**Laboratory Biosafety:**

 **Performing a Biosafety Risk Assessment**

**Created March 2010 by:**

**Wisconsin State Laboratory of Hygiene**

**In Collaboration with the Risk Assessment Subcommittee**

**of the**

 **Wisconsin Clinical Laboratory Technical Advisory Group (LabTAG)**

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**Revised: September, 2015**

 **September, 2017**

***Please complete the following:***

**Name of your Facility**

**Address/City/State/Zip:**

**Name of Individual(s) Completing this Risk Assessment**

**Email and Phone# of Individual Submitting this Risk Assessment:**

**Please choose the level of service that most accurately describes your laboratory:**

[ ]  **Laboratory provides full microbiology service that includes Gram stain, bacterial identification and antimicrobial susceptibility testing (may or may not include specialties such as mycobacteriology, mycology, anaerobes, parasitology, and virology).**

[ ]  **Laboratory provides full microbiology service that includes Gram stain, bacterial identification and antimicrobial susceptibility testing, but only on limited specimen sources (e.g. culture only on urines, throats, etc.)**

[ ]  **Laboratory performs Gram stain, culture set-up and screens plates or blood culture bottles for growth; refers positives for further work-up to a reference laboratory.**

[ ]  **Laboratory performs Gram stain and culture set-up only; refers all culture reading and work-up to a reference laboratory.**

[ ]  **Laboratory refers both Gram stains and primary specimens to a reference laboratory.**

**Number of beds:**

**Billable microbiology test volume:**

**How many total FTEs in microbiology:**

**How many of those total FTEs are dedicated to microbiology:**

**How many of those total FTEs are generalists:**

**Which shifts are the following tasks performed on? (Check all that apply)**

 **1st Shift 2nd Shift 3rd Shift**

**Primary gram stain reading and reporting** [ ] [ ] [ ]

**Plate reading with preliminary report** [ ] [ ] [ ]

**Organism identification and/or susceptibility testing** [ ] [ ] [ ]

**Molecular testing** [ ] [ ] [ ]

**Have you had any of the following changes in your laboratory within the last year:**

**Yes No**

**New staff** [ ] [ ]

**New procedure/method/or instrumentation** [ ] [ ]

**New physical surroundings/facility or remodeling** [ ] [ ]

**Work with new agent** [ ] [ ]

**If you answered yes to any of the above have you performed a biosafety risk assessment related to the change?**

**Yes No**

[ ] [ ]

**Do you have a written plan or SOP for when you perform a biosafety risk assessment?**

**Yes No**

[ ] [ ]

**Do you review your completed biosafety risk assessments at least annually?**

**Yes No**

[ ] [ ]

**Do you have a written biosafety plan?**

**Yes No**

[ ] [ ]

**Do you review your biosafety plan at least annually?**

**Yes No**

[ ] [ ]

**Have you, or do you plan to incorporate biosafety into your employee competency assessments?**

**Yes No**

[ ] [ ]

***Please use this comment section to explain any “no” answers:***

|  |
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| **Comments:** |

 **Laboratory Biosafety: Performing a Biosafety Risk Assessment**

**The goal of biosafety is to protect people from dangerous pathogens**

**All individuals in your laboratory should be trained**

**to safely assess the risk of the tasks they perform and**

**to properly use the required personal protective equipment**

 **(including fit testing for N-95 masks or PAPR)**

**This document is meant to serve as a tool in performing a biosafety risk assessment for your laboratory. The document provides questions to ask when performing a biosafety risk assessment, lists mandatory biosafety requirements and offers guidance for additional protection – preferred and additional protection - alternative biosafety practices. The document is divided into two sections; a facility/processes assessment and a task assessment. Red print has been used in this document to draw your attention to important items. Blue print is used to provide directions or to indicate items for you to complete as you use the tool to perform your risk assessment.**

**Regardless of your facility or the level of testing performed in your laboratory, the following items, if known, must be considered when assessing biosafety risk and may indicate a need to take extra precautions beyond your normal biosafety practices:**

***Do you routinely consider the following when assessing biosafety risk in your laboratory:***

**Yes No**

[ ] [ ] What is the specimen source and which organisms are likely to be recovered?

[ ] [ ] What is the method of transmission and the infectious dose for any organisms that may be encountered?

[ ] [ ] What is the test request? (Requests for culture for systemic molds, acid fast bacteria (AFB), viruses, or bioterrorism (BT) agents, etc. require additional precautions.)

[ ] [ ] What are the patient symptoms and travel history? (Known travel to an area where infections with high risk agents are possible requires additional precautions.)

[ ] [ ]  What is the patient’s occupation? (Individuals who work with animals may acquire animal pathogens that are also high risk human pathogens requiring additional precautions.)

[ ] [ ] What are the risk factors of the individuals performing the testing? (e.g. immunization status, compromised immune status due to pregnancy, illness or treatment, physical disabilities, or training and experience, etc. which may require additional precautions.)

**Part I: Facility/Processes Biosafety Risk Assessment**

**There are four biosafety levels designated as BSL-1, BSL-2, BSL-3, and BSL-4 and each level has specific controls for containment of biological agents. The primary risks that determine levels of containment are infectivity, severity of disease, transmissibility, and the nature of the work conducted. Other important risk factors that should be considered are origin of the microbe or the agent in question and the route of exposure. Each biosafety level has its own specific containment, engineering, and administrative controls that are required for the following:**

* **Laboratory practices**
* **Safety equipment**
* **Facility construction**

**Please Note: Most CLIA designated moderate and high complexity clinical laboratories are designed as BSL-2 laboratories. BSL-1 design is more commonly used by teaching laboratories, some research laboratories, and by physician’s office laboratories*.*** **We provide information about BSL-4 laboratories even though a BSL-4 facility is beyond the scope of the clinical diagnostic laboratory.**

**Your laboratory may occasionally receive a specimen suspected of containing a pathogen, such as Ebola, where the recommended biosafety level for the organism is BSL-4. Laboratories must be prepared to safely handle and transfer these specimens to the appropriate facility without having a BSL-4 laboratory to work in. Additionally, laboratories must have staff certified in the packaging and shipping of Category A specimens to package and ship these agents.**

***Identify the various rooms/sections of your laboratory and the testing performed in each section. Using that information, identify the biosafety level of your laboratory by checking the box(s) for the Biosafety Level(s) that most accurately describes the biosafety level(s) of your laboratory. (Check multiple biosafety levels if applicable.)***

The following biosafety level definitions are adapted from

 *“Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition”*

[ ]  **Biosafety 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.

[ ]  **Biosafety Level 2 (BSL-2):** Builds upon BSL-1. 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.

[ ]  **Biosafety 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. Secondary barriers for this level include controlled access to the laboratory and ventilation requirements that minimize the release of infectious aerosols from the laboratory.

[ ]  **Biosafety 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.

***Now that you have identified the biosafety level of your laboratory, assess each room/section of your facility for the necessary components specific for your determined biosafety level. Please check the appropriate yes/no box for each question listed under the biosafety level(s) that best describe(s) your laboratory. Each biosafety level builds upon the previous level. (e.g. If your laboratory is a BSL-2 facility check the boxes for both Biosafety Level 1 and Biosafety Level 2. If you have a separate BSL-3 area in your laboratory, please also complete the additional BSL-3 checklist for that specific area of your laboratory.)***

***Use the “comment” section to report all of the biosafety gaps you identify in your laboratory. Write in the number of the item(s) where you marked the “No” box and explain why you are unable to meet that requirement.***

**The numbered items listed below each of the biosafety levels are considered minimal requirements for that biosafety level, therefore, any “No” answers are considered biosafety gaps that must be addressed.**

The items listed below for Biosafety Levels 1, 2 and 3 are recommendations adapted from *“Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition*” and other reference materials.

**Biosafety Level 1:**

**Yes No**

[ ] [ ]  1.) Laboratory has doors to control access to the laboratory and a laboratory supervisor enforces access policies.

[ ] [ ]  2.) 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.

[ ] [ ]  3.) Eating, drinking, smoking, handling contact lenses, applying cosmetics and storage of food for consumption are not permitted in the laboratory.

[ ] [ ]  4.) Mouth pipetting is prohibited; mechanical pipetting devices must be used.

[ ] [ ]  5.) Policies for safe handling of “sharps” are developed and implemented (e.g. needles, scalpels, pipettes, broken glassware).

[ ] [ ]  6.) Procedures are performed to minimize the creation of splashes and/or aerosols.

[ ] [ ]  7.) Work surfaces are decontaminated after completion of work and after any spills or splashes of potentially infectious material with appropriate disinfectant.

[ ] [ ]  8.) Cultures, stocks and other infectious materials are decontaminated before disposal.

