

IAPM: PROPOSED GUIDANCE FOR VARIOUS LABS IN VIEW OF COVID-19

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Your and your Lab staff safety is most important than any other work

- All Pathologists and Microbiologists should follow the instructions of central and state guidelines.
- All specimens collected for lab investigations should be considered as potentially infectious. As per the available data the reported infectivity of various samples is as follows -

Sputum: 72%; **BAL** 93 %; **Nasal swab** 63%; **Pharyngeal swab** 32%

Fibrobronchoscopic brush sample 46%

Stool: 29%, **Anal swabs:** 20.5%, **Rectal swabs:** 17.4%

Blood: 1%; **Conjunctival swab:** 1.1%;

Urine: 00%; **Vaginal swabs:**00%; **Semen sample:** 00%

A. Routine Laboratory Precautions & Biosafety Guidance:

- Use standard precautions to maintain a barrier between the specimen and personnel while handling.
- All procedures must be performed based on risk assessment and only by trained personnel as per the relevant SOPs at all times.
- Initial processing (before inactivation) of all specimens should take place in a validated biological safety cabinet (BSC) or primary containment device.
- Staff should be advised that maintaining a safe workplace is of primary importance.
- No shortcuts should be taken despite potentially increased workloads.
- Tests not necessary for the treatment of the patient and those that are not a priority should be deferred.
- Reduce non-urgent testing to minimize patient contact with health care workers.
- All technical procedures should be performed in a way that minimizes the formation of aerosols and droplets.
- Centrifugation of specimens should be performed using sealed centrifuge rotors or sample cups. These rotors or cups should be loaded and unloaded in a BSC.
- A dedicated hand-wash sink should be available in the laboratory.
- Mouth pipetting must be strictly forbidden.
- Adequate biohazard containers should be available for appropriate disposal of contaminated materials and be located in the immediate working area.
- Eating, drinking, smoking, applying cosmetics, and handling contact lenses should be prohibited in the laboratory working areas.
- Entire lab and the specific work area should be regularly disinfected using proper disinfectants. [See 'M' below]
- Patient's specimens from suspected or confirmed cases should be transported as UN3373 'Biological Substance Category B'. Virus cultures or isolates should be transported as category A, UN2814, Infectious substance, affecting humans, according to WHO Biosafety guidelines GMPP.
- Needles must not be used as substitutes for pipetting or any other purpose.
- All needles should always be collected in puncture-proof sharps containers fitted with covers and not resheathed.
- Only one attendant per patient should be allowed during any procedure.
- Patient and the attendant both should be educated to wear face masks, follow 'Social distancing' and also to wash their hands with soap and water or rub with sanitizer.

- Use of centralized air conditioners should be avoided at all times. Split ACs can be used.
- Work should be performed in a certified Class II BSC.
- Turn the BSC on at least few minutes before the procedure so that the airflow is established.
- All infectious/suspected materials to be discarded in yellow bag/bin labeled with biomedical hazard sticker and additionally written as COVID-19.
- External surface of Analyzers should be disinfected regularly especially the frequently touched areas.
- Shared microscopes should be properly disinfected using alcohol based solutions.

B. Care of Staff & Laboratory Personnel:

- Staffing should be restricted to a minimum.
- Frequent hand hygiene including hand wash and hand rub should be encouraged.
- Use of full Personal protective equipment (PPE) is vital. **(Refer C1 below)**
- The donning and doffing space of PPE should not be in the workspace.
- PPE must be removed only at the time of finally leaving the laboratory.
- All PPE must be changed as per doffing guidelines and hand washing must be performed thoroughly for more than 20 seconds after the procedure.
- Avoid touching eyes, mouth, and nose or face until hands are washed.
- Beard prevents proper fitting of the masks so regular shaving should be done.
- All laboratory personnel working with samples from suspected or confirmed COVID 19 patients should immediately report development of any symptoms to their medical authorities.
- Special extra precautions to be taken by staff who are elderly, or have history of cardiovascular disease, diabetes mellitus, chronic respiratory problem, Immunocompromised etc.

