Texas Department of State Health Services
Laboratory Services Section
Risk Assessment Template for Sentinel Laboratories

Introduction:
Hazards and risks are present in every laboratory environment. Biosafety practices must be adhered to in all areas of the laboratory that encounter potentially infectious materials. Identifying hazards and mitigating risks associated with these hazards are essential to ensuring laboratory personnel, the public, and the environment remain safe.

A risk assessment by definition is a structured process of gathering and evaluating available information on hazardous substances and determining the possible risks associated with potential exposure. Risk assessments also help laboratorians to gauge the changes occurring within the laboratory and the need to reassess work and safety measures to mitigate the identified risks. Risk assessments analyze the biosafety measures in place with respect to: pathogen, procedure, personnel performing the work, personal protective equipment (PPE), and laboratory facility.

After the identification of hazards and their associated risks within the laboratory environment, the mitigation of these risks may include implementing controls. Risk Control is a method of managing the risk with the primary emphasis on controlling the hazards at source. For a risk that is assessed as "high", steps should be taken immediately to minimize risk of injury. The method of ensuring that risks are controlled effectively done by using the "hierarchy of controls" which include: elimination (remove the hazard), substitution (replace the hazard), engineering controls (create barriers between people and the hazard), administrative controls (change the way people work), and PPE (worn clothing or equipment that aids as a barrier between the hazard and the people). The conclusions of the risk assessment should be reviewed with staff and management. The team utilizing this document will discuss implementation of mitigation measures. Finally, a follow-up risk assessment will be performed to determine the effectiveness of the mitigation measures.

A risk assessment should be performed: before analysis begins, whenever the procedure location is moved, when laboratories are renovated, when new employees begin working, when reagents are changed (manufacturer, type of reagent, etc.), before new equipment is used, and repeated when changes are made to the procedure, facility, and the employee.

Purpose:
This document is provided to assist in the selection of biosafety levels, microbiological practices, use of safety equipment, and facility safeguards to prevent laboratory-acquired infections (LAI) and environmental exposures. Risk assessments should be performed by a qualified individual(s) and the observations compared before conclusions are made and mitigation measures implemented.

Responsibilities:
It is the responsibility of the Laboratory Supervisor to conduct a biosafety risk assessment before conducting any procedure in the laboratory. All laboratory staff members must be familiar with the risk assessments in which they are involved and follow all SOPs and policies and procedures that are developed from those risk assessments. To adequately assess risk, the hazards associated with the chemical or biological agent must be assessed. Equipment, procedures, and competency of the laboratory staff must all be considered when assessing risk.

Risk Assessment Directions:
Please note that Risk Assessments should be performed: annually, when new testing/methods are introduced, equipment is moved or introduced into the laboratory, potential for aerosolization is introduced, potential for needle-sticks is introduced, laboratory space is physically altered or decommissioned, a new pathogen is detected, staffing changes, and annually for assays performed in the laboratory.

1. Identify the activity/procedure/SOP/test

2. Identify the individuals who should be involved in the process.
    a. Management, supervisors, and lab workers must be involved in performing the risk assessment and implementing the safety measures that are decided upon.

3. Understand the limitations of a Risk Assessment.
    a. Risk Assessments are a subjective process that involves professional judgements based on knowledge and experience of past events.
    b. Potential hazards identified may be based on incomplete knowledge, personal differences in what constitutes a risk, and what is an acceptable level of risk.
    c. It is not usually possible to eliminate all risks; aim for what is reasonably practical. This means avoiding any unnecessary risk; it is not practical to anticipate unforeseeable risks.

4. Gather information
    a. Review the process/procedure/activity being assessed.
    b. Tour the workplace—consider the activities, processes or reagents involved.
    c. Review the manufacturer's instructions for potential hazards and safety features.
    d. Review previous accident, illness and surveillance reports.
    e. Review the Chemical and Biological Safety Data Sheets for hazards and suggested guidelines for safe handling (PPE, BSC, fume hood, etc.).
    f. Review the organism/agent's properties, stability and persistence in the environment.
    g. Think about long-term hazards to health (for example and if more than one chemical is used the synergist effects may be greater than the combined risks listed on the individual MSDSs).

5. Consider all steps in a procedure
    a. Review the steps from the time a specimen is collected until it is permanently disposed (Pre-analytical, Analytical, Post-analytical phases).

6. Identify the Hazards—what can go wrong?
    a. For each activity/task, consider what can go wrong?
    b. List potential hazards in the appropriate column on the Risk Assessment. Each activity or task may have more than one hazard associated with it. Hazards are rarely a simple case of one singular cause resulting in one singular effect.

7. Identify the Current controls
    a. Risk control is a method of managing the risk with the primary emphasis on controlling the hazards at the source.
    b. List the controls that are in place for each hazard. There may be several controls in place for each hazard.

