

INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH

Guidance document for State Nodal & Testing VRDLs for nCoV

You have been identified as the State Nodal Laboratory for ensuring collection and transport of suspected nCoV sample to ICMR-NIV, Pune. In addition, you are also identified as a testing laboratory for nCoV.

Your roles and responsibilities are as follows:

- You are supposed to make phone calls to VRDLs in your State (list of VRDLs and contact numbers are attached) and inform them the following:
 - If they collect any suspect samples of nCoV directly or through State Health Authorities/IDSP, they should inform you immediately (on real time basis).
 - As soon as you get the information about a sample collected from suspect case, you are supposed to contact Sequel Logistics or World Courier and arrange pick up of samples from the respective sites. Contact details of the relevant agencies are placed at **Annexure 1**.
- Once the courier agency picks up the sample, you need to coordinate with the concerned courier agency for getting the sample(s) delivered to NIV, Pune by the shortest route in shortest time.
- Pick up of the sample by the courier agency will be directly from the VRDL where the sample has been collected and stored. You are not supposed to ask any VRDL to ship the sample to your centre.
- Once the sample is shipped, immediate notification of dispatch of sample along with details should be sent to:
 - Dr. Sumit Bharadwaj – sumitduttbhardwaj@gmail.com;
 - DHR-ICMR - vrldtechnicalevaluation@gmail.com and
 - Whatsapp group (DHR-ICMR VRDLs).

For State Nodal VRDLs who are also the testing sites, following are the directives:

- Till the time you receive the reagents, nCoV primers and probes from NIV Pune, you should ship the samples to ICMR-NIV, Pune.
- Once you receive the reagents, you have to acknowledge on the Whatsapp group (Preparedness for nCoV) immediately. After the receipt of samples before opening a positive control, first aliquot reagents and primers. Then aliquot positive control. Run the PCR assay with appropriate positive and negative controls (as indicated in the SOP), and share the results with NIV, Pune within 24 hrs. The results should include the gel doc pictures showing the molecular ladder and the band for the positive control.
- After the Positive Control PCR results are verified by NIV, Pune, your VRDL must initiate the **testing of respiratory samples collected from suspected nCoV cases.**
- After initiation of testing for nCoV at your VRDL, **aliquots of all respiratory samples tested POSITIVE** for nCoV must be shared with NIV, Pune. Minimum volume of 2 ml of positive respiratory sample needs to be shared with NIV, Pune.
- In addition, the first 10 respiratory samples tested negative must also be shared with NIV, Pune for verification of results. Minimum volume of 1 ml of negative respiratory sample should be sent to NIV, Pune.
- **Shipment of all the positive respiratory samples and the first 10 negative respiratory samples to NIV, Pune needs to be on a real-time basis.**
- **In case you get any positive result by testing suspect nCoV respiratory sample, you are not supposed to disclose the results to anyone.** You should only **advise the treating clinician to isolate the patient in an appropriate facility and follow all biosafety precautions till further confirmation.** In such situations you should immediately send an aliquot of sample to ICMR-NIV, Pune for nCoV reconfirmation. **A positive result (if any) would only be declared by NIV, Pune after reconfirmation.**
- In case of a negative respiratory sample, results should be reported as tentative clearly mentioning that confirmation is awaited from NIV, Pune.

- Blood samples (whole blood in EDTA vacutainer and yellow serum vacutainer for serum) should also be collected from all suspected cases.
- **Blood samples from cases tested positive for nCoV need to be shipped to NIV, Pune on a real-time basis.**
- **For any positive cases, a convalescent serum sample needs to be collected after 2 weeks.**
- Blood samples (serum and plasma) from negative cases should be frozen after aliquoting and then sent to NIV, Pune in batches.
- Ensure **proper precautions to prevent cross-contamination and ensure PCR quality**. Some of the important precautions are as follows-
 - Ensure proper calibration of Micropipettes.
 - Make multiple aliquots of primers, nuclease free water for PCR and for the Positive control plasmids.
 - Strictly ensure uni-directional workflow in the molecular biology laboratory.
 - Ensure that the reagents for the nCoV assay are stored separately from the Positive control.
 - Positive Control should be added in a separate area than the extracted sample RNA.
 - Ensure proper disinfection measures as well as avoiding cross-contamination by cleaning all work surfaces in the molecular biology laboratory with bleach followed by 70% ethanol.
 - Strictly follow SOP shared by NIV Pune and include positive control and negative controls as per the instructions.

- ***Please Note: No results for nCoV should be reported on NIE portal. However, other respiratory virus screening should be reported as usual.***

You are requested to read the advisories on following web-links:

<https://mohfw.gov.in/diseasealerts/novel-corona-virus>

[http://niv.co.in/SOP Specimen Collection 2019-nCoV.pdf](http://niv.co.in/SOP_Specimen_Collection_2019-nCoV.pdf)

[http://niv.co.in/Specimen referral form.pdf](http://niv.co.in/Specimen_referral_form.pdf)

Annexure 1

Sequel Logistics:

Deba Prasad Sahoo – 9019642443

Hardik Shah – 7738350002

World Courier:

Mr. Pradeep - 9004367878