C.1 Universal and additional PPE:

- ❖ Gown & Suits: Valved fold flat and moulded protection mask or whole-body suit. Alternatively, solid-front or wrap-around waterproof gowns with coveralls having sleeves that fully cover the forearms (typically a surgical gown) may be used.
- ❖ Plastic apron (especially when working in a high fluid flow lab).
- ❖ Head coverings or surgical cap should be worn.
- ❖ Eye and face protection (goggles or clear face shield).
- ❖ Certified N95 or equivalent masks should always be worn.
- ❖ Double layer of gloves preferably Nitrile type should be used.
- ❖ Rubber boots with metal toe caps, dedicated shoes or disposable shoe covers

C.2 Guidelines for use of mask:

The correct procedure of wearing triple layer/ surgical mask is:

1. Perform hand hygiene
2. Unfold the pleats; make sure that they are facing down.
3. Place over nose, mouth and chin.
4. Fit flexible nose piece over the nasal bridge.
5. Secure with tie strings (upper string to be tied on top of head above the ears –lower string at the back of the neck.)
6. Ensure there are no gaps on either side of the mask, adjust to fit.
7. Do not let the mask hang from the neck.
8. Change the mask after six hours or as soon as they become wet or moist.
9. While removing the mask great care must be taken not to touch the potentially infected outer surface of the mask
10. For removing the masks first untie the string below and then the string above. Handle the mask using the upper strings.
11. Disposable masks should never to be reused and must be discarded immediately after use.
12. Disposal of used masks: Used mask should be considered as potentially infected medical waste and discarded in the closed yellow bin.

D.1 Sample Collection, transportation & Processing of samples:

- SOPs for sample collection, transportation and processing of samples collected from suspected/confirmed patients of COVID-19 should be prepared in all laboratories.
- There is danger of aerosol generation during processing of clinical samples so the existing SOPs should be modified to minimize the risk for health care workers/laboratory staff.
- All GOOD LAB PRACTICES such as proper hand washing, use of protective measures should be followed.
- Place samples in leak-proof bags followed by secondary containers to minimize the potential for breakage or a spillage. The patient's label should be on the primary container.
- Use a vaccine/ice box type container for transportation.
- Clean outer container with disinfectant, zip lock pouch and, open the samples in BSC (whenever required).
- Deliver all specimens manually whenever possible. DO NOT use pneumatic-tube systems to transport specimens.
- Notify the laboratory as soon as possible that the specimen is being transported.

D.2 Referral of specimens to laboratories with appropriate containment measures in place

- Laboratories not able to meet the above biosafety recommendations should consider transferring specimens to national, regional or international reference laboratories on coronaviruses.

E. Phlebotomy and sample handling:

- Specific guidance on handling blood and urine samples should be followed as potentially Infective, especially when the status of patient is not known.
- Technicians and coordinate staff should use mask, gloves, gowns/ impervious aprons, goggles/face shields and, shoe covers while handling the samples.
- Use disposable Tourniquets (preferably) or sanitize after every use.
- Phlebotomy area should be separate.
- Ideally phlebotomy chairs should be sanitized after every use.
- All samples should be packed in triple layer: using primary container, secondary container and zip lock pouch.
- Biomedical waste rules should be strictly followed as always.

E2. Handling of Requisition slips:

- The requisition forms should not be packed or rolled up along with the samples but placed in a separate zip lock packet to avoid cross-contamination or spillage from leakage of the sample containers.
- In case the hospital has HIS then e-form or else requisition forms via email can be received.
- Another alternative is to dedicate a printer cum scanner and get a Xerox copy of the requisition form for lab use.
- The original form can be disinfected by UV rays or baking in oven at 60 – 65°C for 15-30 minutes.

F. Haematology Section:

- Use vacutainers ONLY and do not open them.
- If EDTA vial needs to be opened, they should be opened in BSC/ or with all safety precautions
- Manual blood smear preparation should be avoided. If unavoidable blood smears should be prepared in class II BSC.
- Smears should be left to dry naturally without blowing air or under the fan.
- Subsequently decontaminate the surface properly with disinfectant as other surfaces.
- Run 2 tubes of 1% Hypochlorite solution before shutting down the analyzer equipment used.

