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Guidance

COVID-19: safe handling and processing for samples in laboratories

Updated 25 April 2020

Contents

This publication is available at https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens

Latest updates to this page

3 April: detail on near-patient testing in Section 3.

1. Scope

Knowledge about the pathogenic potential and transmission risks for the novel coronavirus, SARS coronavirus-2[1] (SARS-CoV-2), and the associated disease it causes, COVID-19[2], is currently very limited. This interim guidance is based on current knowledge of the virus and other coronaviruses. It aims to minimise risks for laboratory staff handling specimens from patients with possible or laboratory-confirmed COVID-19.

This interim guidance is specific to clinical diagnostic laboratory practice in England and may differ from guidance produced by agencies in other countries, including recommendations about containment levels and control measures. Advice offered here relates to laboratory procedures conducted in clinical diagnostic laboratories. It does not cover virus isolation, propagation, research work, or work involving animals infected with SARS-CoV-2.

This PHE guidance has been produced in collaboration with the Health and Safety Executive and will be updated when new information becomes available.

2. Background

The Advisory Committee on Dangerous Pathogens (ACDP) met in early 2020 to discuss the proposed Hazard Group (HG) for SARS-CoV-2. Whilst this is a novel coronavirus it is anticipated that the existing safe systems of work for similar HG3 coronaviruses can be used to effectively manage the risks of SARS-CoV-2. Based on the current information, the ACDP committee agreed on a provisional classification of SARS-CoV-2 as a HG3 pathogen.

For the related Middle East respiratory syndrome coronavirus (MERS-CoV), tissue tropism appears to be broad in humans and although MERS-CoV is zoonotic, human-to-human transmission of MERS-CoV has occurred in households and healthcare facilities through close contact with infected individuals. There is a human-to-human transmission risk (and an assumed potential zoonotic source) for SARS-CoV-2 infection (COVID-19).

MERS-CoV RNA has been detected in a variety of human specimens, including urine, faeces and blood, and it is reasonable to assume this could be the case for SARS-CoV-2 until more is known about the virus. Human tissue specimens may also pose an infection risk, based on information obtained from studies of infected animals.

Laboratory-acquired infections with the Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) have been reported previously but only in laboratories performing virus propagation. To date, laboratory-acquired infection has not been reported for SARS-CoV-2.

Based on knowledge of other coronaviruses, infection with SARS-CoV-2 could occur by inhalation of aerosolised virus or by contact with droplets and contaminated fomites. Exposure to upper and lower respiratory tract specimens in the absence of appropriate containment and control measures is likely to represent the greatest risk of SARS-CoV-2 laboratory acquired infection.

It is possible that laboratory workers could become infected if appropriate precautions are not taken when handling biological samples from patients with COVID-19. Since a patient with suspected COVID-19 may present to any healthcare facility, it is important that all clinical diagnostic laboratories take appropriate

measures to contain potentially infectious materials and prevent secondary infections and onward transmission.

3. Risk assessment

Clinical staff should notify laboratory staff when specimens are submitted from a patient with suspected or confirmed COVID-19, through proper completion of request forms or electronic test ordering systems, and by direct communication with the laboratory.

It is possible that clinicians may not have considered COVID-19 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.

Clinical laboratories must perform their own risk assessments for handling biological specimens from patients with suspected or confirmed COVID-19.

Near-patient testing (also known as point-of-care tests) for suspected and confirmed COVID-19 cases, including blood gas analysis, must be avoided unless a local risk assessment has been completed and shows that it can be undertaken safely. Near-patient tests for viral nucleic acid amplification vary widely in their general safety and where aerosols or droplets may be generated. If a local risk assessment can show that any aerosol or droplet generation occurs within a closed analyser, and external surfaces can be cleaned with detergent-based disinfectant, then these tests may be used.

A suitable and sufficient assessment of the risks when handling samples potentially containing SARS-CoV-2 must be undertaken prior to the work starting. Samples for confirmation of known or presumptive positives must be processed at full containment level (CL3). See section 5 for additional guidance on aspects of sample processing that may not need full CL3 containment.

