APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

APRIL 2026

Handling a Specimen Suspected of Containing a High Consequence Pathogen

A Checklist for Clinical Laboratories

This checklist is intended for any laboratory that might handle a specimen containing a suspected high consequence pathogen (HCP) and is designed to help identify potential gaps in institutional biosafety plans. This will allow the laboratory to prepare for and respond to an HCP and provide the necessary training to mitigate any enhanced exposure risks.

High consequence pathogen (HCP): HCPs, which can include select agents, are characterized as causing an acute infectious disease with a high mortality rate in otherwise healthy people, where the pathogen is easily transmitted from person-to-person with epidemic or pandemic potential. In addition, there may not be effective prophylaxis or treatment, or the pathogen may be difficult to recognize rapidly. There is a heightened risk in a laboratory handling a potential HCP.

Biorisk management (BRM): The process by which laboratories and facilities combine safety and security measures to control or minimize risks associated with the handling, storage and disposal of biological agents and toxins. Strong BRM practices are essential for laboratories working with potential HCPs to ensure the protection of laboratory personnel, the public and the environment.

The checklist consists of five sections:

Note: The checklist questions are included to guide biosafety discussions within the laboratory and do not address biosecurity practices. Additionally, some questions may not be applicable and some laboratories may want to add other questions to this tool.

Information gained from this tool can be used to help identify areas for improvement in biosafety practices. This checklist can be modified to meet the specific needs of any laboratory.

HCP Preparedness and General Laboratory Safety

Preparedness and Safety Questions	Answer	Comments
Has your facility developed a BRM program?	☐ Yes ☐ No ☐ N/A	
Is there supporting documentation that outlines biosafety and biosecurity training and competency requirements? e.g., biosafety plan or training records	☐ Yes ☐ No ☐ N/A	
Are staff competencies in biosafety and biosecurity assessed and documented?	☐ Yes ☐ No ☐ N/A	
Is biosafety and biosecurity training provided at regular intervals?	☐ Yes ☐ No ☐ N/A	
Is there guidance on how to conduct a biological risk assessment?	☐ Yes ☐ No ☐ N/A	
Has a biological risk assessment been conducted for all procedures to include equipment where a potential HCP specimen may be handled?	☐ Yes ☐ No ☐ N/A	
Are protocols in place to identify and respond to an HCP?	☐ Yes ☐ No ☐ N/A	
Is there a current biosafety manual or plan available, including any enhanced HCP-specific controls?	☐ Yes ☐ No ☐ N/A	
Is there documentation that staff have reviewed and understand the biosafety manual?	☐ Yes ☐ No ☐ N/A	
Has the APHL Laboratory Instrument Pre-purchase Risk Assessment Checklist been implemented?	☐ Yes ☐ No ☐ N/A	
Is a certified Class II biological safety cabinet (BSC), Class III BSC or glove box available, and if not are procedures in place to allow for the safe handling of laboratory specimens?	☐ Yes ☐ No ☐ N/A	

Preparedness and Safety Questions	Answer	Comments
Are staff trained in appropriate safe use of laboratory equipment? e.g., centrifuge, autoclave, BSC	☐ Yes ☐ No ☐ N/A	
Does the occupational health plan have protocols to identify risks to laboratory personnel working with an HCP?	☐ Yes ☐ No ☐ N/A	
Is the appropriate personal protective equipment (PPE) available to those who handle and package for transport specimens that might contain an HCP (to include fit testing of respirators when appropriate)?	☐ Yes ☐ No ☐ N/A	
Are staff trained on which PPE to use and how to correctly don and doff PPE when handling a specimen that might contain an HCP?	☐ Yes ☐ No ☐ N/A	
Are appropriate packaging and shipping materials available? i.e., Category A or Category B Shippers	☐ Yes ☐ No ☐ N/A	
Is a trained staff member available for packaging and shipping of Category A or Category B shipments?	☐ Yes ☐ No ☐ N/A	
Is a communication plan in place to identify a person under investigation for an HCP to coordinate testing with all sections of the laboratory involved in the management of the patient?	☐ Yes ☐ No ☐ N/A	
Have HCP-specific exercises or drills been conducted related to the following areas: • **Biosafety procedures** (e.g., spill response, containment breach) • **Exposure or incident response** (e.g., needlestick, aerosol exposure) • **Emergency preparedness** (e.g., high-risk pathogen response) • **Biosecurity or security events** • **Other (please describe)**	☐ Yes ☐ No ☐ N/A	If yes, describe the type and frequency of drills conducted:
Are staff trained and understand emergency procedures for exposures or response to other lab incidents?	☐ Yes ☐ No ☐ N/A	
Does the laboratory include training on the applicable select agent program requirements for clinical/diagnostic laboratories?	☐ Yes ☐ No ☐ N/A	

Planning for a Potential HCP Event (Pre-analytical Phase)

This section ensures that clinical laboratories are prepared to handle a potential HCP specimen through risk assessments, equipment checks, training, communication and procedural planning.