[ ] [ ]  9.) A biohazard sign is posted at the entrance to the laboratory when infectious agents are present.

[ ] [ ]  10.) An effective pest management program is implemented in the laboratory.

[ ] [ ]  11.) All personnel have received appropriate training regarding their duties and the necessary precautions to prevent and evaluate exposures.

[ ] [ ]  12.) Personal protective equipment, laboratory coats, gloves, protective eyewear, are available and used appropriately.

[ ] [ ]  13.) If present, all windows in the laboratory that open to the exterior are fitted with screens.

[ ] [ ]  14.) Bench tops are impervious to water and resistant to heat, organic solvents, acids, alkalis and other chemicals.

[ ] [ ]  15.) The laboratory design allows for easy cleaning (e.g. no rugs or carpets, chairs covered in a non-porous material).

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| **Comments:** |

**Biosafety Level 2:**

**Must meet all the requirements listed in Biosafety Level 1 plus the following items.**

**Yes No**

[ ] [ ]  16.) The laboratory has **self-closing doors that may be locked** to control access to the laboratory.

[ ] [ ]  17.) Persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.

[ ] [ ]  18.) 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.

[ ] [ ]  19.) Laboratory equipment is decontaminated routinely, before repair or maintenance, and after spills and splashes with contaminated material.

[ ] [ ]  20.) All potentially infectious laboratory waste is decontaminated before disposal (e.g. autoclave, chemical disinfection, incineration, etc.). *(Check the box below if this is true.)*

[ ]  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.

[ ] [ ]  21.) A biohazard sign is posted at the entrance to the laboratory. Sign must include the following information. *(Check the boxes below if the information is included.)*

[ ]  Laboratory’s biosafety level

[ ]  Supervisor’s or other responsible person’s name

[ ]  Telephone number

[ ]  Required procedure for entering/exiting the laboratory

[ ] [ ]  22.) 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.

[ ] [ ]  23.) 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.

[ ] [ ]  24.) Medical surveillance is provided to laboratory personnel and appropriate immunizations have been offered to laboratory personnel.

[ ] [ ]  25.) A biosafety manual containing established policies and procedures is available and accessible.

[ ] [ ]  26.) Personal protective clothing is removed before leaving for non-laboratory areas.

[ ] [ ]  27.) 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. *(Check the box below if this is true.)*

[ ]  The BSC is located away from doors, windows, heavily traveled areas and other possible airflow disruptions.

[ ] [ ]  28.) Animals and plants not associated with the work being performed must not be permitted in the laboratory.

[ ] [ ]  29.) Centrifuges have centrifuge safety cups/carriers or sealed rotors and cups/carriers are only opened in a biosafety cabinet.

[ ] [ ]  30.) Vacuum lines are protected with HEPA filters, or their equivalent. Filters are replaced as needed. Liquid disinfection traps may be required.

**Biosafety Level 2: (continued)**

**Yes No**

[ ] [ ]  31.) An eyewash station is readily available.

[ ] [ ]  32.) Windows in the laboratory that open to the exterior are not recommended, but any present must be fitted with screens.

[ ] [ ]  33.) 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.

[ ] [ ]  34.) If present, the chemical fume hood is in proper working order and is certified annually.

[ ] [ ]  35.) All equipment is decontaminated before removal from the laboratory.

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| **Comments:** |

**Biosafety Level 3:**

**Must meet all the requirements listed in both Biosafety Levels 1 and 2 plus the following items.**

**Yes No**

[ ] [ ]  36.) The laboratory must enforce policies that control access to the laboratory.

[ ] [ ]  37.) The laboratory has a series of two self-closing doors that may be locked to control access to the laboratory. *(Check the boxes below if this is true.)*

[ ]  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.

[ ] [ ]  38.) 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.

[ ] [ ]  39.) 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. *(Check the boxes below if this is true.)*

[ ]  Protective clothing is not worn outside the laboratory.

[ ]  Reusable clothing is decontaminated before laundering.

[ ]  Clothing is changed when contaminated.

**Biosafety Level 3 (continued):**

**Yes No**

[ ] [ ]  40.) Eye and face protection (goggles, mask, face shield or splatter guard) is used for anticipated splashes or sprays of Infectious and other hazardous materials.

[ ] [ ]  41.) Gloves are worn to protect hands from exposure to hazardous materials.

[ ] [ ]  42.) If present, all windows in the laboratory are sealed.

[ ] [ ]  43.) The laboratory design allows for easy cleaning (e.g. no rugs or carpets, chairs covered in a non-porous material): *(Check the boxes below if this is true.)*

[ ]  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.

[ ] [ ]  44.) The laboratory has negative pressure in comparison to the rest of the facility: *(Check the boxes below if this is true.)*

[ ]  A ducted air ventilation system is required.

[ ]  This system provides sustained directional airflow by drawing air into the laboratory from “clean” areas toward “potentially contaminated” areas.

[ ]  The laboratory is designed such that under failure conditions the airflow will not be reversed.

[ ]  A visual monitoring device allows laboratory personnel to verify directional air flow at entry to the lab.

[ ]  An audible alarm notifies personnel of air flow disruption.

[ ] [ ]  45.) 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. *(Check the box below if this is true.)*

 [ ]  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.

[ ] [ ]  46.) 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. *(Check the box below if this is true.)*

[ ]  These HEPA filters are tested and/or replaced at least annually.

[ ] [ ]  47.) BSL-3 facility design, operational parameters and procedures are verified and documented prior to operation and annually thereafter.

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| **Comments:** |

**The following is the definition of a Sentinel Clinical Laboratory:**

**“The laboratory is certified to perform high complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare and Medicaid Services (CMS) for the applicable Microbiology specialty or the laboratory is a Department of Defense (DoD) Laboratory certified under the DoD Clinical Laboratory Improvement Program or the laboratory is a veterinary medical diagnostic laboratory that is fully accredited by the American Association of Veterinary Laboratory Diagnosticians (AAVLD). Laboratory in-house testing includes Gram stains and at least one of the following: lower respiratory tract, wound, or blood cultures.”**

***Please answer the following questions related to Sentinel Clinical Laboratory responsibilities.***

 **Yes No**

[ ] [ ] Does your laboratory in-house testing include Gram Stains and at least one of the following culture types? *(Please check the cultures that your laboratory performs in-house.)*

[ ]  Lower respiratory tract culture

[ ]  Wound culture

[ ]  Blood culture

[ ] [ ] Does your laboratory have at least 2 individuals who are certified in the packaging and shipping of infectious substances?*(If you answer no to this question, please explain why not.)*

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| **Comments:** |

**Part II: Task/Procedure Based Biosafety Risk Assessment**

**In Part II, each of the items listed under the “Control (Mitigation)” column as “Required” are requirements for that procedure. All “Required” boxes that are not checked are considered biosafety gaps that must be addressed. Additional protection - “Preferred” and or “Alternative” controls are recommended to further reduce risk.**

**Regardless of your facility’s biosafety level design, or the tasks/procedures performed in your laboratory, the following items are required “Controls (Mitigations)” that must be put into place in all laboratories:**

***For each task/procedure performed in your laboratory, do you routinely do the following:***

 **Yes No**

[ ] [ ]  Document and maintain training files.

[ ] [ ]  Conduct, document and maintain a biosafety component in each employee’s competency assessment file.

[ ] [ ]  Written SOPs are available for each test performed and, when applicable, a biosafety section is included in the SOP.

[ ] [ ]  Personnel are required to document review of all applicable SOPs initially and whenever changes are made to the SOP.

[ ] [ ]  Continuous Quality Improvement (CQI) program includes the monitoring of occurrence management reports and accident reports for any unusual events.

[ ] [ ]  Continuous Quality Improvement (CQI) program includes annual review of laboratory biosafety risk assessments.

[ ] [ ]  Comply with OSHA’s respiratory protection and blood-borne pathogens regulations.