4. Personal protective equipment

Laboratory staff must wear personal protective equipment (PPE) when conducting work in the laboratory. PPE must be removed on leaving the laboratory and hygiene practices including hand washing must be rigorously maintained.

PPE must include disposable gloves and a laboratory coat or gown as a minimum, and may also include eye protection and other equipment, as identified by risk assessment. Respiratory protective equipment such as masks or respirators are not necessary when respiratory tract, urine, faecal or tissue samples are handled inside a microbiological safety cabinet (MSC).

Masks or respirators are not an appropriate substitute for processing samples in an MSC when there is a risk of aerosols being generated.

5. A risk-based approach to sample processing

Under normal circumstances, any procedure with HG3 pathogens involving potentially infectious material where there is a risk of generating aerosols, droplets or splashes, must be performed within a MSC at CL3 as defined in the Approved Code of Practice and Guidance for the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (https://www.hse.gov.uk/pubns/books/l5.htm) (as amended).

However, in light of the exceptional circumstances posed by SARS-CoV-2 and the potential impact on the diagnostic sector, a risk-based proportionate approach has been adopted in agreement with ACDP and HSE where certain laboratory activities can be undertaken within a MSC at containment level 2 (CL2). These are

described in 5.2 below.

5.1 Work that may be conducted at CL2

Routine laboratory blood tests can be carried out in auto-analysers using standard practices and procedures at CL2, but only after a suitable and sufficient risk assessment has been conducted which considers the potential for the generation of infectious aerosols. Auto-analysers should be disinfected following local procedures after sample processing and before scheduled maintenance in accordance with manufacturers recommendations.

Some auto-analyser protocols for routine laboratory tests may require specimen tubes to be opened first, or initial processing of the sample to be performed. Evidence suggests that capping and uncapping of samples is not a high-risk aerosol generating procedure which is dependent on the cap and tube design. These factors must be considered in a suitable and sufficient risk assessment which also considers if the sample needs to be centrifuged, vortexed or pipetted manually. The risk assessment must include consideration of whether a MSC needs to be used.

The following work may also be conducted at CL2 following standard laboratory precautions, where this is consistent with the terms of the local risk assessment for those activities:

- diagnostic assays using whole blood, serum and plasma, including routine biochemistry and haematology, unless there is a risk of generating aerosols
- assays using virus-inactivated specimens, including molecular testing of inactivated specimens
- examination of bacterial or fungal cultures
- staining and microscopy of heat-fixed or chemically-fixed smears
- centrifugation of routine blood samples. However, where there is infectious potential, samples must be centrifuged using sealed centrifuge rotors or sample cups which are loaded and unloaded in a MSC.

5.2 Work that should be conducted within a MSC at CL2

Following completion of a suitable and sufficient risk assessment, the following work with samples potentially containing SARS-CoV-2 may be conducted in a MSC at CL2:

- preparation of specimens for molecular testing (for example respiratory virus PCR) prior to sample inactivation
- division, aliquoting, or diluting of respiratory tract specimens, faecal specimens, urine specimens, and tissue specimens in which virus has not been inactivated[3]
- inoculation of bacterial or fungal culture media from high risk patients
- urine antigen testing (such as for detection of Legionella pneumophila or Streptococcus pneumoniae)
- rapid antigen tests of respiratory tract specimens
- processing of any non-inactivated specimen that might result in the generation of aerosols
- preparation and fixing (chemical or heat) of smears for microscopy
- haematological or immunological work
- rapid diagnostic tests for malaria parasites

Where risk assessment has identified that work should be conducted within an MSC at CL2 the following still applies to work activities:

- only fully trained and competent staff must undertake the work; in addition to this the level of training provided should be appropriate to the level of risk and the complexity of the procedures being undertaken
- inactivation methods must be in place before removal of sample from MSC; these methods must be validated to ensure effectiveness of the method (for example through use of a surrogate marker)
- effective emergency procedures, including methods for dealing with spillage, are in place

- waste routes for samples are appropriate for HG3 samples (see section 9).

