Biosafety guidance for diagnostic laboratories handling specimens from individuals with possible, probable or confirmed infection with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Middle East respiratory syndrome Coronavirus or Avian Influenza A

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Background

This guidance has been reviewed in the context of the emergence of with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in the area of Wuhan, Hubei province in China. As yet, we do not fully understand the pathogenic potential and transmission dynamics of SARS-CoV-2, for further information refer to the hpsc website.

Middle East respiratory syndrome coronavirus (MERS-CoV), which is genetically distinct from the SARS coronavirus, has caused a number of infections in humans. To date cases have been mainly associated with the Middle East but a small number of imported cases have occurred in European countries. Healthcare workers providing direct patient care are at significant risk of acquisition of the SARS-CoV-2, MERS-CoV and SARS. Acquisition of any of these infections had never been reported as associated with diagnostic laboratory testing.

Laboratory-acquired infection with SARS coronavirus has been described in a small number of cases in the setting of laboratories involved in propagation of the virus.

Avian influenza is a contagious disease of animals caused by viruses that normally infect only birds and, less commonly, other animals such as pigs. Avian influenza viruses are highly species-specific, but have, on rare occasions, crossed the species barrier to infect humans. Current viruses that have the potential to begin circulating among humans include H5, H9 and H7 strains of avian influenza.

The following guidance summarises current recommendations from the World Health Organization (WHO) and are based on the WHO Laboratory Biosafety Manual (3rd Edition), available at: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

Note: the following guidance relates to laboratory procedures in primary diagnostic laboratories and does not address biosafety requirements for viral isolation or work with animals infected with SARS-CoV-2 , MERS-CoV or avian influenza A.

Recommendations for routine laboratory procedures

Clinical staff should notify laboratory staff when specimens are submitted from a patient with suspected or confirmed infection, through proper completion of request forms or electronic test ordering systems, or by direct communication with the laboratory.

Clinicians may not have considered infection as a potential diagnosis, prior to sending specimens to the laboratory. Good laboratory practice, including the use of standard biological safety precautions, regular training of staff, and the use of standard operating procedures, will help minimise potential risks.

The hospital must ensure that appropriate biosafety measures are in place to ensure that essential clinical diagnostic tests are performed in a timely manner.

Laboratory staff should wear personal protective equipment (PPE) appropriate to the biological safety level for the work being conducted and consistent with the risk assessment. This should include disposable gloves and a laboratory coat or gown, and may also include eye protection and other equipment, as appropriate

Appropriate physical containment devices (e.g., centrifuge safety buckets; sealed rotors) should be used for centrifugation.

Perform any procedures outside a Biological Safety Cabinet (BSC) (either class I or class II is suitable for use) in a manner that minimizes the risk of exposure to an inadvertent sample release.

After specimens are processed, decontaminate work surfaces and equipment with appropriate disinfectants with proven activity against enveloped viruses (e.g. chlorine, alcohol, peroxygen, quaternary ammonium compounds and phenolic compounds) according to manufacturer's recommendations

Minimize the use of hypodermic needles and syringes. Always collect contaminated sharps in puncture-proof containers fitted with covers, and treat them as infectious waste.

Handle, transport and dispose of infectious laboratory waste according to Department of Health Segregation, Packaging and Storage Guidelines for Healthcare Risk Waste (available

from http://www.lenus.ie/hse/handle/10147/120929). All disposable waste should be autoclaved.

Waste from autoanalysers is unlikely to pose significant risk due to low sample volume and dilution steps therefore special waste disposal precautions are not recommended for autoanalyser waste.

Biosafety Level-2 facilities and BSL-2 work practices are standard in diagnostic medical laboratories. Laboratories should operate on the basis that any sample at any time may contain an infectious agent.

The following activities may be performed in BSL-2 facilities using standard BSL-2 work practices:

- Diagnostic assays using whole blood, serum and plasma, including routine biochemistry and haematology, unless performing steps with the potential to generate fine-particulate aerosols (e.g., vortexing or sonication of specimens in an open tube)
- Manipulations involving neutralized or inactivated (lysed, fixed, or otherwise treated) virus particles and/or incomplete, non-infectious portions of the viral genome
- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Routine examination of bacterial and fungal cultures
- Routine staining and microscopic analysis of fixed smears
- Final packaging of specimens for transport to diagnostic laboratories for additional testing.
- Specimens should already be in a sealed, decontaminated primary container
- Electron microscopic studies with glutaraldehyde-fixed grids
- Blood cultures may be collected and placed in incubators as per standard procedures.

Any procedure with the potential to generate fine-particulate aerosols (e.g., vortexing or sonication of specimens in an open tube) should be performed in a Biological Safety Cabinet (BSC). Masks or respirators are not necessary when respiratory tract, urine, faecal or tissue samples are handled **inside** a Biological Safety Cabinet (BSC).

The following activities involving manipulation of potentially infectious specimens in the laboratory should be performed as above and in a biological safety cabinet (BSC):

- Aliquoting and/or diluting potentially infectious samples
- Inoculating bacterial or fungal culture media

- Testing samples for viral or bacterial antigens (for example urine for legionella antigen or respiratory samples for respiratory antigen)
- Nucleic acid extraction procedures
- Preparation and chemical- or heat-fixing of smears for microscopic analysis
- Loading and unloading of centrifuge rotors and buckets (in so far as possible)

Recommendations for Point of Care Tests

Point of care testing should not be performed on potentially infectious samples where alternatives exist for effective patient care because it is difficult to manage the risk with such samples in a clinical setting.

However, point of care blood gas analysis is practically unavoidable in many critical care situations without compromising patient care. If point of care blood gas analysis is necessary to manage a critically ill patient the incremental risk to healthcare workers beyond the risk of delivering direct patient care is likely to be minimal and it may be performed with the following precautions.

1. The operator should scrupulously attend to infection prevention and control practice throughout the procedure.
2. After the needle has been removed and disposed of safely and the adaptor applied to the tip of the syringe, if air must be expelled from the sampling syringe this should be performed in the patient care zone with the syringe pointing away from the operator and while wearing all appropriate PPE.
3. Ideally a blood gas analysis machine should be placed within the patient room.
4. If a blood gas analysis machine is not in the patient room the syringe should laid flat in a disposable plastic tray with deep sides for transport to the blood gas analyser. The analysis may be performed as normal. The residual blood in the syringe should be discarded as per standard practice and the instrument and its surrounding be left clean and ready for use.

Reference (WHO Laboratory Biosafety Manual (3rd Edition))

Shipping Requirements

Comply with applicable national regulations for the Transport of dangerous Goods by Road (available from www.hsa.ie)

- **Specimens** suspected or confirmed of containing SARS-CoV-2, avian influenza A virus, or MERS-CoV can safely be shipped as biological substance, **Category B**

Immediately report incidents or accidents involving potential or actual exposure to SARS-CoV-2, MERS-CoV or avian influenza A virus and appropriately decontaminate any affected area or equipment. Following an exposure, seek medical advice as soon as possible.

Immediately report any symptoms of infection to the laboratory management and Occupational Health service