

Interim Guideline for the establishment and
operationalization of molecular laboratory for COVID 19
testing in Nepal

Physical Infrastructure:

The laboratory should have at least 3 rooms with physical barriers, with unidirectional workflow of humans and materials to be maintained

Equipment:

All the equipment in the laboratory needs to be calibrated/validated for its performance periodically by an agency mandated for quality validation. As most of the equipment require uninterrupted power supply, the lab should have dedicated feeder line for electricity supply or linked to automated electric power generator or UPS. A 10KVA UPS would satisfy the need for the required equipment.

- Functional Biosafety cabinet type 2A/2B- 1
- Laminar Flow hood /PCR cabinet -1
- Real time PCR machine-1
 - with UPS for minimum two hour uninterrupted power supply(10KVA capacity)
 - Air conditioned room to maintain the room temperature
- Autoclave -1
- Deep freezer (-20 °C):1
- Deep freezer (-80 C): Optional for storage of samples.



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- With compartments for reagents and samples (better to have separate deep freezers for samples and reagent storage)
- Refrigerator with temperature range of 2-8 °C -1
- Microfuge/Refrigerated centrifuge with adjustable rotors for PCR tubes -1
- Vortex Mixer-2
- Spinner-2 (for strip as well as Eppendorf)
- Automatic Pipette with stands:
 - Fixed volume: 1000µl- 1; 500µl-1, 200µl-1, 10µl-2
 - Adjustable: 0.5 to 10 µl-2nos; 2 to 20 µl- 2 nos; 10-100 µl-2; 20 to 200 µl- 2 nos; 100 to 1000 µl- 2 nos

Consumables:

- Personnel Protective Equipment (disposable gowns, masks, gloves, eye cover and face shield, shoe covers etc.) –as required
- Pipette tips with filters & compatible with pipette size – as per requirement , minimum 1000 each
- Sample and PCR tubes: Eppendorf tubes 1.8 ml capacity: minimum 1000 pcs. Cryovials with capacity of 2 ml as per requirement, minimum 1000
- Steel container to store Eppendorf tubes: 1
- Cryobox with 81/100 slots for storage of reagents, samples, products-10 (can be more depending upon sample size)
- Real time PCR compatible PCR strip (with cap)- as per requirement
- PCR cooler -2
- Icebox -2



Rueso

- Gel packs – as required
- Dust bin -6 pieces (minimum 2 colour coded)
- Biohazard bag as per requirement
- Discard Jars -3
- Aluminium foil as per requirement
- Reagents required for PCR

Human Resource

- Masters level Medical Microbiologist (preferable)/Masters in life science- 1; Some experience in microbiological molecular work will be desirable.
- Supporting laboratory staffs with Bachelor/Certificate level in Laboratory sciences- 2

Personnel working in a PCR laboratory should undergo training in the methodology that covers PCR theory and practice. The course work should also include biosafety in a PCR laboratory as well as quality issues and troubleshooting PCR-related problems. Hands-on training should be completed for each technique under the supervision of experienced personnel. The time required for training will vary depending on the trainee and technique. Personnel should demonstrate that they can successfully perform the method by testing confirmed positive and negative control samples before being allowed to analyse diagnostic samples.

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