G.1 Histopathology Lab:

- Specimens should be properly fixed in 10% formalin preferably overnight.
- Formalin and Glutaraldehyde decreases the infectivity of the virus in a temperature- and time-dependent manner. Formalin inactivated the virus in 24 hours at a temperature of 37⁰C; at temperature of 56 °C for 90 min, 67 °C for 60 min, or 75 °C for 30 min. Glutaraldehyde fixation required 2 days for inactivating the virus.
- Larger specimens should be sliced and then dipped in formalin.
- Use full PPE while handling the specimens.
- While grossing especially use face shield, head cover or caps and impervious aprons.
- Paraffin-embedded blocks carry a low risk of infectivity.
- Promote remote reporting / use of Digital pathology especially in the present situation.
- The histopathology specimens should be placed in a leak proof container.
- It is preferred to have double or secondary containers *i.e.* container within a bigger container.
- The level of formalin should be sufficiently above the tissue level.
- Biohazard label should be pasted on all specimen containers.
- Specimen container must be thoroughly decontaminated using alcohol based liquids or 0.1% Hypochlorite solution before processing.

G.2 Frozen Section:

- Reduce the use of fresh-frozen sections to a strict necessity basis, as cryostat disinfection takes a long time and many laboratories have only one cryostat available for fresh-frozen sections.

H.1 Cytopathology lab:

- Limit the number of FNACs to bare minimum and should be advised only if it really affects medical management of the patient.
- During FNA procedure the personnel should use full PPE.
- Patients who come for FNA should wear a mask. They should also be counseled not to cough during the entire procedure. The procedure should be deferred in uncooperative patients.
- After aspiration the material should be gently expelled and smearing should be made cautiously (Preferably in a closed cabinet).
- While making a smear it is recommended that slides are held as far as possible from the personnel.
- Drying of the smears by shaking or blowing of air should not be done as it can lead to generation of aerosol and small droplets. Air-drying of the smears should be ideally performed in class II biosafety cabinets (BSCs).
- Clean surface top using disinfectant after every smear preparation.
- Rapid onsite evaluation (ROSE) should be deferred.
- The used needles should be discarded in sharp-resistant puncture proof waste containers.
- The entire syringe should be disinfected and discarded.
- Promote remote reporting / use of Digital pathology especially in the present situation.

H.2 Sample processing in the cytopathology laboratory:

- The samples should be collected in a properly labeled, tightly-capped, sterile tubes/containers and sent to the cytopathology laboratory in a double pack zip-lock bag and finally transported in a leak-proof cryobox.
- The technicians should take full protective measures as mentioned earlier.
- Fresh, unfixed specimens should be transported by hand, and NOT transported via pneumatic-tube system.
- Opening of the sample containers, removing tightly fitted caps of the tubes, diluting, shaking, vortexing, and centrifugation may lead to aerosol generation. Care should be taken to minimize the exposure to the aerosol generated during the sample processing by performing these steps in class II BSCs.

- Following centrifugation the machine should be rested for at least 10 minutes followed by gently opening the lid and cautiously opening the sample caps.
- Fixation of the cytology samples in alcohol-based fixatives (with alcohol concentration more than 70%) or formalin should be preferred. However, in case the fixation is done using weaker alcohol-based fixatives, additional precautionary measures (As above) should be followed.

I. Biochemistry lab:

- Avoid splash/agitation, leaking of samples.
- After centrifuge, the sample tubes should be allowed to stand for at least 10 minutes leading to settling down of the droplets.
- Open tubes in level 2 Biosafety cabinet or take appropriate precautions.
- Prefer use fully automated instruments and Analyzers.

J. Routine Microbiology Section:

- Sputum samples that are non-purulent should not undergo routine culture.
- Routine mycology testing can be stopped.