8. Likelihood of Hazards Occurring
    a. Consider the likelihood.
    b. How often is the task done? Does this make the harm more or less likely?
    c. How often are people near the hazard?
    d. Has it ever happened before? How often?
    e. What is the likelihood of the hazard identified happening?
        i. Rare: may happen only in exceptional circumstances
        ii. Unlikely: might happen at some point
        iii. Possible: could occur occasionally
        iv. Likely: will probably occur in most circumstances
        v. Almost certain: expected to occur in most circumstances

9. Consequence if the hazard did occur
    a. Minimal: hazard or near miss requiring reporting and follow up action
    b. Minor: potential first aid injury
    c. Moderate: potential medical treatment injury or illness
    d. Major: potential lost time injury, non-permanent disability
    e. Severe: potential fatality or injury or illness with permanent disability

10. Mitigate Remaining Hazards/Actions based on Risk Matrix

11. Develop Risk Control Plan
    a. Describes practices, procedures, and resources needed to ensure the safety on an activity.
    b. List the controls required for the activity.

12. Review the Risk Assessment/Monitor
    a. Annually
    b. When operational conditions change
    c. When equipment changes
    d. Following an accident or incident
    e. When personnel changes
    f. When new knowledge is obtained regarding the hazards associated with the work.

Section I: Microbiological Risks
(Please select all that apply)

Procedure Name:

Sample Risk Group 2 Viral Pathogen SOP* (Risk Assessment is an example ONLY)

Microbe/Agent of Investigation

Sample Risk Group 2 Viral Pathogen

Vaccine Available

☐ Yes ☑ No

There are 4 Risk Group Classifications (NIH Guidelines for Research Involving Recombinant DNA Molecules, 2002):

- *Risk Group 1* (RG1): Agents that are not associated with disease in healthy adult humans.
- *Risk Group 2* (RG2): Agents that are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available.
- *Risk Group 3* (RG3): Agents that are associated with serious or lethal disease which preventative or therapeutic interventions maybe available (high individual risk but low community risk).
- *Risk Group 4* (RG4): Agents that are likely to cause serious or lethal human disease which preventative or therapeutic interventions are not usually available (high individual risk and high community risk).

Microbe Risk Group (Please use www.absa.org and the Canadian Pathogen Safety Data Sheets to determine the risk group of your microbe/agent of investigation)

○ 1 ◉ 2 ○ 3 ○ 4

For Risk Group 2-4:
Likelihood that an exposure would cause an LAI: (please refer to Appendix A to determine the likelihood)

☐ Almost certain ☐ Likely ☐ Possible ☑ Unlikely
☐ Rare

Consequence of an exposure: (please refer to Appendix A to determine consequence)

☐ Minimal ☐ Minor ☑ Moderate ☐ Major ☐ Severe

Overall Risk level: (please refer to Appendix A to determine the likelihood)

☐ Low ☑ Medium ☐ High ☐ Extreme

Severity of consequences if an LAI occurred: (check all that apply)

☐ Carrier ☑ Acute Infection
☑ Chronic Infection ☑ Asymptomatic Infection
☐ Death ☐ Toxicity, oncogenicity, allergenicity

Microbiological Risk Mitigation Measures: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Engineering: work in a Class II BSC; Administrative: work in a BSL2 facility with BSL2 work practices; PPE: gloves, liquid resistant back closing disposable gown, face shield

Section II: Procedure Risks

There is a potential to be exposed to many pathogens during specimen manipulation (pre-analytical, analytical, post-analytical) depending on the patient's health, how the specimen was collected and transported, and the integrity of the specimen when it is received in the lab.
Routes of Transmission/Entry: mucous membranes, respiratory tract (inhalation), gastrointestinal tract (ingestion/oral), skin (Non-intact skin/percutaneous)

Please review the steps in the procedure being analyzed for this risk assessment. Check off all procedure risks that are applicable below. After determining the potential procedural risks, fill out the form in Appendix B.

1. *Manipulation of Sharps:* (Select all that apply)
*Potential Hazards include: exposure to biohazardous material through inhalation of infectious aerosols; exposure to bloodborne pathogens; parenteral inoculations with syringe needles or other contaminated sharps; possible cuts from sharps used in specimen collection; spills and splashes onto skin or mucous membranes

- [ ] Subculturing positive culture bottles
- [ ] Making blood smears
- [ ] Expelling air from tubes or bottles
- [ ] Withdrawing needles from stoppers
- [ ] Separating needles from syringes
- [ ] Aspirating and transferring body fluids
- [ ] Harvesting tissues
- [x] Use of pipette tips
- [ ] Other

Controls currently present when manipulating sharps: (Select all that apply)

- [x] Wear appropriate PPE
- [ ] Manipulation of samples in a BSC (Class I or II)
- [ ] Use of safer sharp products to sample blood from culture bottles
- [ ] Dispose of sharps in a rigid container
- [ ] Replace in-line HEPA filtering every six months or when they become wet or noticeably blocked
- [x] Use safe sharp products
- [ ] Minimize separation of needles from syringes
- [ ] Carefully eject tips
- [x] For infectious agents that are Risk Group 2 or 3, use pipette tips with barrier filters

- [ ] Switch from glass to plastic materials
- [ ] Dispose of sharps container when 2/3 full
- [ ] Other

Mitigation measures that can be applied to activities involving the manipulation of sharps: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Engineering: work in a Class II BSC; Administrative: train personnel to not expel the last drop from pipette

