




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_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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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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: <ul style="list-style-type: none">• 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 clinician.• 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. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 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 www.mohfw.gov.in | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Specimen collection details: (Adapted from the WHO guidelines on 2019-nCoV): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table><tr><th>Specimen type</th><th>Collection materials</th><th>Transport to laboratory</th><th>Storage till testing</th><th>Comment</th></tr><tr><td># Nasopharyngeal and oropharyngeal swab</td><td>Dacron or polyester flocked swabs*</td><td>4 °C</td><td>≤5 days: 4 °C >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 >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 >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 >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 >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 >5 days: –70 °C</td><td>Collect paired samples:<ul style="list-style-type: none">• 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></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: <ul style="list-style-type: none">• 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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| <i>*For transport of samples for viral detection, use VTM (viral transport medium) containing antifungal and antibiotic supplements. Avoid repeated freezing and thawing of specimens. # Priority specimens . Other specimens need to be sent as per the clinical condition of the patient</i> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Specimen labelling and processing: <ul style="list-style-type: none">• 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.• 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 paraffin</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 Bharadwaj (Scientist B, Influenza Group) on email: sumitduttbhardwaj@gmail.com, phone 020-26006290/26006390 | | | |