Pre-analytical Phase Questions	Answer	Comments
Are specimen collection, packaging, and shipping procedures available?	☐ Yes ☐ No ☐ N/A	
Are staff trained in proper specimen handling to minimize exposure risks to suspect HCP specimens?	☐ Yes ☐ No ☐ N/A	
Are policies in place for the safe transport of HCP infectious materials within the facility documented and understood?	☐ Yes ☐ No ☐ N/A	

Response to an HCP Event (Analytical and Post-analytical Phases)

This section ensures clinical laboratories are prepared to respond to handling of specimens that are presumptive for or confirmed to contain an HCP.

Analytical and Post-analytical Phase Questions	Answer	Comments
Are staff trained and competent in performing the required rule in/rule out tests for HCPs? Resource: Biothreat Agents Identification Bench Cards for Sentinel Laboratories	☐ Yes ☐ No ☐ N/A	
Are contingency plans in place for equipment failures and does equipment have backup power available in the event of a failure? e.g., UPS, generator	☐ Yes ☐ No ☐ N/A	
Are procedures accessible for the transport of infectious materials outside the facility documented and understood? e.g., courier, shipping activities	☐ Yes ☐ No ☐ N/A	
Does the laboratory have a documented and understood plan for both: • **Communicating critical or potential HCP results to appropriate partners* and** • **Referring specimens or isolates to the jurisdictional or state or local public health laboratory for confirmatory testing?** * e.g., EMS, infection control, and public health agencies	☐ Yes ☐ No ☐ N/A	

Analytical and Post-analytical Phase Questions	Answer	Comments
Are protocols for disposal of HCP-contaminated waste and sharps documented and understood?	☐ Yes ☐ No ☐ N/A	
Are protocols in place to describe processes for decontamination of a potential HCP specimen (waste management)?	☐ Yes ☐ No ☐ N/A	
Are protocols for the disinfection, decontamination, and disposal of potentially HCP contaminated surfaces, equipment and materials clearly documented, communicated and understood by staff?	☐ Yes ☐ No ☐ N/A	
Are staff trained and familiar with all instrument decontamination procedures in the event an HCP was confirmed?	☐ Yes ☐ No ☐ N/A	
Does the laboratory have a process available for identifying and storage of a specimen/isolate while awaiting confirmation testing and prior to decontamination?	☐ Yes ☐ No ☐ N/A	
Do all laboratory sections have an occupational health plan to monitor staff for symptoms following the testing of a specimen that contained an HCP?	☐ Yes ☐ No ☐ N/A	
Is there a clear and documented procedure for reporting a potential exposure?	☐ Yes ☐ No ☐ N/A	
Is there a clear and documented procedure for working with external stakeholders*? *e.g., state/local public health laboratories?	☐ Yes ☐ No ☐ N/A	
Are plans available to perform a post-incident review to assess response effectiveness and to identify lessons learned for inclusion in future trainings and updates to protocols as appropriate?	☐ Yes ☐ No ☐ N/A	

Compliance with Select Agent Regulations When a Select Agent is Confirmed

Select Agent Compliance Questions	Answer	Comments
Upon identification of a select agent, are procedures available to comply with the Federal Select Agent Program regulations to include destruction (using acceptable decontamination method) or transfer of any materials that might contain a select agent, and the reporting of a potential exposure event?	☐ Yes ☐ No ☐ N/A	If yes, describe the method:
Is the laboratory, in consultation with the Federal Select Agent Program, prepared to complete Sections C and D of the CDC Form 4A and submit to the Division of Regulatory Science and Compliance's Federal Select Agent Program within the stipulated regulatory timeframe following HCP confirmation?	☐ Yes ☐ No ☐ N/A	

Laboratory personnel need to be interviewed to determine what procedures/activities were performed, where they were performed, what types of instruments were used and whether personnel exposure to blood and body fluids could have occurred.

From the above information, determine the level of risk based on activities performed and characteristics of pathogen detected:

If high risk:

- Exclude from work and medical surveillance/symptom monitoring provided for appropriate length of days based on pathogen present.
- Offer post exposure prophylaxis, if available.
- If signs and symptoms consistent with illness detected/reported transport to assessment or treatment hospital and evaluate patient and perform testing if indicated.

If low risk:

- Medical surveillance/Symptom monitoring provided for appropriate length of days based on pathogen present.
- Offer Post Exposure Prophylaxis, if available.

Addendum: Evaluation of Post-exposure risks

This section is to assist in the evaluation of post-exposure risks for laboratory personnel who have handled patient specimens that have been documented to contain an HCP that can be transmitted by blood and body fluids.

☐ **Does the laboratory have access to biosafety, infection control or occupational health professionals to help identify any potential exposures or other "releases" involving a select agent that requires completion of a CDC Form 3 and submission to FSAP? If so, please describe:**

Specimen Inactivation

Inactivating specimens renders them noninfectious.