2. Manipulation of inoculating needles, loops, or pipettes: (Select all that apply)
*Potential Hazards include: exposure to biohazardous material through inhalation of infectious aerosols; exposure to bloodborne pathogens

- [ ] Flaming loops
- [ ] Cooling loops in culture media
- [ ] Subculturing and streaking culture media
- [x] Expelling last drop from pipette
- [ ] Other

Controls currently present during manipulation of inoculating needles, loops or pipettes: (Select all that apply)

- [x] Wear appropriate PPE
- [ ] Manipulation of samples in a BSC (Class I or II)
- [ ] Do not use a Bunsen burner in a BSC
- [ ] Use plastic loops in BSC
- [ ] Other

Mitigation measures that can be applied to activities involving inoculating needles, loops, or pipettes: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Engineering: work in a Class II BSC; Administrative: train personnel to not expel the last drop from pipette

3. *Manipulation of specimens and cultures:* (Select all that apply)
*Potential Hazards include: exposure to biohazardous material through inhalation of infectious aerosols; exposure to biohazardous material via direct contact of specimens, specimen containers, patient's skin, or contaminated work surfaces with employee's skin; exposure to biohazardous materials through ingestion or mucous membranes, exposure to bloodborne pathogens, spills and splashes onto skin or mucous membranes

- [x] Centrifugation
- [x] Vortexing
- [ ] Use of an aerosol chamber
- [ ] Sonicating
- [ ] Setting-up cultures
- [ ] Removing caps from culture containers
- [ ] Opening lyophilized cultures

- [ ] Opening cryotubes
- [ ] Filtering specimens under vacuum
- [ ] Preparing isolates for automated id
- [ ] Preparing isolates for susceptibility test
- [ ] Preparing smears
- [ ] Preparing blood smears
- [ ] Performing heat fixing/flame slides
- [ ] Staining slides
- [ ] Performing catalase test
- [ ] Performing serology
- [ ] Rapid antigen test
- [ ] Wet preps
- [ ] Slide agglutinations
- [ ] Disposal of biohazard waste
- [ ] High spill potential
- [x] Use of serological pipettes
- [x] Mechanical pipetting
- [ ] Screening cultures
- [ ] Susceptibility testing
- [ ] Other

Controls currently present during manipulation of specimens and cultures: (Select all that apply)

- [x] Wear appropriate PPE.
- [ ] Clean spills wearing PPE and respiratory protection.
- [ ] Allow aerosols to settle before opening equipment.
- [x] Manipulation of samples in a BSC (Class I or II).
- [x] Apply manufacturer's safety features to equipment.
- [x] O-rings on centrifuge buckets.
- [ ] Equipment used inside a BSC (Class I or II).
- [ ] Work in a BSC and use BSL-3 practices if a specimen is known or suspected to have a highly infectious disease transmitted by aerosols or droplets.
- [ ] Use a fume hood when using hazardous chemicals.
- [x] For risk group 2 and 3-, specimen manipulation with pipette tips with barrier filters.
- [ ] Use of safety cups (i.e. sealed tubes, screw-cap buckets, or sealed rotors).
- [x] Wait for centrifuge to stop before opening.
- [x] Perform work in a Class II BSC for high risk pathogens.

- [ ] Use a sound proof cabinet and wear earphone-type sound mufflers (for sonicating).
- [ ] Do not sonicate in a room containing people not wearing ear protection and shut doors.
- [ ] Use plastic backed absorbent paper over work surface.
- [x] Carefully eject tips.
- [x] Disinfect pipettes regularly.
- [x] Disinfect equipment after use or immediately after a spill.
- [ ] Perform culture set-up in a BSC.
- [ ] If AFB stain/culture is ordered on a specimen, perform all culture set-up in a Class II BSC using BSL-3 practices.
- [x] Wear additional eye protection when there is a risk of a splash or spray.
- [ ] Examine screening media for growth in a Class II BSC.
- [ ] Allow any organism smears for Gram stain to air dry or dry on a heating block in a BSC before removing. Do not use a flame to heat fix.
- [ ] Allow slides to air dry or dry on a heating block.
- [ ] Work behind a full safety shield and wear eye protection (i.e. face shield).
- [ ] Always remove caps behind a bench fixed splash shield, or wear additional PPE appropriate to protect from splashes or aerosols.
- [ ] Place gauze or biowipe over the cap and then slowly pry or push the cap off with an away-from body motion (never reuse gauze).
- [ ] Use safety transfer devices.
- [ ] Use forceps for opening lyophilized cultures.
- [ ] Use insulated cryolabeled gloves for opening cryotubes
- [ ] Replace in-line BSC HEPA filters every 6 months or when they become wet or noticeably blocked.
- [ ] Change vacuum flasks when 3/4 full.
- [ ] Filter potentially infectious agents in a BSC.
- [ ] Utilize vacuum protectors.
- [ ] Ensure instrument safety shields and containment devices are in place at time of work.
- [ ] Fill aliquot tubes using mechanical devices, never decant (pour).
- [ ] Do not use flame to heat fix, use a slide-warming tray.
- [ ] Monitor and record the temperature of the slide warmer each day of use.
- [ ] Heat fix steps on electric slide warmer.
- [x] Dispose of waste appropriately.
- [ ] Test performed in a BSC, covered Petri dish or contain aerosols in a disposable tube (for catalase test).
- [ ] Wear additional respiratory protection and disposable gown if patient is known or suspected of having an infectious disease transmitted by aerosols or droplets.
- [ ] Open plates in BSC.