***If all boxes aren’t checked, please explain why not.***

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| **Comments:** |

***To complete the following “Task/Procedure” based biosafety risk assessment section, check the box(s) to indicate all the tasks/procedures that are performed in your laboratory. Also check the box(s) under “Control (Mitigation)” to indicate which of the “Required”, “Additional Protection” - “Preferred”, and/or “Alternative” mitigations you perform to reduce risk. An unmarked box in the required control (mitigation) section is considered a “no” answer and is considered to be a biosafety gap. Report all of biosafety gaps you identify. Use the comment box after each procedure to explain why you are unable to check all of the “Required” boxes.***

**Specimen Collection and Transport:**

(*Complete this section if your laboratory performs Specimen Collection and Transport. If your laboratory does not perform any Specimen Collection and Transport, skip to Specimen Processing and Handling.)*

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| **Specimen Collection and Transport:** |
| **Pathogen(s):** There is a potential to be exposed to many pathogens during specimen collection dependent on the patient’s health, the type of specimen being collected and the method used for collection. |
| **Infectious Dose:** Dependent on the pathogen. |
| **Routes of Transmission:** * Parenteral inoculation from a needle stick or other sharps
* Ingestion from spill or splash into mouth
* Contact from touching, or from a spill or splash onto a mucous membrane or non-intact skin
* Inhalation of infectious aerosol
 |
| **Requirement:** When you perform any type of specimen collection, at a minimum, follow standard precautions and wear a lab coat and gloves. Add a mask and eye protection, if there is a risk of aerosol or splash production. Additionally, follow any requirements listed below by specimen type.**Additional Requirement when performing phlebotomy:** Use appropriate safety needle collection devices for blood collection and if necessary, use appropriate safety transfer devices to transfer blood from a syringe to a tube or bottle. Dispose of all sharps in approved sharps containers.**Additional Protection –Preferred or Alternative:**  Provide additional best practice recommendations and considerations based on particular type of specimens. |

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| **Specimen Collection and Transport: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Perform Phlebotomy**  | 1. Confirm patient identification (2 identifiers).
2. Disinfect phlebotomy site and any blood culture media.
3. Collect blood specimen into various collection tubes or bottles for laboratory testing via venipuncture (Follow correct order of draw).
4. When draw is completed cap the needle using the needle safety capping device. Never manually recap a needle holding the cap in your hand.
5. If a syringe draw, transfer blood from the syringe into collection tubes or bottles for laboratory testing using a safety transfer device
6. Dispose of contaminated needle puncture device into a sharps container.
7. Apply pressure to patient’s venipuncture site until bleeding stops.
8. Cover venipuncture site with gauze and tape or bandage.
9. Label specimens.
 | * Needle stick with a clean or contaminated needle during specimen collection, or when employing safety capping device
* Spill, splash or spray of blood into mouth, mucous membrane or onto non-intact skin
 | Moderate | **Required:**[ ]  Follow written phlebotomy policy.[ ]  Wear PPE: lab coat and gloves. Wear additional PPE: N-95 respirator/PAPR and/or disposable gown if patient is known or suspected of having an infectious disease transmitted by aerosols or droplets (i.e. TB, MERS, SARS, Avian Influenza, mumps, measles, etc.). [ ]  Use needles with safety capping devices.[ ]  Dispose of used needles in a rigid sharps container.**Additional Protection - Preferred:**[ ]  Wear eye protection.[ ]  Ask patient about travel outside the USA in the past 30 days.[ ]  If patient has a known contagious disease/condition such as MRSA, VRE, MRO, CRE, C. diff, mumps, measles, etc., disinfect the drawing area before using the area for another patient.. | Low |
| **Comments:** |

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| **Specimen Collection and Transport: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Collect nasal or NP swabs** | 1. Confirm patient identification (2 identifiers).
2. Use an appropriate sterile swab to collect the specimen.
3. Label specimen.
 | * Exposure to aerosol or droplets if patient sneezes or coughs during collection
 | Moderate | **Required:**[ ]  Follow written nasal/NP specimen collection policy.[ ]  Wear PPE: lab coat, gloves and additional eye protection if a risk of splash or spray.[ ]  Wear additional PPE: N-95 respirator/PAPR and/or a disposable gown if patient is known or suspected of having an infectious disease transmitted by aerosols, or droplets (i.e. TB, MERS, SARS, Avian Influenza, mumps, measles, etc.). **Additional Protection - Preferred:**[ ]  Ask patient about travel outside the USA in the past 30 days.[ ]  If patient has a known contagious disease/condition such as MRSA, VRE, MRO, CRE, C. diff, measles, etc., disinfect the drawing/collection area before using the area for another patient. | Low |
| **Comments:** |

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| **Specimen Collection and Transport: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Collect throat swabs** | 1. Confirm patient identification (2 identifiers).
2. Use an appropriate sterile swab to collect the specimen.
3. Label specimen.
 | * Exposure to aerosol or droplets if patient sneezes or coughs during collection
 | Moderate | **Required:**[ ]  Follow written throat specimen collection policy.[ ]  Wear PPE: lab coat, gloves and additional eye protection if a risk of splash or spray.[ ]  Wear additional PPE: N-95 respirator/PAPR and/or a disposable gown if patient is known or suspected of having an infectious disease transmitted by aerosols or droplets (i.e. TB, MERS, SARS, avian influenza, mumps, measles, etc.).**Additional Protection - Preferred:**[ ]  Ask patient about travel outside the USA in the past 30 days.[ ]  If patient has a known contagious disease/condition such as MRSA, VRE, MRO, CRE, C. diff, measles, etc., disinfect the drawing area before using the area for another patient. | Low |
| **Comments:** |

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| **Specimen Collection and Transport: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Assists with Collection of Fine Needle Aspirations** | 1. Confirm patient identification (2 identifiers).
2. Prepare/label slides.
3. Stain adequacy slides.
4. Process/fix biopsy sections.
5. Process/package samples.
 | * Needle stick with a clean or contaminated needle during specimen collection.
* Exposure to droplets/aerosols:
	+ During specimen collection process
* From the syringe needle
* Spill, splash or spray of specimen into mouth, mucous membrane or onto non-intact skin during collection, processing, packaging, or transport process.
 | Moderate | **Required:**[ ]  Wear PPE: lab coat/gown, foot covers, gloves, mask, and face shield/eye protection.[ ]  Wear additional PPE: N-95 respirator/PAPR if patient is known or suspected of having an infectious disease transmitted by aerosols, droplets (i.e. TB, MERS, SARS, Avian Influenza, mumps, measles, etc.).[ ]  If CT-guided collection, wear additional lead gown, thyroid shield and radiation badge to monitor exposure. **Additional Protection – Preferred:**  [ ]  Obtain travel history (e.g. outside the USA in the past 30 days) prior to procedure.  | Low |
| **Comments:** |

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| **Specimen Collection and Transport: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Assists with Collection of Bone Marrow Aspirations** | 1. Confirm patient identification (2 identifiers).
2. Prepare/label slides.
3. Prepare core touch preparations.
4. Process/fix core and clot sections.
5. Process/package samples.

. | * Needle stick with a clean or contaminated needle during specimen collection.
* Exposure to droplets/aerosols:
	+ During specimen collection process
* From the syringe needle
* Spill, splash or spray of specimen into mouth, mucous membrane or onto non-intact skin during collection, processing, packaging, or transport process.
 | Moderate | **Required:**[ ]  Wear PPE: lab coat/gown, gloves, and eye protection.[ ]  Wear additional PPE: N-95 respirator/PAPR and disposable gown if patient is known or suspected of having an infectious disease transmitted by aerosols, droplets (i.e. TB, MERS, SARS, Avian Influenza, mumps, measles, etc.).[ ]  If CT-guided collection, wear additional lead gown, thyroid shield and radiation badge to monitor exposure. **Additional Protection - Preferred:**[ ]  Obtain travel history (e.g. outside the USA in the past 30 days) prior to procedure. | Low |
| **Comments:** |

**Note: The laboratory is not typically involved in the collection of other specimens other than to provide collection containers for urine, stool, and sputum for the patients to self-collect and return to the laboratory. If your laboratory routinely performs other type of specimen collections, please add it to your risk assessment using the format we’ve established.**

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| **Specimen Collection and Transport: (continued)**  |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Perform Specimen Transport** | 1. Transport specimens safely to the laboratory by hand, or via pneumatic tube system.
 | * Specimen is not bagged properly:
* Specimen leaks into transport tube system.
* Hand transported specimen is dropped and spills.
 | Low | **Required:**[ ]  Transport specimen in a biohazard bag or per healthcare system protocol.[ ]  Wear appropriate PPE: lab coat, gloves, and additional eye protection when there is a risk for a splash or spray.[ ]  Follow written protocol for proper use of transport tube system including spill clean-up.**Additional Protection - Preferred:**[ ] Irretrievable specimens and known or suspect highly pathogenic specimens (i.e. suspect Ebola) are not transported via pneumatic tube system, but are transported by hand. | Low |
| **Comments:** |