K. Laboratory Waste Management & Sample discarding:

- Handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as special guidelines for COVID-19. All other bio hazardous wastes in the laboratory should be disposed as per BMW guidelines.
- All the residual samples should be discarded in appropriate disinfectants with virucidal activity. These include 0.1% Sodium hypochlorite solution, 0.5% Hydrogen peroxide, 62–71% Ethanol, Quaternary ammonium compounds, or Phenolic solutions.
- The sample tubes and containers should also be disinfected by spraying of 0.1-1% Hypochlorite solution (to be prepared fresh each day) or other disinfectants, followed by discarding in yellow biohazard waste bags.
- Double layered bags (using 2 bags) should be used for collection of waste from COVID-19 isolation wards so as to ensure adequate strength and prevent leakages.
- Biomedical waste should be collected and stored separately prior to handing over to the Biomedical Waste (BMW) management team.
- Use dedicated trolleys and collection bins labeled as “COVID-19” for priority treatment and immediate disposal.
- Biomedical waste collected from such isolation wards should be kept separately in a temporary storage room and lifted directly from there into the BMW collection van.
- Use dedicated vehicles to collect COVID-19 ward waste.
- The vehicles and the inner and outer surface of containers/bins/trolleys used for storage of COVID-19 waste should be disinfected after each collection using 1% Sodium hypochlorite solution.
- Dedicated sanitation workers for handling such wastes should be there.
- Sanitation workers shall be provided with adequate PPEs including three layer masks, splash proof aprons/gowns, nitrile gloves, gum boots and safety goggles.
- Adequate training should be provided to the biomedical waste staff for sanitization, collection of biomedical waste and, precautionary measures to handle such waste.
- Always use freshly prepared 1% sodium hypochlorite.
- For preparing 70% Bleaching powder add 7g powder to 1 liter clean water.
- **Management of sample spills in the laboratory:** Decontamination of laboratory surfaces in case of sample spillage should be done immediately using 1% Sodium hypochlorite solution.

L. Disinfection of Offices & Work Surface:

- High contact surfaces such elevator buttons, railings, door handles, call buttons, escalator handrails, public counters, intercom systems, chairs, pens, diary, files equipment including telephones, printers, scanners, keyboards, mouse, mouse pad, tea/coffee dispensing machines

and other office machines should be cleaned twice daily by mopping with a linen/absorbable cloth soaked in 1% Sodium hypochlorite or Alcohol based solutions.

- For metallic surfaces like door handles, security locks, keys etc. 70% alcohol should be used.
- Follow manufacturer's recommendations for dilution, contact time, and safe handling.
- Work surfaces must be decontaminated after any spill of potentially dangerous material and at the end of the batch or entire day's work.
- Hand sanitizing stations should be installed in the office premises (especially at the entry point) and at the exit point of high contact surfaces.
- Personnel must wash their hands often – especially after handling infectious materials and animals, before leaving the laboratory working areas, and before eating.
- Exhaust air from the laboratory room should not be recirculated to other areas within the building. Air should be HEPA filtered, if reconditioned and recirculate within the laboratory.
- Only freshly prepared Sodium hypochlorite should be used.
- For surface cleaning use 0.1% Sodium hypochlorite solution and in case blood spillage has occurred use 1% Sodium hypochlorite solution.
- Apply disinfectant solution for at least half an hour.

M. Disinfectants:

- For surfaces use 62–71% Ethanol, 0.5% Hydrogen peroxide, or 0.1-1% Sodium hypochlorite.
- 0.05-0.2% benzalkonium chloride or 0.02% Chlorhexidine digluconate are less effective.
- Irradiation with UV light for at least 60 minutes at 37°C or room temperature can be done.

N. Cleaning of Toilets & Washrooms:

- Sanitary workers must use separate set of cleaning equipment (mops, nylon scrubber) for wash basins and commodes).
- They should always wear disposable protective gloves while cleaning a toilet.
- Toilet pot and commode especially the lid should be cleaned with 1% Sodium hypochlorite and soap water using a long handle angular brush.
- While flushing take care to close the lid and then flush.
- Sink and toilet floor should be washed using soap powder /detergent and then 1% Sodium hypochlorite which should be left as such for some time.
- Taps and fittings should be rinsed with warm water, detergent powder using nylon scrubber and finally 1% Sodium hypochlorite.
- For metallic or coated fittings 70% alcohol should be preferred.
- Care should be taken to clean the underside of taps and fittings.
- Soap dispensers should be cleaned daily with detergent and water and air dried.

Further Reading:

1. Public Health England. COVID-19: guidance for sampling and for diagnostic laboratories secondary COVID-19: guidance for sampling and for diagnostic laboratories, 2020. Available: <https://www.gov.uk/government/publications/Wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories>
2. More information on disinfection and sterilization is provided in the WHO Laboratory biosafety manual, 3rd edition.
3. <https://main.icmr.nic.in/content/covid-19>
4. Wang W, Xu Y, Gao R, Lu R, Han K, Wu G *et al.* Detection of COVID-19 in different type of clinical specimens. JAMA 2020; 323:1843-4.