- [ ] Use tube extraction and filtration for suspected infectious agents that can be transmitted by aerosol (MALDI-TOF).
- [ ] Other

Mitigation measures that can be applied to activities involving the manipulation of specimens and cultures:
(Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Engineering: work in a Class II BSC, move vortex into BSC; Administrative: train personnel to wait for centrifuge to stop before opening, train personnel to allow aerosols to settle before opening equipment, competency training to

4. *Potential to generate aerosols:*
*Potential Hazards include: exposure to biohazardous material through inhalation of infectious aerosols; exposure to biohazardous materials through ingestion or mucous membranes; exposure to bloodborne pathogens; spills and splashes onto skin or mucous membranes

- [x] Pipetting
- [ ] Subculturing positive blood culture bottles
- [ ] Expelling air from tubes or bottles
- [ ] Withdrawing needles from stoppers
- [ ] Aspirating and transferring body fluids
- [ ] Harvesting tissues
- [ ] Flaming loops
- [ ] Cooling loops in culture media
- [ ] Subculturing and streaking culture media
- [x] Expelling last drop from pipettes
- [x] Centrifugation
- [x] Vortexing
- [ ] Use of an aerosol chamber
- [ ] Sonicating
- [ ] Setting-up cultures
- [ ] Removing caps or swabs from culture container
- [ ] Opening lyophilized cultures
- [ ] Opening cryotubes
- [ ] Filtering specimens under vacuum
- [ ] Preparing isolates for automated id
- [ ] Preparing isolates for susceptibility test
- [ ] Use of an automated id system
- [ ] Preparing smears
- [ ] Performing heat fixing/flaming slides to heat fix

- [ ] Staining slides
- [ ] Performing catalase test
- [ ] Rapid antigen test
- [ ] Wet preps
- [ ] Slide agglutinations
- [ ] High spill potential
- [ ] Spotting MALDI-TOF plates
- [ ] Perform MALDI-TOF testing

Controls currently present when there is potential to generate aerosols: (Select all that apply)

- [x] Wear appropriate PPE
- [x] Clean spills wearing PPE and respiratory protection
- [x] Allow aerosols to settle before opening equipment
- [x] Manipulation of samples in a BSC (Class I or II)
- [ ] Apply manufacturer's safety features to equipment
- [x] O-rings on centrifuge buckets
- [x] Equipment should never be allowed to exceed design parameters
- [x] Equipment used inside a BSC (Class I or II)
- [ ] Work in a BSC and use BSL-3 practices if specimen is known or suspected to have a highly infectious disease transmitted by aerosols or droplets
- [x] For risk group 2 and 3-, specimen manipulation with pipette tips with barrier filters
- [x] Use of safety cups (i.e. sealed tubes, screw-cap buckets, or sealed rotors)
- [x] Wait for centrifuge to stop before opening
- [ ] Perform work in a Class II BSC for high risk pathogens
- [ ] Use plastic backed absorbent paper over work surface.
- [x] Carefully eject tips.
- [x] Disinfect equipment after use or immediately after a spill.
- [ ] Perform culture set-up in BSC
- [ ] If AFB stain/culture is ordered on a specimen, perform all culture set-up in a Class II BSC using BSL-3 practices
- [x] Wear additional eye protection when there is a risk of a splash or spray.
- [ ] Examine screening media for growth in a Class II BSC
- [ ] Allow any organism smears for Gram stain to air dry or dry on a heating block in a BSC before removing. Do not use a flame to heat fix.
- [ ] Allow slides to air dry or dry on a heating block.
- [ ] Work behind a full safety shield and wear eye protection (i.e. face shield).

- [ ] Always remove caps behind a bench fixed splash shield, or wear additional PPE appropriate to protect from splashes or aerosols.
- [ ] Place gauze or biowipe over the cap and then slowly pry or push the cap off with an away-from body motion (never reuse gauze)
- [ ] Use safety transfer devices.
- [ ] Use forceps for opening lyophilized cultures.
- [ ] Use insulated cryolabeled gloves for opening cryotubes
- [ ] Replace in-line BSC HEPA filters every 6 months or when they become wet or noticeably blocked
- [ ] Filter potentially infectious agents in a BSC
- [ ] Utilize vacuum protectors
- [ ] Ensure instrument safety shields and containment devices are in place at time of work.
- [ ] Fill aliquot tubes using mechanical devices, never decant (pour)
- [ ] Do not use flame to heat fix, use a slide-warming tray
- [ ] Heat fix steps on electric slide warmer
- [ ] Dispose of waste appropriately