**Specimen Processing and Handling:**

*(Complete this section if your laboratory performs Specimen Processing and Handling. If your laboratory does not perform any Specimen Processing and Handling skip to Commercial Rapid Antigen Testing Assays.)*

|  |
| --- |
| **Specimen Processing and Handling:** |
| **Pathogen(s):** There is a potential to be exposed to many pathogens during specimen handling dependent on the patient’s health, the specimen type, how the specimen was collected and transported, and the integrity of the specimen when it is received in the lab. |
| **Infectious Dose:** Dependent on the pathogen. |
| **Routes of Transmission:** * Parenteral inoculation from a needle stick or other sharps
* Ingestion from spill or splash into mouth
* Contact from touching, or a spill or splash onto mucous membrane or non-intact skin
* Inhalation of infectious aerosol
 |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Use of Biosafety Cabinet (BSC)** | 1. Turn on biosafety cabinet (BSC) for 4 minutes before using.
2. Check airflow to make sure BSC is working properly before using.
3. Make sure that no items in BSC are disrupting the airflow.
4. Remove all equipment/supplies that will not be used.
5. Use proper technique when working in BSC so as not to disrupt the airflow.
6. Decontaminate items before removing from the BSC.
7. Clean and disinfect BSC after use.
8. Allow BSC to run for 4 minutes after completing all work before turning off.
 | * Airflow disruption caused by:
	+ Moving in and out of BSC too quickly
* Items placed on the air ducts
* Too many items in BSC
* Location of hood in busy traffic area
* BSC stops functioning properly while in use.
 | Moderate | **Required:**[ ]  Follow written policy for use of BSC, cleaning/disinfection, and maintenance.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk for a splash or spray.[ ]  Check on air handling capabilities to determine if BSC needs to remain running at all times or can be turned off when not in use.[ ]  Make sure that the BSC contains only the essential items necessary for the work being performed when working in the BSC.**Additional Protection - Preferred:**[ ]  Audible alarm sounds if BSC stops working correctly and airflow is not within the acceptable range. | Low |
| **Comments:** |

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| **Specimen Processing and Handling: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Use of Fume Hood** | 1. Check airflow to make sure is working properly before using.
2. Minimize clutter in fume hood to ensure proper airflow within the fume hood.
3. Adjust fume hood sash to the proper position for working in the fume hood.
4. Clean fume hood after use.
5. Lower fume hood sash when done.
 | * Airflow disruption caused by:
* Improper sash position
* Too many items in fume hood
* Splash or spill of chemical
 | Moderate | **Required:**[ ]  Follow written policy for use of fume hood.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk for a splash or spray.[ ]  Laboratory chemical safety plan.[ ]  Check on air handling capabilities to determine if fume hood needs to remain running at all times or can be turned off when not in use.**Additional Protection – Preferred:**[ ]  Wear additional acid apron and gloves when working with strong acids or bases.[ ]  Audible alarm sounds if fume hood stops working correctly and air flow is not within the acceptable range. | Low |
| **Comments:** |
| [ ]  **Perform Specimen Receipt** | 1. Receive specimen into the laboratory
 | * Handling a leaking specimen
* Handling a syringe with an attached needle
 | Low | **Required:**[ ]  Wear appropriate PPE: lab coat, glove and additional eye protection when there is a risk for a splash or spray. | Low |
| **Comments:** |

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| **Specimen Processing and Handling: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Perform Specimen Processing/** **Handling**  | 1. Check specimen integrity and ensures that specimen is labeled properly with 2 patient identifiers.
2. Follow specimen rejection policies as necessary.
3. Process specimen, centrifuging or splitting specimen as necessary.
4. Distribute specimen for in-house testing or packages specimen for shipment to testing reference lab.
5. Store any remaining specimen appropriately.
 | * Specimen is not received in a biohazard bag.
* Specimen is leaking.
* Outside of specimen was contaminated during collection.
* Specimen is received in a syringe with an attached needle.
* Specimen tube breaks during centrifugation creating a spill and an aerosol risk.
* Specimen is spilled during processing.
* Specimen is splashed or sprayed into mouth, mucous membrane or onto non-intact skin during uncapping, or pouring, or pipetting aliquots to split the specimen.
 | Moderate | **Required:**[ ]  Follow written Processing/Handling policy.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk for a splash or spray.[ ]  Specimens with a request for Mycobacteria or fungal culture are split or processed in a Class II BSC. [ ]  Specimens with a request for Mycobacteria or fungal culture are centrifuged in covered cups/carriers and the centrifuged cups/carriers are opened in a Class II BSC.**Additional Protection - Preferred:**[ ]  Process all specimens in a BSC.[ ]  Use gauze or bio-wipe to cover cap when uncapping specimen. [ ]  Wear additional PPE: N-95 respirator/PAPR and a disposable gown if patient is known or suspected of having an infectious disease transmitted by aerosols or droplets (i.e. TB, MERS, SARS, avian influenza, mumps, measles, etc.).**Additional Protection - Alternative:**[ ]  Process specimens behind a safety shield/face shield and wear eye protection.  | Low |
| **Comments:** |

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| **Specimen Processing and Handling: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Perform Packaging and Shipping** | 1. Classify specimen for shipping.
2. Package Category A, Category B and exempt specimens according to regulations.
3. Properly label the package and complete all documentation.
 | * Incorrectly packaged specimen may subject lab to monetary fines and legal action.
* Incorrectly packaged specimen breaks open exposing courier and community to possible pathogen.
 | Moderate | **Required:**[ ]  Personnel are certified in Packaging and Shipping and have required documentation to prove it.[ ] Personnel who are certified in Packaging and Shipping receive documented refresher training and demonstrate competency every 2 years. | Low |
| **Comments:** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Specimen Storage** | 1. Store specimen at appropriate temperature for appropriate time.
2. Store sealed specimens in racks, or boxes, or in sealed biohazard bags to prevent leaks and spills.
 | * Leak or spill during storage
 | Low | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Wear additional freezer gloves if storing in ultra low (-70○ C) freezer. | Low |
| **Comments:** |

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| **Specimen Processing and Handling: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Discarding Waste** | 1. Discard waste into appropriate double bagged biohazardous waste containers or biohazardous sharps container
 | * Leak or spill while discarding waste or while storing discarded waste.
* Possible poke through biohazard bag if sharps not disposed of properly in a rigid biohazard container.
 | Slight | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Double bag all biohazardous waste and use rigid biohazardous sharps container for sharps.[ ]  Discard biohazardous sharps containers when 2/3 full.[ ]  Cover partially filled biohazardous waste containers when not in use.[ ]  Disinfect workspace and any spills with an appropriate disinfectant.  | Low |
| **Comments:** |

**Commercial Rapid Antigen Testing Assays:**

*(Complete this section if your laboratory performs any Commercial Rapid Antigen Testing Assays. If your laboratory does not perform any Commercial Rapid Antigen Testing Assays, skip to Direct Microscopic Examination)*

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| **Commercial Rapid Antigen Testing Assays:** |
| **Pathogen(s):** There is a potential for aerosol production when performing the commercial rapid antigen assays. Remember that although your test may be for a specific organism, the specimen may contain other pathogens than the one being tested for. Consider the specimen source and pathogens that are typical for that source (i.e. a specimen sent for ẞ-Strep Group A may actually contain an avian influenza.) |
| **Infectious Dose:** Dependent on the pathogen. |
| **Routes of Transmission:** * Parenteral inoculation from a needle stick or other sharps
* Ingestion from spill or splash into mouth
* Contact from touching, or a spill or splash onto mucous membrane or non-intact skin
* Inhalation of infectious aerosol
 |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| **Perform Rapid Antigen Testing:**[ ]  **ẞ-Strep group A** [ ]  ***Streptococcus pneumoniae*** [ ]  **Cryptococcus** [ ]  **Influenza** [ ]  **RSV** [ ]  **Rotavirus**[ ]  **Crypto/Giardia** [ ]  **C. difficile** [ ]  **Shigatoxin** [ ]  **Campylobacter** [ ]  **Legionella** [ ]  **Malaria** [ ]  **Other rapid antigen** **(Be specific) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | The process steps will vary according to the test being performed and whose test kit you use. **Follow the manufacturer’s directions included in the test kit.****List your specific process steps here.** | * Creation of aerosols during:
	+ Pipetting
	+ Vortexing
	+ Uncapping tubes
* Possible spill or splash of specimen.
 | Moderate | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.**Additional Protection -Preferred:**[ ]  Perform any vortexing/mixing/ inoculating steps in your assay in a BSC.[ ]  Wear additional PPE: N-95 respirator/PAPR and a disposable gown if patient is known or suspected of having an infectious disease transmitted by aerosols or droplets (i.e. TB, MERS, SARS, avian influenza, mumps, measles, etc.).[ ]  Provide Meningococcal vaccines for staff[ ]  Use gauze or bio wipe to cover tubes and prevent aerosols when uncapping tubes **Additional Protection - Alternative:**[ ]  If there isn’t a vortexing/mixing step in your assay, may work behind a full safety shield/face shield and wear eye protection.  | Low |
| **Comments:** |

