SARS-CoV-2 LABORATORY BIOSAFETY GUIDANCE

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cdc.gov/coronavirus
DISCLAIMER

The information provided is based on current information regarding best practices obtained from guidance and publications issued by the U.S. Centers for Disease Control and Prevention as well as other international, federal, state and local public health officials, as of May 7, 2020.
OVERVIEW

- Discuss definitions
- SARS-CoV-2 pathogenesis
- Review current CDC and WHO laboratory biosafety guidance
- Discuss the concepts of risk assessment
- Resources
DEFINITIONS

- **Biosafety** – application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents.

- **Coronaviruses** – spherical, enveloped, positive sense single-stranded RNA viruses with club-shaped glycoprotein projections giving the appearance of a crown.

- **Infection Prevention Control** – preventing the spread of infections in healthcare settings.

- **Disinfection** – chemically or physically removing labile, vegetative forms of pathogenic organisms.*

- **Biological Risk Assessment** – the process of identifying potential adverse events associated with handling a specific pathogen, including the probability of occurrence and severity of impact on human health or the environment.

- **Standard Precautions** – practices used to prevent transmission of diseases that can be acquired by contact with blood, body fluids, non-intact skin (including rashes), and mucous membranes.

*https://www.cdc.gov/infectioncontrol/guidelines/disinfection/introduction.html
SARS-CoV-2 PATHOGENESIS

- COVID-19 is the disease, caused by a new or “novel” coronavirus, named SARS-CoV-2.

- Coronaviruses are commonly found in people and animals, such as camels, cattle, cats, and bats. They are:
  - Transmitted by infectious aerosols and droplets on mucosal surfaces.
  - Replicate in epithelial cells causing short term cell damage in lungs and intestinal mucosa.

- In some cases, cell damage can release inflammatory mediators causing a “cytokine storm” and more serious complications.
Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Summary of Recent Changes

Revisions made on May 11, 2020 include recommendations for:
- Point-of-Care testing guidance for COVID-19

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General Guidance
- Virus Isolation
- Decontamination
- Laboratory Waste Management
- Specimen Packing and Shipping
- Resources

Environmental Specimen Testing

Laboratory biosafety

Background
The purpose of this document is to provide interim guidance on laboratory biosafety related to the testing of clinical specimens of patients who meet the case definition of coronavirus disease (COVID-19). This version is an update to the interim guidance adding recommendations on point-of-care (POC) or near-POC assays.

Background
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Labratory biosafety

It is essential to ensure that health laboratories adhere to appropriate biosafety practices. Any testing for the presence of SARS-CoV-2, the virus that causes 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 laboratory biosafety should be followed in all circumstances. For general information on laboratory biosafety guidelines, see the WHO Laboratory biosafety manual: third edition (3) in the interim before the fourth edition is released.

Key points
- Each laboratory should conduct a local (that is, institution) risk assessment to ensure that all work associated with testing is appropriately performed with appropriate risk-control measures in place as exemplified in Annex II.
- When handling and processing specimens, including blood and related biological materials, the laboratory staff and procedures must be based on good microbiological and procedural (GMP) practices.
- The handling and processing of specimens from patients with suspected or confirmed COVID-19, and from laboratory personnel, must be conducted in a manner that minimizes the potential for occupational exposure.
- Laboratory staff involved in the handling and processing of clinical specimens should be informed of the potential risks associated with handling such materials.

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Perform a site-specific and activity-specific **Risk Assessment** to identify and mitigate risks based on:
- Procedures to be performed
- Hazard identification
- Personnel competency level
- Laboratory equipment and facility
- Available resources, such as PPE and disinfectant

Use **Standard Precautions** to handle all clinical specimens.
- Hand hygiene
- PPE such as laboratory coats or gowns, gloves, and eye protection
- If potential for aerosol generation, use Class II BSC or additional PPE such as mask or face shield

Follow **routine laboratory practices and procedures** for decontamination of work surfaces and management of laboratory waste.

ROUTINE DIAGNOSTIC TESTING

Work in a BSL-2 laboratory, following Standard Precautions for:

- Using automated instruments and analyzers.
- Processing initial samples.
  - Considerations for Biosafety Cabinet (BSC) use is included in following slides
- Molecular analysis of extracted nucleic acid preparations.
- Packaging sealed, decontaminated primary containers with specimens for transport to diagnostic laboratories.
- Handling specimens inactivated in nucleic acid extraction buffer.