- [ ] Test performed in a BSC, covered Petri dish or contain aerosols in a disposable tube (for catalase test)
- [ ] Wear additional respiratory protection and disposable gown if patient is known or suspected of having an infectious disease transmitted by aerosols or droplets.
- [ ] Open plates in BSC
- [ ] Use tube extraction and filtration for suspected infectious agents that can be transmitted by aerosol (MALDI-TOF)
- [ ] Other

Mitigation measures that can be applied to activities when there is potential to generate aerosols: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Engineering: work in a Class II BSC, move vortex to BSC

5. Use of animals:
*Potential Hazards include: cuts, bites, and scratches; exposure to bloodborne pathogens; exposure to biohazardous materials through ingestion or mucous membranes, exposure to biohazardous material through inhalation of infectious aerosols (i.e. urine and feces); exposure to biohazardous material via direct contact of specimens/containers/contaminated work surfaces; long-term use may lead to allergies

- [ ] Yes
- [x] No

Controls currently present when animals are used: (Select all that apply)

- [ ] Wear appropriate PPE
- [ ] Caging that provides protection from aerosols
- [ ] Manipulation in a BSC

Mitigation measures that can be applied to activities when animals are used: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

6. Production of large volumes or concentrations of potential pathogens/agents (Cell, viral, fungal, and microbial cultures, toxins):
Potential Hazards include: exposure to biohazardous material through inhalation of infectious aerosols; exposure to biohazardous materials through ingestion or mucous membranes; exposure to bloodborne pathogens; spills and splashes onto skin or mucous membranes

☐ Yes ☑ No

Controls present during the production of large volumes or concentrations of potential pathogens/agents: (Select all that apply)

☐ Wear appropriate PPE

☐ Perform culture set-up in a BSC

☐ Use additional BSL3 practices if specimen is known or suspected to have a highly infectious disease transmitted by aerosols and droplets

Mitigation measures that can be applied to activities when large volumes or concentrations of potential pathogens/agents are used: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Section III: Staff Capability

Has the procedure been evaluated, validated, and verified?

☑ Yes ☐ No

Has testing personnel read and signed off on the applicable procedure?

☑ Yes ☐ No

Has testing personnel been observed to be competent in collection, preparation, handing, and processing?

☑ Yes ☐ No

Has testing personnel been trained to perform relevant instrument maintenance and function checks?

☑ Yes ☐ No ☐ N/A

Has testing personnel been observed to complete the procedure safely?

☑ Yes ☐ No

If a fume hood, laminar flow cabinet, or BSC is used, does the supervisor evaluate competence of the lab personnel annually?

☑ Yes ☐ No ☐ N/A

Have personnel been trained and are aware of the PPE required for handling samples in either the pre-analytical, analytical, or post-analytical stages of processing?

☑ Yes ☐ No

Personnel Considerations: (select all that apply)

- ☑ Behavior
- ☑ Education, experience, competence
- ☑ Immune status
- ☑ Preexisting conditions
- ☐ Stress, fatigue, mental status
- ☐ Duration and frequency of exposure
- ☐ Genetic predisposition
- ☑ Overall health
- ☑ Pregnancy
- ☑ Perception (attitude, safety, etc.)

Staff Capability Mitigation Measures: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Administrative: all personnel pass a medical surveillance program before working on a procedure; all staff are trained and evaluated for competency prior to working on the procedure; all lab personnel and women of child bearing age are provided with information regarding immune competence and conditions that may predispose them to infection; PPE: immune compromised and pregnant individuals are aware of the risks of exposure and may opt for more PPE

Section IV: Facility & Equipment Risks

Facility Biological Safety Level (BSL):
Please review the descriptions of the 4 Levels provided. Further reference the BMBL 5th edition.

Biological Safety Level-1 (BSL-1)
Suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science. Represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended other than a sink for hand washing.

Please select all that currently apply to your area.

- [x] Laboratory has doors to control access to the laboratory.
- [x] There is a hand washing sink available near the laboratory exit for hand washing after working with potentially hazardous materials and before exiting the laboratory.
- [x] Eating, drinking, smoking, handling contact lenses, applying cosmetics and storage of food for consumption are not permitted in the laboratory.
- [x] Mouth pipetting is prohibited, mechanical pipetting devices must be used.
- [x] Policies for safe handling of "sharps" are developed and implemented (e.g. needles, scalpels, pipettes, broken glassware).
- [x] Procedures are performed to minimize the creation of splashes and/or aerosols.
- [x] Work surfaces are decontaminated after completion of work and after any spills or splashes of potentially infectious material with appropriate disinfectant.
- [x] Cultures, stocks and other infectious materials are decontaminated before disposal.
- [x] A biohazardous sign is posted at the entrance to the laboratory when infectious agents are present.
- [x] An effective pest management program is implemented in the laboratory.
- [x] All personnel have received appropriate training regarding their duties and the necessary precautions to prevent and evaluate exposures.
- [x] Personal protective equipment, laboratory coats, gloves, protective eyewear, are available and used appropriately.
- [x] If present, all windows in the laboratory that open to the exterior are fitted with screens.
- [x] Bench tops are impervious to water and resistant to heat, organic solvents, acids, alkalis and other chemicals.
- [x] The laboratory design allows for easy cleaning (e.g. no rugs or carpets, chairs covered in a non-porous material).