5.3 Work to be conducted at CL3

The following work must be conducted at CL3:

- any propagation, culturing or deliberate work on SARS-CoV-2 for diagnostic or research

6. Centrifugation

Centrifugation of specimens with infectious potential must be performed using sealed centrifuge rotors or sample cups which are loaded and unloaded in a MSC.

7. Movement of samples within the laboratory

External surfaces of specimen containers and vials must be decontaminated using a disinfectant with proven activity against enveloped viruses, prior to their removal from the MSC in CL3. Take care to avoid accidental contamination of the exterior surfaces of all vessels and containers, regardless of containment level.

8. Packaging and transport of samples

Final packaging of potentially infectious specimens (for example, to send to a reference laboratory) may be performed at CL2 if the specimens are already contained within a sealed and decontaminated primary container. Cultured samples for research or calibration must be transported in accordance with Category A transportation regulations. All potentially infectious samples must be transported in accordance with Category B transportation regulations (UN3373). (https://www.gov.uk/government/publications/packaging-and-transport-requirements-for-patient-samples-un3373)

Public Health England (PHE) follows the guidance on regulations for the transport of infectious substances 2019 to 2020 (https://www.who.int/ihr/publications/WHO-WHE-CPI-2019.20/en/), published by the World Health Organization.

Sample type	Dangerous goods classification	Additional external labelling required for samples sent to PHE	Recommended method of transportation
Suspect patient sample	Category B	White label with Priority 10 printed in red	Same day delivery courier
Presumptive positive patient sample	Category B	White label with Priority 20 printed in red	Same day delivery courier
Confirmed positive samples for follow up	Category B	White label with Priority 20 printed in red	Same day delivery courier
Contacts of known positive patients	Category B	White label with Priority 10 printed in red	Same day delivery courier
Cultured samples for research or calibration	Category A	None	Mandatory ADR approved Category A courier

8.1 Packaging samples being sent to PHE

For all packaged samples sent to PHE, make sure that:

- packaging is clearly labelled ‘PRIORITY 10’ or ‘PRIORITY 20’ as specified above per sample type
- contact details for reporting results are provided on the accompanying request form
- accompanying paperwork is **not** placed inside the packaging with or within the primary container

See additional specific packaging guidance (https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-laboratory-specimens-and-packaging).

Transport using same day delivery courier is recommended for all sample types, except for cultured samples for research or calibration which must be transported by an approved Category A carrier.

9. Cleaning and handling of waste

Irrespective of the containment level, work surfaces and equipment must be decontaminated after specimens have been processed. Pay attention to all surfaces that may have come into contact with specimens or specimen containers.

Use a disinfectant solution or disinfectant wipe with proven activity against enveloped RNA viruses, in accordance with local policies and following the manufacturer's instructions.

Dispose of clinical waste according to local and national policies appropriate to the categorisation of the waste. Waste from auto-analysers is unlikely to pose a significant risk due to the low sample volume and dilution steps, therefore special waste disposal precautions are not recommended for auto-analyser waste.

10. Emergency procedures

Emergency procedures must be reviewed according to the results of risk assessments. Fumigation of laboratory spaces will not be possible where samples are spilt outside of CL3, therefore consideration must be given to what to do in the event of a spillage, and how effective decontamination of the area will be completed. Staff must be trained on updated emergency procedures.

11. Maintaining service delivery

It is recommended that urgent and essential clinical diagnostic tests are not postponed pending the results of SARS-CoV-2 (COVID-19) testing, provided this is consistent with the local risk assessment for the planned work and that appropriate containment measures are in place.

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1. The International Committee for Taxonomy of Viruses named the causative virus SARS-CoV-2 on 7 Feb 2020 ↩
2. The World Health Organisation officially named the disease COVID-19 on 11 February 2020 ↩
3. Inactivation refers to recognised processes that inactivate viral particles and render the virus replication incompetent, for example, addition of nucleic acid extraction buffer containing guanidinium thiocyanate. The minimum requirement would be the use of an extraction buffer containing guanidinium thiocyanate. Heat inactivation may also be used in addition to this step, but this method would still require validation. ↩