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| **Commercial Rapid Antigen Testing Assays: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Specimen Storage** | 1. Store specimen at appropriate temperature for appropriate time.
2. Store sealed specimens in racks, or boxes, or in sealed biohazard bags to prevent leaks and spills.
 | * Leak or spill during storage.
 | Low | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Wear additional freezer gloves if storing in ultra low (-70○ C) freezer. | Low |
| **Comments:** |
| [ ]  **Discarding Waste** | 1. Discard waste into appropriate double bagged biohazardous waste containers or sharps containers.
 | * Leak or spill while discarding waste or while storing discarded waste.
* Possible poke through biohazard bag if sharps not disposed of properly in a rigid biohazard container.
 | Low | **Required:** [ ]  Follow written procedure. [ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray. [ ]  Double bag all biohazardous waste and use rigid biohazardous sharps container for sharps. [ ]  Discard biohazardous sharps containers when 2/3 full. [ ]  Cover partially filled biohazardous waste containers when not in use. [ ]  Disinfect workspace and any spills with an appropriate disinfectant. | Low |
| **Comments:** |

**Direct Microscopic Examination:**

*(Complete this section if your laboratory performs Direct Microscopic Examinations. If your laboratory does not perform any Direct Microscopic Examinations, skip to Culture Set-up.)*

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| **Direct Microscopic Examination:** |
| **Pathogen(s):** There is a potential to be exposed to many pathogens preparing slides for direct microscopic examination dependent on the patient’s health, the specimen type, how the specimen was collected and transported, and the integrity of the specimen when it is received in the lab. |
| **Infectious Dose:** Dependent on the pathogen. |
| **Routes of Transmission:** * Parenteral inoculation from a needle stick or other sharps
* Ingestion from spill or splash into mouth
* Contact from touching, or a spill or splash onto mucous membrane or non-intact skin
* Inhalation of infectious aerosol
 |

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| **Direct Microscopic Exam: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| **Perform:**[ ]  **Vaginal wet mounts** [ ]  **KOH/calcoflour/India ink preparations** [ ]  **Gram stains**[ ]  **Use cytospin to prepare Gram stain** [ ]  **AFB stains**[ ]  **Use cytospin to prepare AFB stain on sterile body fluid**[ ]  **Viral immunofluorescent (IF) stains** [ ]  **Use cytospin to prepare viral IF stain**[ ]  **Cell count and differential**[ ]  **Urinalysis** | The process steps will vary according to the microscopic exam being performed.**List your test specific process steps here.** | * An aerosol may be created during pipetting, cytocentrifuging, centrifuging, uncapping tubes, or preparing the slide
* Possible spill or splash of specimen
 | Moderate | **Required:**Follow written procedures. [ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  If AFB stain/culture is ordered on a specimen, perform all work, including cytocentrifugation, in a class II BSC using BSL-3 practices (controlled access to the area when working, decontamination of all waste, must wear a solid front gown with cuffed sleeves, gloves and respirator/PAPR). Dry slides in the BSC before removing. **Additional Protection - Preferred:**[ ]  Perform all work in a BSC.[ ]  Prepare cytospin slide in a BSC. If cytospin cannot be operated in a BSC, open the centrifuged cytospin removable sealed rotor in a BSC. Allow slides to dry in the BSC before removing for staining. [ ]  Lab has mechanism in place for notification of possible high risk infectious agents.[ ]  Use additional BSL-3 practices when patient is known or suspected to have an infectious disease transmitted by aerosols or droplets (i.e. MERS, SARS, avian influenza, mumps, measles, etc.). **Additional Protection - Alternative:**[ ]  Work behind a full safety shield/face shield and wear eye protection.[ ]  Do not flame slides, but allow slides to air dry or dry on a heating block/slide dryer prior to fixing and staining. | Low |
| **Comments:** |

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| **Direct Microscopic Exam: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| **Perform:**[ ]  **Parasitology examination**[ ]  **Direct smear**[ ]  **Concentrated smear**[ ]  **Trichrome stained smear**[ ]  **Other special smear (Be specific)****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | The process steps will vary according to the microscopic exam being performed.**List your test specific process steps here.** | * An aerosol may be created during pipetting, cytocentrifuging, centrifuging, uncapping tubes, or preparing the slide
* Possible spill or splash of specimen
* Exposure to some hazardous chemicals during stool concentration or trichrome staining
 | Moderate | **Required:**[ ]  Follow written procedures.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.**Additional Protection - Preferred:**[ ]  Prepare all smears in a BSC.[ ]  Perform trichrome staining in a fume hood if using xylene.**Additional Protection - Alternative:**[ ]  Work behind a full safety shield/face shield and wear eye protection. | Low |
| **Comments:** |
| [ ]  **Specimen Storage** | 1. Store specimen at appropriate temperature for appropriate time.
2. Store sealed specimens in racks, or boxes, or in sealed biohazard bags to prevent leaks and spills.
3. Store slides in rigid slide boxes to prevent slides from breaking.
 | * Leak or spill during storage
* Cut or abrasion from broken slide or coverslip
 | Low | **Required:**[ ]  Follow written procedures.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Wear additional freezer gloves if storing in ultra low (-70○ C) freezer. | Low |
| **Comments:** |

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| **Direct Microscopic Exam: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Discarding Waste** | 1. Discard waste into appropriate double bagged biohazardous waste containers or sharps containers
 | * Leak or spill while discarding waste or while storing discarded waste.
* Possible poke through biohazard bag if sharps not disposed of properly in a rigid biohazard container.
 | Low | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Double bag all biohazardous waste and use rigid biohazardous sharps container for sharps.[ ]  Discard biohazardous sharps containers when 2/3 full.[ ]  Cover partially filled biohazardous waste containers when not in use.[ ] Disinfect workspace and any spills with an appropriate disinfectant.[ ]  Dispose of chemicals used for trichrome stain according to chemical plan.[ ] Disinfect/autoclave liquid waste before disposing of it when it is known or suspected of containing highly pathogenic organisms (i.e. AFB, Ebola, etc.). |  Low |
| **Comments:** |

**Culture Set-up:**

*(Complete this section if your laboratory performs any Culture Set-up. If your laboratory does not perform any Culture Set-up, skip to Culture Work-up.)*

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| --- |
| **Culture Set-up:** |
| **Pathogen(s):** There is a potential to be exposed to many pathogens during culture set-up dependent on the patient’s health, the specimen type, how the specimen was collected and transported, and the integrity of the specimen when it is received in the lab. |
| **Infectious Dose:** Dependent on the pathogen. |
| **Routes of Transmission:** * Parenteral inoculation from a needle stick or other sharps
* Ingestion from spill or splash into mouth
* Contact from touching, or a spill or splash onto mucous membrane or non-intact skin
* Inhalation of infectious aerosol
 |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| **Perform Culture Set-up of:**[ ]  **Blood culture** [ ]  **Isolator set-up**[ ]  **Inoculate blood culture bottles, but transfer to another site for incubation**[ ]  **Inoculate blood culture bottles, incubate and monitor for positive**[ ]  **Gram stain & Subculture positive bottles** [ ]  **Bacterial (aerobic/anaerobic) culture** [ ]  **AFB culture**[ ]  **Fungal culture**[ ]  **Viral culture** | The process steps will vary according to the type of culture set-up.**List your test specific process steps here.** | * An aerosol may be created during the following processes:
	+ Vortexing/mixing
	+ Pipetting
	+ Centrifuging
	+ Uncapping tubes
	+ Stomaching
	+ Mincing/grinding
* Possible spill or splash of specimen during culture set-up
 | ModerateHigh (AFB) | **Required:**[ ]  Follow written procedures.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  If AFB stain/culture is ordered on a specimen, perform all culture set-up in a class II BSC using BSL-3 practices (controlled access to the area when working, decontamination of all waste, must wear a solid front gown with cuffed sleeves, gloves and respirator). **Additional Protection - Preferred:**[ ]  Perform all culture set-up in a BSC.[ ]  Use additional BSL-3 practices if patient is known or suspected to have a highly infectious disease transmitted by aerosols, or droplets (i.e. MERS, SARS, avian influenza, mumps, measles, etc.). [ ]  Allow positive blood culture slides for Gram stain to air dry or dry on a heating block in BSC before removing. Do not use a flame to heat fix.**Additional Protection - Alternative:**[ ]  Work behind a full safety shield/face shield and wear eye protection.[ ]  Do not use a flame to heat fix positive blood culture slides for Gram stain. | Low |