Comments:

The facility where this procedure is being performed meets all the BSL1 requirements.

Biological Safety Level-2 (BSL-2)

Must meet all the requirements listed in Biosafety Level 1 plus the following items. BSL-2 is suitable for work involving a broad spectrum of indigenous agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in biosafety cabinets (BSCs) or other physical containment equipment. Secondary barriers such as hand washing sinks and waste decontamination facilities must be available to reduce potential environmental contamination.

Please select all that currently apply to your area.

- [x] The laboratory has self-closing doors that may be locked to control access to the laboratory.
- [x] Persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
- [x] There is an automatic or manually operated hands-free hand washing sink available near the laboratory exit for hand washing after working with potentially hazardous materials and before exiting the laboratory.
- [x] Laboratory equipment is decontaminated routinely, before repair and maintenance, and after spills and splashes with contaminated material.
- [x] All potentially infectious laboratory waste is decontaminated before disposal (e.g. autoclave, chemical disinfection, incineration, etc.)
- [x] If infectious waste is decontaminated outside of the immediate laboratory, the infectious material is placed in a durable, leak-proof container and secured for transport.
- [x] A biohazard sign is posted at the entrance to the laboratory. Sign must include the following information: Laboratory's biosafety level, supervisor's or other responsible person, telephone number, required procedure for entering/exiting the laboratory.
- [x] All personnel have received appropriate training regarding their duties on the necessary precautions to prevent and evaluate exposures and have demonstrated competency in standard and special microbiological practices.
- [x] Incidents that may result in exposure to infectious materials are immediately evaluated and reported to a responsible person. Treatment is provided, and documentation of the incident is recorded.
- [x] Medical surveillance is provided to laboratory personnel and appropriate immunizations have been offered to laboratory personnel.
- [x] A biosafety manual containing established policies and procedures is available and accessible.
- [x] Personal protective clothing is removed before leaving for non-laboratory areas.
- [x] All procedures involving the manipulation of infectious materials that may generate an aerosol are conducted within a properly maintained and annually certified BSC (preferably Class II) or other physical containment device. The BSC must be installed so that fluctuations of room air supply and exhaust do not interfere with proper operations.
- [x] The BSC is located away from doors, windows, heavily traveled areas and other possible airflow disruptions.

Biosafety Level 2 continued:

- [x] Animals and plants not associated with the work being performed must not be permitted in the laboratory.
- [x] Centrifuges have centrifuge safety cups/carriers or sealed rotors and cups/carriers are only opened in a biosafety cabinet.
- [x] Vacuum lines are protected with HEPA filters, or their equivalent. Filters are replaced as needed. Liquid disinfection traps may be required.
- [x] An eyewash station is readily available.
- [x] Windows in the laboratory that open to the exterior are not recommended, but any present must be fitted with screens.
- [x] The laboratory has sufficient air exchanges (e.g. 6-8 exchanges/hour) and exhausts away from occupied areas to clear the air in the event of a spill.
- [x] If present, the chemical fume hood is in the proper working order and is certified annually.
- [x] All equipment is decontaminated before removal from the laboratory.

Comments:

The facility where this procedure is being performed meets all of the BSL2 requirements.

Biological Safety Level-3 (BSL-3)

Applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation route exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures. All procedures involving the manipulation of infectious materials must be conducted within BSCs, other physical containment devices, or by personnel wearing appropriate personal protective equipment. All procedures involving the manipulation of infectious materials that may generate an aerosol are conducted within a properly maintained and annually certified BSC or other physical containment device.

Please select all that currently apply to your area.

- [ ] The laboratory must enforce policies that control access to the laboratory.
- [ ] The laboratory has a series of two self-closing doors that may be locked to control access to the laboratory.
- [ ] A clothing changing room (anteroom) may be included in the passageway between the two doors.
- [ ] Persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
- [ ] The laboratory must be separated from areas open to unrestricted traffic flow within the building.
- [ ] If the laboratory is segregated into different rooms/zones, there is an automatic or manually operated hands-free hand washing sink available near the exit in each room/zone.
- [ ] Protective laboratory clothing with a solid-front such as tie-back of wrap-around gowns, scrub suits, or coveralls are worn by workers when in the laboratory.
- [ ] Protective clothing is not worn outside the laboratory.
- [ ] Reusable clothing is decontaminated before laundering.
- [ ] Clothing is changed when contaminated.
- [ ] Eye and face protection (goggles, mask face shield, or splatter guard) is used for anticipated splashes or sprays of infectious and other hazardous materials.
- [ ] Gloves are worn to protect hands from exposure to hazardous materials.
- [ ] If present, all windows in the laboratory are sealed.
- [ ] The laboratory design allows for easy cleaning (e.g. no rugs or carpets, chairs covered in a non-porous material)
- [ ] Seams, floors, walls, and ceiling surfaces are sealed.
- [ ] Spaces around doors and ventilation openings are sealed to facilitate room decontamination.
- [ ] Floors are slip resistant, impervious to liquids and resistant to chemicals.
- [ ] Walls and ceilings are constructed with a sealed smooth finish that can easily be cleaned and decontaminated.