DECENTRALIZED AND POINT-OF-CARE TESTING

- For procedures with a high likelihood to generate aerosols or droplets, use either a certified Class II Biological Safety Cabinet (BSC) or additional precautions to provide a barrier between the specimen and personnel (CDC).
  - Procedures associated with generation of infectious aerosols or droplets include: centrifugation, pipetting, vortexing, mixing, shaking, removing caps, aliquoting specimens, spilling specimens, cleaning up spills.

- Initial processing (before inactivation) of all specimens, including those for sequencing and NAAT, should take place in an appropriately maintained and validated BSC or primary containment device (WHO).

GENERATING DROPLETS AND/OR AEROSOLS

- Activities with a high likelihood of generating aerosols or droplets, use either a certified Class II Biological Safety Cabinet (BSC) or additional precautions to provide a barrier between the specimen and personnel.

- Additional precautions for reducing the risk of exposure to laboratory personnel may include:
  - Surgical mask, face shield, or other physical barriers such as a splash shield
  - Centrifuge safety cups
  - Sealed centrifuge rotors

VIRUS ISOLATION

- Biosafety Level 3 (BSL-3) laboratory using BSL-3 practices is necessary for virus isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens.

- Site- and activity-specific biosafety risk assessments determine if additional biosafety precautions are necessary based on situational needs.

DECONTAMINATION

- Decontaminate work surfaces and equipment using disinfectants known to be effective against SARS-CoV-2 (e.g., US EPA registration list).
  - Follow manufacturer’s recommendations for concentration, contact time, and safe handling.

- WHO guidance: Use disinfectants with proven activity against enveloped viruses such as hypochlorite (bleach), alcohol, hydrogen peroxide, quaternary ammonium compounds and phenolic compounds.

https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2
LABORATORY WASTE MANAGEMENT

- Handle laboratory waste from testing suspected or confirmed SARS-CoV-2 patient specimens as all other biohazardous waste in the laboratory.
- Note that because Cepheid GeneXpert cartridges for SARS-CoV-2 contain guanidinium thiocyanate (GTC), high temp incineration is recommended for proper disposal.
- Currently, there is no evidence suggesting additional packaging or disinfection procedures are necessary.

PACKING AND SHIPPING SAMPLES

Follow the International Air Transport Association (IATA) Dangerous Goods Regulations (DGR).

- Patient specimens from suspected or confirmed cases to be used for diagnostic or investigational purposes should be packaged and transported as UN3373, “Biological Substance Category B.”
  
  - Personnel packing, and shipping patient specimens, cultures or isolates, must be trained in the regulations for Division 6.2.

- Viral cultures or isolates should be transported and packed as Category UN2814, “infectious substance, affecting humans.” (WHO)

https://www.iata.org/contentassets/90f8038b0eaa42069554b2f4530f49ea/covid-19-dangerous-goods-guidance.pdf
DEVELOP A RISK ASSESSMENT

- Protects the worker plus their colleagues, family and community against infection and prevents environmental contamination.

- Site- and activity-specific risk assessments determine the additional biosafety precautions warranted for each situation.

- Note recent APHL COVID-19 Risk Assessment free seminar.

"Biosafety is an inexact science, and the interacting system of agents and activities and the people performing them are constantly changing." 

- Every etiologic agent is different.
- Every laboratory is different.
- Every person is different.

RISK MANAGEMENT PROCESS

RISK MANAGEMENT steps

- Assess Hazards
- Identify Hazards
- Make Risk Decision & Develop Controls
- Implement Controls
- Supervise & Evaluate
RISK MANAGEMENT PROCESS

- There is risk in **everything** we do.
- Never take too lightly the potential of biological organisms.
- Don’t underestimate the value of **good training**.
- Assume **any unknown illness** in your lab is a potential Laboratory Acquired Infection (LAI), until proven otherwise.
- Be conservative when dealing with **unknown or unfamiliar pathogens**.
- Have a **plan** to deal with community acquired illness among laboratory staff.
- Develop an overall **communication plan**.\(^2\)

\(^2\)https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF
COVID-19 BIOSAFETY RESOURCES

WHO:


COVID-19 BIOSAFETY RESOURCES

US CDC

ABSA International SARS-CoV-2/COVID-19 Toolbox
- https://absa.org/covid19toolbox/

Africa CDC

APHL Free COVID-19 Risk Assessment Seminar
QUESTIONS?
For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.