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| **Culture Set-up: (continued)** |
| **Comments:** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Specimen Storage** | 1. Store specimen at appropriate temperature for appropriate time.
2. Store sealed specimens in racks, or boxes, or in sealed biohazard bags to prevent leaks and spills.
 | * Leak or spill during storage
 | Low | **Required:**[ ]  Follow written procedure[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray[ ]  Wear additional freezer gloves if storing in ultra low (-70○ C) freezer. | Low |
| **Comments:** |
| [ ]  **Discarding Waste** | 1. Discard waste into appropriate double bagged biohazardous waste containers or sharps containers
 | * Leak or spill while discarding waste or while storing discarded waste.
* Possible poke through biohazard bag if sharps not disposed of properly in a rigid biohazard container.
 | Low | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Double bag all biohazardous waste and use rigid biohazardous sharps container for sharps.[ ]  Discard biohazardous sharps containers when 2/3 full.[ ]  Cover partially filled biohazardous waste containers when not in use.[ ]  Disinfect workspace and any spills with an appropriate disinfectant.[ ] Disinfect/autoclave liquid waste before disposing of it when it is known or suspected of containing highly pathogenic organisms (i.e. AFB, Ebola, etc.). | Low |
| **Comments:** |

 **Screening Cultures:**

*(Complete this section if your laboratory performs Screening Cultures. If your laboratory does not perform any Screening Cultures skip to Culture Work-up.)*

**NOTE: Screening Cultures can mean either of the following:**

* **Examining culture plates to screen for growth – discarding negative cultures and forwarding cultures with growth to a reference laboratory for further workshop**
* **Culturing to a specific media that selects/screens for a specific pathogen (e.g. MacConkey Sorbitol for *E. coli O 157* )**

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| **Screening Cultures:** |
| **Pathogen(s):** There is a potential to be exposed to pathogens that may be isolated on screening media dependent on the patient’s health, the type of specimen that is being screened and the screening media that is used. |
| **Infectious Dose:** Dependent on the pathogen. |
| **Routes of Transmission:** * Parenteral inoculation from a needle stick or other sharps
* Ingestion from spill or splash into mouth
* Contact from touching, or a spill or splash onto mucous membrane or non-intact skin
* Inhalation of infectious aerosol
 |

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|  **Screening Cultures: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| **Perform Screening Cultures on the following cultures types:**[ ]  **Urine**[ ]  **Throat**[ ]  **MRSA**[ ]  **Other (Be specific)****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | 1. Examine culture media for growth, or screening media for growth of the specific pathogen being screened for.
2. If suspicious colonies are growing, proceed to culture work-up, or forward to reference laboratory for ID and possible AST.
3. Discard plates with no growth and plates negative for the organism that is being screened for.

**List your test specific process steps here.** | * An aerosol may be created opening the plate and or performing any spot testing for identification (i.e. preparing smear for Gram stain, oxidase, catalase)
* Risk of contamination by touching growth
 | Moderate | **Required:**[ ]  Follow written procedures.[ ]  Wear PPE: lab coat**Additional Protection - Preferred:**[ ]  Wear gloves and additional eye protection when there is a risk of a splash or spray. If wear gloves when handling cultures, establish clean and dirty areas and be sure to remove gloves and wash hands before touching anything in a clean area (i.e. telephones, door handles, computer keyboards).[ ]  Examine screening media for growth in a Class II BSC.[ ]  Perform all spot testing on suspicious growth in a Class II BSC.[ ]  Use additional BSL-3 practices if patient is known or suspected to have a highly infectious disease transmitted by aerosols, or droplets (i.e. MERS, SARS, avian influenza, mumps, measles, etc.). [ ]  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.**Additional Protection - Alternative:**[ ]  Work behind a full safety shield/face shield and wear eye protection.[ ]  Allow slides to air dry or dry on a heating block.  | Low |
| **Comments:** |

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| --- |
|  **Screening Cultures: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Culture Retention** | 1. Store completed culture media at appropriate temperature for appropriate time per procedure.
2. Store sealed specimens in racks, or boxes, or in sealed biohazard bags to prevent leaks and spills.
3. Document what is stored and where.
 | * Leak or spill during storage
 | Low | **Required:**[ ]  Follow written procedure[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray[ ]  Wear additional freezer gloves if storing in ultra low (-70○ C) freezer. | Low |
| **Comments:** |
| [ ]  **Discarding Waste** | 1. Discard waste into appropriate double bagged biohazardous waste containers or sharps containers
 | * Leak or spill while discarding waste or while storing discarded waste.
* Possible poke through biohazard bag if sharps not disposed of properly in a rigid biohazard container.
 | Low | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Double bag all biohazardous waste and use rigid biohazardous sharps container for sharps.[ ]  Discard biohazardous sharps containers when 2/3 full.[ ]  Cover partially filled biohazardous waste containers when not in use.[ ]  Disinfect workspace and any spills with an appropriate disinfectant. | Low |
| **Comments:** |

**Culture Work-up:**

*(Complete this section if your laboratory performs any Culture Work-up. If you do not perform Culture Work-up, skip to Molecular Assays.)*

**Note: Laboratories who refer microbiology culture work-up to a reference lab, but who have blood culture instruments on site and perform Gram stain and culture set-up on positive blood culture bottles need to be aware of the indicators of possible high risk pathogens. Always be aware of how long a blood culture has been incubated before it becomes positive. Cultures that don’t become positive until ≥ 48hours should always be suspected of having a possible high risk pathogen. Share the information that the organism is a possible high risk pathogen with the reference lab, so they take appropriate precautions when performing the culture work-up.**

**Laboratories should offer appropriate vaccines to staff working with high risk pathogens (e.g. Meningococcal, Hepatitis B, and Influenza)**

**Table 1:**

|  |  |
| --- | --- |
| **Indicators of Possible High Risk Pathogen** | **Aerosol-Generating Activities** |
| * *Slow growing tiny colonies at 24-48 hours and gram stain shows GNR or GNCB*
* *Slow growth in blood culture bottles (i.e., positive at ≥ 48 hours) and gram stain shows small GNR or GNCB*
* *Growth only on chocolate agar*
* *Rapid growth of flat non-pigmented, non-hemolytic, irregular colonies with comma projections and ground glass appearance. Gram stain shows boxcar shaped GPR with or without spores.*
 | * *Agglutination testing*
* *Catalase testing*
* *Centrifuging,*
* *Discarding contaminated items*
* *Entering a positive blood culture bottle with a syringe for smear or subculture*
* *Flaming slides to heat fix*
* *Flaming or incinerating loops (hot looping media)*
* *Manipulating any organism growth*
* *Performing wet mount, or wet mount-motility*
* *Pipetting (blowing out last drops)*
* *Preparing McFarland broths*
* *Preparing smears*
* *Spotting Maldi-TOF plates and perform Maldi-TOF testing*
* *Streaking plates*
* *Tissue grinding, or stomaching*
* *Vortexing, shaking, sonicating, or flicking*
 |

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| **Culture Work-up:** |
| **Pathogen(s):** There is a potential to be exposed to many pathogens when manipulating organisms that may be isolated on culture media dependent on the patient’s health, the type of specimen that is being screened and the media that is used. **(See Table 1 on the prior page for indicators that you may have isolated a possible high risk pathogen and be aware of the activities that produce aerosols. Stop all work on the open bench and perform all work in a Class II biosafety cabinet if there is a possibility you have a high risk pathogen.)** |
| **Infectious Dose:** Dependent on the pathogen. |
| **Routes of Transmission:** * Parenteral inoculation from a needle stick or other sharps
* Ingestion from spill or splash into mouth
* Contact from touching, or a spill or splash onto mucous membrane or non-intact skin
* Inhalation of infectious aerosol
 |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| **Performs:**[ ]  **Aerobic/anaerobic bacterial culture identification and susceptibility testing using automated systems:**[ ]  **Vitek**[ ]  **Microscan** [ ]  **Phoenix**[ ]  **Sensititre**[ ]  **Other (Be specific)****\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | 1. Examine media for growth.
2. Work up cultures as per laboratory policy based on specimen source.
3. Perform AST as per laboratory policy based on specimen source.
4. Prepare standardized inoculum.
5. Inoculate or load test system
6. Read and report results
7. Discard waste into appropriate container

**List your test specific process steps here.** | * Risk of aerosol production (See Table 1 for aerosol generating activities)
* Risk of contamination by touching growth
* Risk of spill or splash when handling liquid media
 | ModerateHigh (*possible high risk pathogens*) | **Required:**[ ]  Follow written procedures.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray. [ ]  Do not touch your face, eyes, nose, or mouth without washing your hands first.[ ]  Perform all aerosol-generating work in a Class II BSC when manipulating possible high risk pathogens using BSL-3 practices (controlled access to the area when working, decontamination of all waste, must wear a solid front gown with cuffed sleeves, gloves and N-95 respirator/PAPR).**Additional Protection – Preferred:**[ ]  Wear gloves and additional eye protection when there is a risk of a splash or spray. If wear gloves when handling cultures, establish clean and dirty areas and be sure to remove gloves and wash hands before touching anything in a clean area (i.e. telephones, door handles, computer keyboards).[ ]  Perform all aerosol-generating work in a Class II BSC.[ ]  Do not use a flame to heat fix Gram stain slides, but allow to air dry, or dry on a heating block. **Additional Protection - Alternative:**[ ]  Perform all aerosol-generating work behind a full safety shield/face shield and wear eye protection. | Low |
| **Comments:** |
| **Culture Work-up: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| **Performs:**[ ]  **Aerobic/anaerobic bacterial culture identification and susceptibility testing using manual methods:**[ ]  **Kirby Bauer**[ ]  **E-test**[ ]  **Manual MIC**[ ]  **Manual ID (e.g. API 20E, Rapid Ana ID, spot IDs, NF panels, etc.)**[ ]  **Other (Be specific)****\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | 1. Examine media for growth.
2. Work up cultures as per laboratory policy based on specimen source.
3. Perform AST as per laboratory policy based on specimen source.
	1. Prepare standardized inoculum.
	2. Inoculate
	3. Incubate
	4. Read
	5. Discard waste into appropriate container.