- [ ] The laboratory has sufficient air exchanges (>12 exchanges/hour) and exhausts away from occupied areas to clear the air in the event of a spill.
- [ ] Laboratory exhaust is not re-circulated to any area of the building but is HEPA filtered and dispersed outside away from occupied areas and air intakes.
- [ ] Equipment that may produce infectious aerosols is contained in devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory.
- [ ] These HEPA filters are tested and/or replaced at least annually.
- [ ] BSL-3 facility design, operational parameters and procedures are verified and documented prior to operation and annually thereafter.

Comments:

N/A

Biological Safety Level-4 (BSL-4)
Required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission. Agents with a close or identical antigenic relationship to agents requiring BSL-4 containment must be handled at this level until sufficient data are obtained either to confirm continued work at this level, or re-designate the level. Laboratory staff must have specific and thorough training in handling extremely hazardous infectious agents. Laboratory staff must understand the primary and secondary containment functions of standard and special practices, containment equipment, and laboratory design characteristics. All laboratory staff and supervisors must be competent in handling agents and procedures requiring BSL-4 containment. The laboratory supervisor in accordance with institutional policies controls access to the laboratory.

Work Practices BSL:

☐ 1 ☑ 2 ☐ 3 ☐ 4

Floor Plan:

☐ Open ☑ Separate Room ☐ Alcove

Biological Safety Cabinet (BSC):
A BSC is not the same as a laminar flow hood/clean bench.

☐ Class I ☑ Class II ☐ N/A

Biological Safety Cabinet Certified: (All BSCs must be certified annually)

☑ Yes ☐ No ☐ N/A

Chemical Fume hood:

☐ Yes ☑ No

Properly Maintained Autoclave:

☑ Yes ☐ No ☐ N/A

Centrifuge with:

☑ Safety Cups ☑ Removable rotors ☑ O rings on buckets
☑ Rotors loaded in a BSC ☐ No ☐ N/A

Hand-washing Sink:

☑ Yes ☐ No

Non-porous Chairs:

☑ Yes ☐ No ☐ N/A

Impervious Bench Tops:

☑ Yes ☐ No

Personal Protective Equipment (PPE):

Gloves:

☐ Latex ☑ Nitrile ☐ Vinyl ☑ Other

Protective Eyewear:
*Eye glasses are not considered protective eyewear.

☐ Safety Glasses ☐ Goggles ☑ Face Shield ☐ N/A

Protective Clothing:

☐ Designated scrubs ☐ Lab coat
☐ Coveralls ☐ Impermeable Gown
☑ Impermeable Closed-front Gown ☐ Tyvek Jumpsuit

Respiratory Protection:

☐ Surgical mask ☐ N95 ☐ PAPR ☑ N/A

Is staff fit-tested annually for respiratory protection?

☐ Yes ☐ No ☑ N/A

Closed-toe shoes that cover entire foot:

☑ Yes ☐ No

Other:

◯ Booties ◯ Bonnet ◯ Sleeve Protectors
◯ Ear plugs

Improperly Maintained Equipment:

☐ Yes ☑ No

Specimens are safely transported: (select all that apply)

☑ Sealed transport container ☑ On a cart

Facility Equipment Risk Mitigation Measures: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Administrative: all personnel are trained to work with equipment and engineering controls (BSC) before work, all personnel are trained and competent in safely donning/doffing PPE

V. Chemical

Proper labeling: All containers labeled with the name of the chemical(s):

☑ Yes ☐ No

Updated chemical inventory:

☑ Yes ☐ No

Safety Data sheets accessible to staff:

☑ Yes ☐ No

Incompatible chemicals segregated:

☑ Yes ☐ No

Flammable liquids stored: rated chemical cabinets:

☑ Yes ☐ No

Flammable liquids stored: stored in flammable-rated refrigerators/freezers:

☑ Yes ☐ No

Excessive chemicals stored in chemical storage room:

☐ Yes ☑ No

Compressed gas cylinders stored in laboratory:

☐ Yes ☑ No

Chemicals stored at eye-level:

☑ Yes ☐ No

Acids and bases stored in:

☑ Cabinet ☐ Labeled area ☐ Free from metals

Chemical fume hoods:

☑ Certified within past year
☑ Sash closed when not in use
☑ Exhaust air not blocked by large equipment or containers
☑ Used for hazardous/toxic or flammable procedures

Chemical spill kit maintained:

☑ Yes ☐ No

Chemical Risk Mitigation Measures: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Administrative: all personnel are trained to separate chemicals, all personnel have access to safety data sheets of all the chemical present in the laboratory

VI. Emergency

Emergency contact information posted:

☑ Yes ☐ No

First aid kit maintained:

☑ Yes ☐ No

Biological spill kit maintained:

☑ Yes ☐ No

Staff aware of occupational injury procedures:

☑ Yes ☐ No

Door sign up-to-date and posted:

☑ Yes ☐ No

Laboratory microwaves and refrigerators labeled with “Not for Food or Drink—Biohazard”:

☑ Yes ☐ No

Equipment used in the laboratory is labeled with a “Biohazard” sticker:

☑ Yes ☐ No

Personal devices are not used in the laboratory (i.e. cell phones, fans, tablets, computers, radios, etc.):

☑ Yes ☐ No

Emergency Risk Mitigation Measures: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Administrative: more frequent drills for emergency procedures (biological spills, power outage, weather emergency, etc.) will be planned and executed.

