Biosafety guidance for diagnostic laboratories handling specimens from individuals with possible or confirmed infection with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

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Background

- This guidance, relating solely to SARS-CoV-2, replaces the previously issued "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" (February 2020).
- The document is specific to clinical diagnostic laboratory practice and should be read in conjunction with the statement from the Health and Safety Authority "Risk Group Classification for Severe Acute Respiratory Syndrome Coronavirus 2".
- This guidance does not cover virus isolation, propagation, research work or work involving animals infected with SARS-CoV-2. Please see the WHO laboratory biosafety guidance related to coronavirus disease (COVID-19) for additional information.
- When handling and processing specimens from all patients, laboratory practices and procedures that are basic to good microbiological practice and procedure (GMPP) should be followed. SARS-CoV-2 RNA has been detected in samples from the respiratory tract and other sample types including blood, faeces urine and CSF. Human tissue specimens may also pose an infection risk. To date, laboratory-acquired infection with SARS-CoV-2 has not been reported.

Risk Assessment

- The European Commission (EC) has classified SARS-CoV-2 as a risk group 3 biological agent. However, in order to ensure sufficient testing capacity, as well as continuity of testing for COVID-19, the EC has included a footnote, which states that non-propagative diagnostic work (routine laboratory procedures) involving SARS-CoV-2 should be conducted at a facility with procedures equivalent to at least containment level or biosafety level (BSL) 2.

- Clinical laboratories must perform their own risk assessments for handling biological specimens from patients with suspected or confirmed COVID-19.
- Clinical staff must notify laboratory staff when specimens are submitted from a patient with suspected or confirmed COVID-19 though proper completion of request forms or test ordering systems.

Personal Protective Equipment (PPE)

- Laboratory staff must wear appropriate PPE when conducting work in the laboratory. PPE must be removed on leaving the laboratory, with careful attention to hand hygiene.
- Respiratory protective equipment is not necessary when samples are handled inside a biological safety cabinet (BSC). However, laboratory staff should be aware of national recommendations on the wearing of face coverings when physical distancing cannot be maintained in a workplace or healthcare setting.

Cleaning and Waste

- Clean surfaces and equipment and disinfect with a disinfectant solution or disinfectant wipe with proven activity against enveloped RNA viruses for the recommended contact time, at the correct dilution and within the expiry date after the working solution is prepared.
- 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 a significant risk due to low sample volume and dilution steps. Special waste disposal precautions for these samples are not required.

Sample Processing

It is recommended that urgent and essential clinical diagnostic tests are not postponed pending the results of SARS-CoV-2 testing.

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). The capping and uncapping of samples is not considered to be a high-risk aerosol generating procedure (AGP).
- Manipulations involving neutralised 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 BSC.

The following activities involving manipulation of samples potentially containing SARS-CoV-2 in the laboratory should be performed as above and in a BSC:

- Aliquoting and/or diluting potentially infectious samples.
- Inoculating bacterial or fungal culture media.
- Testing samples for viral or bacterial antigens (e.g., 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).
- Processing of any non-inactivated specimen that might result in the generation of aerosols.

Where it is not possible (for example the instrument does not fit inside a BSC), undertake a local risk assessment.

Recommendations for Near-Patient Testing (formerly Point-of-Care Tests / POCT)

- Near-patient testing (NPT) 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.
- NPT should be delivered within a local governance structure, in keeping with guidelines for safe and effective management and use of NPT
- https://acslm.ie/wp-content/uploads/2020/04/NPT-Guidelines-Final-Beta-Version-Apr-20-2020.pdf
- Where NPT for viral nucleic acid amplification are in use, a local risk assessment must be performed to show that any aerosol or droplet generation occurs within a closed analyser and

external surfaces can be cleaned with detergent-based disinfectant.

- However, near-patient blood gas analysis is practically unavoidable in many critical care situations without compromising patient care. If it 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 be 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 surroundings left clean and ready for use.

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 can safely be shipped as UN3373 biological substance, **Category B.**
- Virus cultures should be transported as Category A UN2814 “infectious substance, affecting humans”.

Immediately report incidents or accidents involving potential or actual exposure to SARS-CoV-2, 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

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