**List your test specific process steps here.** | * Risk of aerosol production (See Table 1 for aerosol generating activities)
* Risk of contamination by touching growth
* Risk of spill or splash when handling liquid media
 | ModerateHigh (*possible high risk pathogens*) | **Required:**[ ]  Follow written procedures.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray. [ ]  Do not touch your face, eyes, nose, or mouth without washing your hands first.[ ]  Perform all aerosol-generating work in a Class II BSC when manipulating possible high risk pathogens using BSL-3 practices (controlled access to the area when working, decontamination of all waste, must wear a solid front gown with cuffed sleeves, gloves and N-95 respirator/PAPR).**Additional Protection – Preferred:**[ ]  Wear gloves and additional eye protection when there is a risk of a splash or spray. If wear gloves when handling cultures, establish clean and dirty areas and be sure to remove gloves and wash hands before touching anything in a clean area (i.e. telephones, door handles, computer keyboards).[ ]  Perform all aerosol-generating work in a Class II BSC.[ ]  Do not use a flame to heat fix Gram stain slides, but allow to air dry, or dry on a heating block. **Additional Protection - Alternative:**[ ]  Perform all aerosol-generating work behind a full safety shield/face shield and wear eye protection. | Low |
| **Comments:** |

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| **Culture Work-up: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| **Performs:**[ ]  **Fungal culture ID and Susceptibility Testing**  | 1. Examine media for growth.
2. Work up cultures as per laboratory procedure based on specimen source.
3. Perform AST as per laboratory procedure based on specimen source.

**List your test specific process steps here.** | * Risk of aerosol production (See Table 1 for aerosol generating activities)
* Risk of contamination by touching growth
* Risk of spill or splash when handling liquid media
 | ModerateHigh (*Systemic molds*) | **Required:**[ ]  Follow written procedures.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray. [ ]  Post a sign on the door warning others when working with possible systemic molds.[ ]  Do not touch your face, eyes, nose, or mouth without washing your hands first.[ ]  Inoculated plates for fungal culture must be taped shut or bagged. [ ]  Perform work-up of mold isolates in a Class II or Class III BSC.[ ]  When working with any possible systemic molds, **u**se BSL-3 practices (controlled access to the area when working, decontamination of all waste, must wear a solid front gown with cuffed sleeves, gloves and N-95 respirator/PAPR).  | Low |
| **Comments:** |

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| **Culture Work-up: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| **Performs:**[ ]  **AFB culture ID and Susceptibility Testing**  | 1. Examine media for growth.
2. Work up cultures as per laboratory procedure based on specimen source.
3. Perform AST as per laboratory procedure based on specimen source.

**List your test specific process steps here.** | * Risk of aerosol production (See Table 1 for aerosol generating activities)
* Risk of contamination by touching growth
* Risk of spill or splash when handling liquid media
 | ModerateHigh(*M. tuberculosis complex*) | **Required:**[ ]  Follow written procedures.[ ]  Post a sign on the door warning others when working with AFB cultures.[ ]  Do not touch your face, eyes, nose, or mouth without washing your hands first.[ ]  Inoculated plates for AFB culture must be taped shut or bagged. [ ]  Perform all work-up of AFB isolates in a Class II BSC using BSL-3 practices (controlled access to the area when working, decontamination of all waste, must wear a solid front gown with cuffed sleeves, glove*s* and N-95 respirator/PAPR).**Optimal: additional - preferred**[ ]  Additional PPE: hair and shoe covers. | Low |
| **Comments:** |

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| **Culture Work-up: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| **Performs:**[ ]  **Viral culture ID** | 1. Examine media for growth.
2. Work up cultures as per laboratory procedure based on specimen source.

**List your test specific process steps here.** | * Risk of aerosol production (See Table 1 for aerosol generating activities)
* Risk of contamination by touching growth
* Risk of spill or splash when handling liquid media
 | ModerateHigh *(MERS, SARS, Avian influenza, etc.*) | **Required:**[ ]  Follow written procedures.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray. [ ]  Do not touch your face, eyes, nose, or mouth without washing your hands first.[ ]  Perform all work with open inoculated media for viral cultures in a Class II BSC. [ ]  Perform all work with suspected or known highly pathogen viruses in a Class II BSC using BSL-3 practices (controlled access to the area when working, decontamination of all waste, must wear a solid front gown with cuffed sleeves, glove*s* and N-95 respirator/PAPR).[ ]  Work with slides for immunofluorescence staining within a Class II BSC until they are fixed. Once slides are fixed, they may be stained outside the BSC on the bench top. | Low |
| **Comments:** |

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| **Culture Work-up: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Isolate/** **Specimen Retention** | 1. Store completed culture media at appropriate temperature for appropriate time per procedure.
2. Store isolates in racks, or boxes, or in sealed biohazard bags to prevent leaks and spills.
 | * Leak or spill during storage
 | Low | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Wear additional freezer gloves if storing in ultra low (-70○ C) freezer. | Low |
| **Comments:** |
| [ ]  **Discarding Waste** | 1. Discard waste into appropriate double bagged biohazardous waste containers or sharps containers.
 | * Leak or spill while discarding waste or while storing discarded waste.
* Possible poke through biohazard bag if sharps not disposed of properly in a rigid biohazard container.
 | LowModerate(*AFB, systemic mold and highly pathogenic bacteria and viruses*) | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Double bag all biohazardous waste and use rigid biohazardous sharps container for sharps.[ ]  Discard biohazardous sharps containers when 2/3 full.[ ]  Cover partially filled biohazardous waste containers when not in use.[ ]  Disinfect workspace and any spills with an appropriate disinfectant.[ ]  Decontaminate or autoclave all waste, including liquid waste, from known or suspect AFB, systemic molds, or highly pathogenic bacteria or viruses before disposing into normal waste stream. | Low |
| **Comments:** |

**Molecular Assays:**

*(Complete this section if your laboratory performs any Molecular Assays. If you do not perform molecular assays skip to MALDI-TOF assays.)*

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| **Molecular Assays:**  |
| **Specimen:** There are many possible specimens that may be collected and received for testing, **d**ependent on the assay and the agent that is targeted/suspected. |
| **Pathogen(s):** There is a potential to be exposed to many pathogens during molecular testing set-up dependent on the patient’s health, the specimen type, how the specimen was collected and transported, and the integrity of the specimen when it was received in the lab. Typically the highest biosafety risk for molecular assays is in the set-up, because extraction steps typically destroy pathogen infectivity. |
| **Infectious Dose:** Dependent on the pathogen. |
| **Route of Transmission:** * Parenteral inoculation from a needle stick or other sharps
* Ingestion from spill or splash into mouth
* Contact from touching, or a spill or splash onto mucous membrane or non-intact skin
* Inhalation of infectious aerosol
 |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Self-contained Sample to Answer:**[ ]  **Panther**[ ]  **Tigris**[ ]  **Other (Be specific)****\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | 1. Load sample onto instrument.
2. Run sample.
3. Remove sample from instrument and discard into waste.
4. Use bleach to clean instrument components and prevent cross-contamination.