VII: Waste Management

Disinfect workspaces and any spills with an appropriate disinfectant.

☑ Yes ☐ No

Chemical waste containers: (select all that apply)

☑ Labeled with chemical names and percent of each chemical
☑ Properly sealed
☑ In good condition for transport

Separate biohazard waste:

☑ Yes ☐ No

Broken glass placed in separate and appropriate container:

☑ Yes ☐ No

Sharps Containers:

☑ Yes ☐ No

Discarding waste:

☑ Double bag all biohazardous waste
☑ Use rigid biohazardous sharps container for sharps disposal
☐ Discard sharps containers when 2/3 full
☐ Disinfect/autoclave liquid waste before disposing of it when it is known or suspected of containing highly pathogenic organisms (Risk Group 3)

Waste Management Risk Mitigation Measures: (Please list controls to mitigate risk: Elimination, Substitution, Engineering Controls, Administrative Controls, and PPE)

Administrative: personnel will be retrained to dispose of sharps when 2/3 full

VIII: Miscellaneous

Specimen Transport

- [x] On a cart
- [x] Open container in a BSC
- [x] Decontaminate all surfaces of transport containers prior to reuse
- [x] Transport containers are air tight and leak proof
- [ ] Map the path the specimen travels throughout workspace
- [ ] Map the path of the specimen from patient to laboratory
- [x] High risk samples are not transported through pneumatic tube system.

Specimen Storage

- [x] Wear additional freezer gloves
- [x] Store sealed specimens in racks, or boxes, or in sealed biohazard bags to prevent leaks and spills.
- [x] Handle all stored infectious substances using standard precautions and aseptic technique.

Specimen check-in

- [x] Use safe sharps for opening packages
- [x] Use BSC to handle leaking specimens

Packaging and Shipping

- [x] Personnel must be certified in Packaging and Shipping and have required documentation to prove it.
- [x] Personnel who are certified in Packaging and Shipping receive documented refresher training and demonstrate competency every 2 years.
- [x] At least two people certified in safe packaging/shipping of International Air Transportation Association (IATA) Division 6.2 infectious substances

Section VIII: Conclusions and Recommendations

Training modules will be updated for all personnel to include: emergency egress procedures, how to move aerosol generating equipment into the BSC (vortex), and an annual refresher safety training.

Final risk level with implementation of controls: (Please refer to Appendix A)

☑ Low ☐ Medium ☐ High ☐ Extreme

Signatures and Dates:

Risk Assessment Completed: xx/xx/xxxx
Biosafety Officer
Safety Officer
Manager
Team Lead
Team

Follow-up Assessment Comments:

The mitigation strategies were implemented in the lab on xx/xx/xxxx. The risk assessment will be re-evaluated in one year.

Overall Risk after risk mitigation: (Please refer to Appendix A)

☑ Low ☐ Medium ☐ High ☐ Extreme

Next Annual Risk Assessment Planned Date:

xx/xx/xxxx

Appendix A:

The Risk Matrix should be used to complete the Risk Assessment and identify Risk Level, Follow these steps:

1. Determine likelihood of specific hazard and record in appropriate column.
2. Determine consequence of specific hazard and record in appropriate column.
3. Determine Risk Level using Likelihood and Consequence using Risk Matrix below.

Low	Risk is tolerable; manage by well-established, routine process/procedures
Medium	A Control Plan must be developed; existing controls need to be reviewed. Target resolution (ideally reduction to low level of risk) should be within 1 month.
High	A "high" risk may also require immediate assessment and senior staff consideration; a Control Plan must be developed; regular monitoring and reports made to the relevant management/staff committee. Target resolution (ideally reduction to low level of risk) should be within 2 weeks.
Extreme	An "extreme" risk requires immediate assessment and senior staff consideration is required; a detailed Control Plan must be developed, the activity should be stopped immediately unless the risk can be reduced to a level of high or less; regular monitoring and reports made to the relevant management/safety committee.

		CONSEQUENCE				
		Minimal: hazard or near miss requiring reporting and follow up action	**Minor**: potential First Aid Injury	**Moderate**: potential medical treatment injury or illness	**Major**: potential lost time injury, non-permanent disability	**Severe**: potential fatality or injury or illness with permanent disability
LIKELIHOOD	**Rare**: may happen only in exceptional circumstances	Low	Low	Low	Low	Medium
	Unlikely: could happen at sometime	Low	Low	Medium	Medium	High
	Possible: might occur occasionally	Low	Medium	High	High	High
	Likely: will probably occur in most circumstances	Low	Medium	High	High	Extreme
	Almost certain: expected to occur in most circumstance	Medium	High	High	Extreme	Extreme

Appendix B: (Please fill out the attached Word Document)

Attached

References and Resources:
This document was generated using the resources and templates, listed below.

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Public Health Agency of Canada, "Pathogen Safety Data Sheets", http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php .