



Revised Interim Biosafety Guidelines When Handling Primary Materials

Despite COVID-19 vaccine availability and public health mitigation measures, the risks associated with primary materials, human and non-human primate materials, used for research still exists. The Institutional Biosafety Committee(IBC) is issuing the following revised guidance for working with primary samples/specimens in the laboratory. This revised guidance reflects the advances made to reach the current phase of COVID-19 pandemic.

Procedural Changes:

The IBC still requires that work with active primary materials be performed using Biosafety Level 2 (BL-2) precautions, including materials that were previously downgraded to BL-1, e.g., unfixed saliva and urine. If samples have been inactivated (loss of infectiousness) using an established and previously IBC approved procedure, then inactivated samples may now be manipulated under BL-1 containment and practices.

Examples of Inactivation procedures:

- Heat treatment with sufficient time at temperature to inactivate potential pathogens, e.g., 65° C for 30 minutes, time may be increased for larger volumes
- Use of denaturing agents containing guanidine salts (quinidine (iso)thiocyanate, *Trizol*®) on samples
- Formalin (10% buffered formalin) fixed samples with enough time that makes it possible to completely penetrate the sample

Primary Samples:

Follow Universal Precautions (outlined below) when handling samples/specimens that may potentially harbor coronavirus, e.g., saliva, mucosal swabs, fecal materials, and blood, all of which may contain potentially infectious materials.

Experiments and analytical procedures, such as the following activities, must be handled using Universal Precautions:

- Using automated instruments and analyzers
- Manipulations (pipetting, vortexing, etc.) of primary human and non-human primate materials
- Packaging of specimens for transport to diagnostic laboratories for additional testing. Specimens should already be in a sealed, decontaminated primary container

Inactivated Samples:

If samples have been inactivated using an established and IBC approved procedure, then inactivated samples may now be manipulated under BL-1 containment and practices.

Experiments and analytical procedures, such as the following activities, may be handled at BL-1:

- Staining and microscopic analysis of fixed smears
- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Using inactivated specimens, such as specimens in nucleic acid extraction buffer
- Performing electron microscopic studies with glutaraldehyde-fixed grids

Universal Precautions:

Use a certified Biosafety Cabinet (BSC) whenever possible or appropriate PPE for BL-2 procedures as described below when working with primary materials.

Procedures in a BSC:

- PPE – Wear laboratory coats or gowns, gloves, and eye protection when working in a BSC
- Hand hygiene - Wash hands for at least 20 seconds after removing PPE
- Follow routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste

Procedures outside of a BSC:

BL-2 procedures that cannot take place in a BSC:

- PPE requirements: surgical mask and safety glasses or a face shield, gloves, and a lab coat or gown

BL-1 procedures (inactivated samples only) that do not take place in a BSC:

- PPE requirements: safety glasses, gloves, and a lab coat or gown

Droplet or Aerosol Producing Procedures:

The risk associated with procedures that have a high likelihood to generate aerosols or droplets (e.g., pipetting, vortexing, etc.). These procedures should take place in a certified Class II BSC.

Centrifuge equipment requirements and procedures:

- Centrifuge safety cups or removable O-ring sealed centrifuge rotors should be used to reduce the risk of exposure to laboratory personnel
- Alternatively, samples should be placed in O-ring sealed tubes
- Safety cups or O-ring tubes should be loaded and unloaded in the BSC
- If the centrifuge procedures occur without safety cups or O-ring tubes, the centrifuge should be moved into the BSC

These guidelines were adapted from the CDC [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 \(COVID-19\)](#).