Laboratory biosafety guidance related to coronavirus disease 2019 (COVID-19)

Interim guidance
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World Health Organization

1. Introduction

The purpose of this document is to provide interim guidance on laboratory biosafety related to the testing of clinical specimens of patients that meet the case definition of the novel pathogen identified in Wuhan, China, that is, 2019 novel coronavirus (2019-nCoV), now known as the virus responsible for coronavirus disease 2019 (COVID-19).

As our understanding of COVID-19 is limited but rapidly growing, the World Health Organization (WHO) continues to monitor developments and will revise these recommendations as necessary.

Highlights of COVID-19 laboratory biosafety

- All procedures must be performed based on risk assessment and only by personnel with demonstrated capability, in strict observance of any relevant protocols at all times.
- Initial processing (before inactivation) of all specimens should take place in a validated biological safety cabinet (BSC) or primary containment device.
- Non-propagative diagnostic laboratory work (for example, sequencing, nucleic acid amplification test [NAAT]) should be conducted at a facility using procedures equivalent to Biosafety Level 2 (BSL-2)
- Propagative work (for example, virus culture, isolation or neutralization assays) should be conducted at a containment laboratory with inward directional airflow (BSL-3).
- Appropriate disinfectants with proven activity against enveloped viruses should be used (for example, hypochlorite [bleach], alcohol, hydrogen peroxide, quaternary ammonium compounds and phenolic compounds).
- Patient specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance Category B". Viral cultures or isolates should be transported as Category A, UN2814, "infectious substance, affecting humans".

2. Laboratory biosafety

It is essential to ensure that health laboratories adhere to appropriate biosafety practices. Any testing for the presence of the virus responsible for COVID-19 or of clinical specimens from patients meeting the suspected case definition *(1)* should be performed in appropriately equipped laboratories, by staff trained in the relevant technical and safety procedures. National guidelines on the laboratory biosafety should be followed in all circumstances. For general information on laboratory biosafety guidelines, see the WHO *Laboratory biosafety manual*, 3rd edition *(2)* in the interim before the 4th edition is released.

Key points

- Each laboratory should conduct a local (that is, institutional) risk assessment to ensure it is competent to safely perform the intended testing with appropriate risk control measures in place.
- When handling and processing specimens, including blood for serological testing, laboratory practices and procedures that are basic to good microbiological practices and procedures (GMPP) should be followed.
- The handling and processing of specimens from cases with suspected or confirmed COVID-19 infection that are intended for additional laboratory tests, such as haematology or blood gas analysis, should follow local guidelines for processing potentially infectious material.
- Non-propagative diagnostic laboratory work, including sequencing and NAAT, on clinical specimens from patients who are suspected or confirmed to be infected with COVID-19, should be conducted adopting the practices and procedures of "core requirements",[1] as detailed in **Annex 1**, and an appropriate selection of "heightened control measures",[2] as informed by the local risk assessment. In the interim, BSL-2 in the WHO *Laboratory biosafety manual*, 3rd edition *(2)* remains appropriate until the 4th edition replaces it.
- Handling of material with high concentrations of live virus (such as when performing virus propagation, virus isolation or neutralization assays) or large volumes of infectious materials should be performed **only by**

[1] **Core requirements:** A set of minimum requirements defined in the 4th edition of the WHO *Laboratory biosafety manual* to describe a combination of risk control measures that are both the foundation for, and an integral part of, laboratory biosafety. These measures reflect international standards and best practice in biosafety that are necessary to work safely with biological agents, even where the associated risks are minimal.

[2] **Heightened control measures:** A set of risk control measures that may need to be applied in a laboratory facility because the outcome of a risk assessment indicates that the biological agents being handled and/or the activities to be performed with them are associated with a relatively high risk that cannot be acceptable solely with the core requirements.