Public Health England

Protecting and improving the nation's health

Interim guidance: handling and processing of specimens associated with Middle East respiratory syndrome coronavirus (MERS-CoV) in clinical diagnostic laboratories

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

Prepared by: Dr Jake Dunning
For queries relating to this document, please contact: Virus Reference Department, National Infection Service, Public Health England, 61 Colindale Ave, London NW9 5EQ. Tel: 020 8327 6017

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Scope and aims

Knowledge about the pathogenic potential and transmission risks for Middle East respiratory syndrome coronavirus (MERS-CoV) is incomplete and continues to evolve. This interim guidance is based on current knowledge and aims to minimise risks for laboratory staff handling specimens from patients with suspected or laboratory-confirmed MERS-CoV infection.

This guidance is specific to clinical diagnostic laboratory practice in England and may differ from guidance produced by agencies in other countries, including recommendations about biosafety levels. Advice offered here relates to laboratory procedures conducted in clinical diagnostic laboratories; it does not cover virus isolation, research work, or work involving animals infected with MERS-CoV. This guidance may change as new information becomes available.

Background

To date, laboratory-acquired infection has not been reported for MERS-CoV, but laboratory-acquired infections with the related SARS coronavirus have been reported (note these have only occurred in a laboratories performing virus propagation). Tissue tropism appears to be broad in humans and although MERS-CoV infection is a zoonosis, human-to-human transmission has occurred in households and healthcare facilities. Infection 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 biological safety measures represents the greatest risk of transmission of MERS-CoV in a laboratory setting. MERS-CoV RNA can also be detected in a variety of human specimens, including urine, faeces and blood. Human tissue specimens may also pose an infection risk, based on information obtained from studies of infected animals.

It is possible that laboratory workers could become infected if appropriate precautions are not taken when handling biological samples from patients infected with MERS-CoV. Since a patient with suspected MERS-CoV infection 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.

General safety measures

Risk assessments and awareness

Clinical laboratories should perform their own risk assessments for handling biological specimens from patients with suspected or confirmed MERS-CoV. Clinical staff should notify laboratory staff when specimens are submitted from a patient with suspected or confirmed MERS-CoV infection, through proper completion of request forms or electronic test ordering systems, and by direct communication with the laboratory.

Clinicians may not have considered MERS-CoV 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.

Personal protective equipment

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/gown, and may also include eye protection and other equipment, as appropriate. Masks or respirators are not necessary when respiratory tract, urine, faecal or tissue samples are handled inside a microbiological safety cabinet (MSC). If a local risk assessment deems that masks/respirators should be used, these should be FFP3 (conforming to EN149:2001) and fit-testing and training should be undertaken prior to use. Masks/respirators are not an appropriate substitute for processing samples in a MSC when this is deemed necessary.

Specific safety measures for samples from patients with suspected or confirmed MERS-CoV infection

Biosafety levels

Any procedure that involves potentially infectious material *and* is associated with a risk of generating aerosols, droplets or splashes, should always be performed within a MSC at biosafety level 3 (BSL3).

Routine laboratory tests should be carried out where possible in auto-analysers using standard practices and procedures at biosafety level 2 (BSL2).

Work that should be conducted at BSL3

It is recommended that the following work is conducted in a MSC at BSL3:

- division, aliquoting, or diluting of respiratory tract specimens, faecal specimens, urine specimens, and tissue specimens in which virus has not been inactivated*
- inoculation of bacterial or fungal culture media
- preparation of specimens for molecular testing (eg respiratory virus PCR) *prior to sample inactivation*
- urine antigen testing (eg for detection of *Legionella pneumophila* or *S. 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

*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.

Work that may be conducted at BSL2

The following work may be conducted at BSL2 following standard laboratory precautions, as long as it is consistent with the terms of the local risk assessment:

- 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
- rapid diagnostic tests for malaria parasites, as long as they are performed within a MSC at BSL2

Centrifugation

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

Movement of samples within the laboratory

Specimen containers and vials should be decontaminated using a disinfectant with proven activity against enveloped viruses, prior to their removal from the MSC in BSL3. Care should be taken to avoid accidental contamination of the exterior surfaces of all vessels and containers, regardless of biosafety level.

Packaging of samples

Final packaging of potentially infectious specimens (eg to send to a reference laboratory) may be performed at BSL2, as long as the specimens are already contained within a sealed and decontaminated primary container. All potentially infectious samples should be transported in accordance with Cat B transportation regulations. PHE follows the guidance on regulations for the transport of infectious substances 2013-2014, published by the World Health Organization (http://www.who.int/ihr/publications/who_hse_ihr_2012.12/en/).

Cleaning and handling of waste

Irrespective of the biosafety level, work surfaces and equipment should be decontaminated after specimens have been processed. Attention should be paid to all surfaces that may have come into contact with specimens or specimen containers. A disinfectant solution or disinfectant wipe with proven activity against enveloped RNA viruses should be used, in accordance with local policies and following the manufacturer's instructions. Clinical waste should be disposed of 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.

Maintaining service delivery

It is recommended that urgent and essential clinical diagnostic tests *are not* postponed pending the results of MERS-CoV testing, as long as this is consistent with the local risk assessment for the planned work and that appropriate biosafety measures are in place.

Additional information

Additional information on MERS-CoV can be found at: https://www.gov.uk/government/collections/middle-east-respiratory-syndrome-coronavirus-mers-cov-clinical-management-and-guidance.