> <li>• 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).</li> <li>• For shipment-related queries/information, kindly contact Dr Sumit Bharadwaj (Scientist B, Influenza Group) on email: <a href="mailto:sumitduttbhardwaj@gmail.com">sumitduttbhardwaj@gmail.com</a>, phone 020-26006290/26006390</li> </ul>			