☐ **The specimen was inactivated prior to testing.**

☐ **If so, was the method used validated for the agent and specimen type? Describe:**

Equipment and Specimen Handling

Open Systems

Open systems have areas that require manual handling of the patient specimen at some point in the testing process—including if specimens are manually handled on the bench—or the instrument design allows for unprotected specimen manipulation that has been associated with aerosolization/droplet formation (see **"Aerosols" on page 9**).

☐ **An open instrument system is in use. Describe:**

Open System Questions	Answer	Comments
Did manipulation include centrifugation, making smears, slide agglutination, needles, syringes or sharps? See Routes of Exposure (page 8) and Aerosols (page 9).	☐ Yes ☐ No	
Does the open system have any points along the specimen handling path that are exposed to the environment?	☐ Yes ☐ No	

Closed Systems

Closed systems protect laboratory personnel from the specimen from the time the specimen (without prior handling or manipulation) is placed in the instrument until the results are generated.

☐ **A close instrument system is in use. Describe:**

Closed System Questions	Answer	Comments
Is the specimen aliquoted or otherwise manipulated prior to placing on the instrument? Manipulation may include (but is not limited to): centrifugation, making smears, slide agglutination, needles, syringes and sharps. See Routes of Exposure (page 8) and Aerosols (page 9).	☐ Yes ☐ No	
Does disposal of the leftover specimen or other waste from testing require direct handling by personnel?	☐ Yes ☐ No	

Routes of Exposure

Evaluate potential routes of transmission of the infectious agent:

- ☐ **Sharps injury (e.g., needles, scalpel, scissors)**
- ☐ **Spills, splashes and droplet contamination**
- ☐ **Blood and body fluid contamination of non-intact skin**
- ☐ **Inhalation of aerosols/droplets (including potential sources from automated equipment)**
- ☐ **Direct mucous membrane contact to mouth, nose and eyes**

If yes to any exposure routes, describe:

Aerosols

Aerosols/droplets can be generated from most routine laboratory procedures done in many areas of the laboratory but often are undetectable.

Use of Personal Protective Equipment

For each procedure in this section that was performed, please note whether the following PPE were used:

- Gloves worn while handling all potentially contaminated materials, containers, equipment, surfaces.
- Lab coat with knit cuffs
- Mucous membrane protection:
  - Surgical mask to cover nose and mouth
  - N95 mask (if airborne pathogen)*
  - Eye protection*

* If no mask or eye protection was used, please note if work was performed in a BSC or behind Plexiglas splash shield.

Using, Manipulating Needles, Syringes and Sharps

Activities	Performed	PPE Worn	Comments
Subculturing positive blood culture bottles, making smears	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Expelling air from tubes or bottles	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Withdrawing needles from stoppers	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Separating needles from syringes	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Aspirating and transferring body fluids	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Dissecting and working with fresh human tissues	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Performing frozen sections on fresh tissue	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	

Manipulating Inoculation Needles, Loops and Pipettes

Activities	Performed	PPE Worn	Comments
Flaming loops	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Cooling loops in culture media	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Subculturing and streaking culture media	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Expelling last drop from a pipette Including Eppendorf pipettes	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	

Manipulating Specimens and Cultures

Activities	Performed	PPE Worn	Comments
Centrifugation	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Setting up cultures, inoculating media	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Mixing, blending, grinding, shaking, sonicating and vortexing specimens or cultures	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Pouring, splitting, or decanting liquid specimens	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Removing caps or swabs from culture containers, opening lyophilized cultures, opening cryotubes	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Spilling infectious material	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	

Activities	Performed	PPE Worn	Comments
Filtering specimens under vacuum	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Preparing isolates for automated identification/ susceptibility testing	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Potential droplet/aerosol generation associated with the automated equipment itself	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Preparing smears, performing heat fixing, staining slides	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Performing catalase test	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Performing serology, rapid antigen tests, wet preps, and slide agglutinations	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Throwing contaminated items into biohazardous waste	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	
Cleaning up spills	☐ Yes ☐ No	☐ All listed PPE worn ☐ Some listed PPE worn ☐ None worn	

References

- APHL Biorisk Management Program Guidance
- APHL Biothreat Agents Identification Bench Cards for Sentinel Laboratories (provides guidance on presumptive identification and referral procedures)
- APHL Laboratory Exposure Assessment Guide
- APHL Risk Assessment Best Practices and Examples
- ASPR Understanding Risk Groups in Laboratory Safety
- CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition, Appendix N—Clinical Laboratories
- CDC Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories
- CDC MMWR Notes from the Field: Response to a Case of Travel-Associated Lassa Fever — Iowa, October–November 2024
- OSHA Bloodborne Pathogens Standard: 29 CFR 1910.1030

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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This project was 100% funded with federal funds from a federal program of $816,629. This publication was supported by Cooperative Agreement #U47CD000001 from the US Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.