**List your test specific process steps** | * Outside of sample contaminated during collection.
* Minimal risk of exposure to hazardous reagents when changing them.
* Minimal biological risk as sample doesn’t contain live organism.
* Exposure to 50% bleach during cleaning.
 | Low | Required:[ ]  Wear appropriate PPE: lab coat, gloves, eye protection.[ ]  Follow written biosafety protocols.  | Minimal |
| **Comments:** |

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| **Molecular Assays: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Sample diluent transfer and then self-contained Sample to Answer:**[ ]  **GeneXpert**[ ]  **BioFire**[ ]  **BD Max**[ ]  **Liat**[ ]  **Alere i**[ ]  **Illumigene**[ ]  **Simplexa**[ ]  **Viper**[ ]  **Luminex - Nanosphere**[ ]  **Genmark**[ ]  **Cobas 4800 - HPV**[ ]  **Other (Be specific)****\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | 1. Transfer specimen to lysis buffer/diluent.
2. Vortex.
3. Transfer to sample test cartridge.
4. Load on instrument.
5. Run sample.
6. Remove sample from instrument and discard into waste.
7. Use bleach or approved product to clean instrument components and prevent cross-contamination.

**List your test specific process steps** | * Outside of sample contaminated during collection
* Risk of spill when transferring the primary specimen and inoculating the sample cartridge.
* Risk of aerosol production during any pipetting or vortexing step.
* Puncture risk if sharps not disposed of in approved sharps container.
 | Moderate(*but varies dependent on the suspect agent*) | **Required:**[ ]  Wear appropriate PPE: lab coat, gloves, eye protection.[ ]  Follow written biosafety protocols. **Additional Protection – Preferred:**[ ]  Use Bio wipe/gauze cover when uncapping tubes.[ ]  Perform specimen transfer in BSC as possible**Additional Protection - Alternative:**[ ]  Perform work outside of a BSC, but wear eye protection and work behind a safety shield or face shield. | Minimal |
| **Comments:** |

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| **Molecular Assays: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Manual or automated extraction, amplification, detection:**[ ]  **Verigene**[ ]  **Luminex – xTag Respiratory and GI panels**[ ]  **eSensor**[ ]  **Laboratory Developed Test (LDT) PCR** **Other?** | **Follow Package insert.****List your test specific process steps** | * Outside of sample contaminated during collection
* Risk of spill when transferring the primary specimen and inoculating the sample cartridge.
* Risk of aerosol production during any pipetting or vortexing step.
* Puncture risk if sharps not disposed of in approved sharps container
* Risk of chemical exposure
* Risk of burn or aerosol production if cap pops open
* Risk of aerosol production from centrifuging specimen.
* Risk of sharps if tube breaks in centrifuge.
 | Moderate to High | **Required:**[ ]  Wear appropriate PPE: lab coat, gloves, eye protection.[ ]  Follow written biosafety protocols. **Additional Protection – Preferred:**[ ]  Use Bio wipe/gauze cover when uncapping tubes.[ ]  Perform specimen transfer in BSC as possible[ ] Perform any manipulation of extract in a dead air box.**Additional Protection - Alternative:**[ ]  Perform work outside of a BSC, but wear eye protection and work behind a safety shield or face shield. | Low |
| **Comments:** |

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| **Molecular Assays: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Discarding Waste** | 1. Dispose of waste in appropriate biohazardous waste.
 | * Leak or spill while discarding waste or while storing discarded waste.
* Possible poke through biohazard bag if sharps not disposed of properly in a rigid biohazard container.
 | Low | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Double bag all biohazardous waste or use rigid sharps container.[ ]  Discard biohazardous sharps containers when 2/3 full.[ ]  Cover partially filled biohazardous waste containers when not in use.[ ]  Disinfect workspace and any spills with an appropriate disinfectant.**Additional Protection – Preferred:**[ ]  Discard consumables into a rigid, puncture proof biohazardous waste container. **Additional Protection - Alternative:**[ ]  Discard consumables into double bagged biohazardous waste. | Low |
| **Comments:** |
| [ ]  **Specimen Storage** | 1. Store specimen appropriately.
 | * Specimen spill in storage.
 | Low | **Required:**[ ]  Follow written procedure.[ ]  Wear PPE: lab coat, gloves and additional eye protection when there is a risk of a splash or spray.[ ]  Store specimens in leak proof containers.**Additional Protection – Preferred:**[ ]  Wear additional freezer gloves if storing in ultra low (-70○ C) freezer. | Low |
| **Comments:** |

**MALDI-TOF Assays:**

*(Complete this section if your laboratory performs any MALDI-TOF assays.)*

**NOTES:**

1. **Use of MALDI-TOF technology is not recommended for the identification of suspect bioterrorism agents. It is recommended to only use MALDI-TOF after all bioterrorism agents have been ruled-out in accordance with the select agent protocols. The MALDI-TOF libraries are not well developed for bioterrorism agents and these organisms have been misidentified by MALDI-TOF.**
2. **If MALDI-TOF technology is being used for the identification of Mycobacteria or other suspected highly pathogenic organisms, the tube extraction method with heat inactivation is recommended before spotting the organism and running the MALDI-TOF assay. (Caution - studies have shown that organisms that produce spores may not be inactivated by this process.)**

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| **MALDI-TOF Assays:**  |
| **Specimen:** Isolates growing on TB culture media, as well as isolate growth on routine aerobic and anaerobic media and fungal media  |
| **Pathogen(s):** MALDI-TOF assays may be used for the identification of *Mycobacterium tuberculosis*, non-tuberculosis mycobacteria, aerobic and anaerobic bacteria, yeast and fungi. It is not recommended to use MALDI-TOF to identify organism that are suspected to be highly pathogenic such as the BT agents. Organisms that produce spores may not be killed even using the tube extraction methods increasing the risk for LAI when performing aerosol generating procedures. |
| **Infectious Dose:** The infectious dose will vary depending upon the organism being identified. The infectious dose for *Mycobacteriium tuberculosis* is < 10 microorganisms. |
| **Route of Transmission:** Inhalation via aerosol or droplet. |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Reagent Preparation**  | 1. Prepare BTS, matrix:
2. 70% formic acid solution
3. 70% ethanol (target cleaning)
4. 80% trifluoroacetic acid (target cleaning
 | * Risk of chemical exposure when aliquoting strong acids and organic solvents (Note: small volumes).
 | Medium (*Exposure to chemicals*) | **Required:**[ ]  Follow written procedures.[ ]  Wear appropriate PPE: (no respirator necessary), lab coat, gloves, eye protection.[ ]  Follow Chemical Hygiene Plan.**Additional Protection – Preferred:**[ ]  Perform work in a fume hood.[ ]  Wear additional chemical resistant gloves, apron.**Additional Protection - Alternative:**[ ]  If perform work outside of a fume hood, wear eye protection and work behind a safety shield or face shield. | Low |
| **Comments:** |

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| **MALDI-TOF Assays: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Reagent Preparation for tube extraction process****(for Mycobacteria and other high risk pathogens)** | 1. Prepare BTS, matrix:
2. 70% formic acid solution
3. 70% ethanol (target cleaning)
4. 80% trifluoroacetic acid (target cleaning
5. acetonitrile
 | * Risk of chemical exposure when aliquoting strong acids and organic solvents (Note: small volumes).
 | Medium (*Exposure to chemicals*) | **Required:**[ ]  Follow written procedures.[ ]  Wear appropriate PPE: (no respirator necessary), lab coat, gloves, eye protection.[ ]  Follow Chemical Hygiene Plan.**Additional Protection – Preferred:**[ ]  Perform work in a fume hood.[ ]  Wear additional chemical resistant gloves.**Additional Protection - Alternative:**[ ]  If perform work outside of a fume hood, wear eye protection and work behind a safety shield or face shield. | Low |
| **Comments:** |
| [ ]  **Concentration and heat inactivation****(for Mycobacteria and other high risk pathogens)** | 1. Concentrate 3-6 ml broth specimen by centrifugation.
2. Pour off supernatant.
3. Add 1 ml water and vortex.
4. Transfer to 1.5 ml tube and centrifuge again.
5. Pour off supernatant.
6. Add 300 ul of water.
7. Make suspension from growth on solid media in 300 ul water and vortex.
8. Heat for 30 minutes at 95-100C degrees.
 | * Risk of aerosols, splashes, and splatter when opening tubes, pouring off supernatant, vortexing and pipetting.
 | High (*MTBC*)Low (*NTM*) | **Required:**[ ]  Follow written procedures.[ ]  Post a sign on the door warning others when working with AFB cultures.[ ]  Perform all work-up of AFB isolates in a Class II BSC using BSL-3 practices (controlled access to the area when working, decontamination of all waste, must wear a solid front gown with cuffed sleeves, glove*s,* eye protection and N-95 respirator/PAPR). [ ]  Use centrifuge w/ sealed carriers.[ ]  Use microcentrifuge tubes with screw cap/gasket. | Low |
| **Comments:** |

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| **MALDI-TOF Assays: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Extraction after heat inactivation** **(for Mycobacteria and other high risk pathogens)** | 1. Add EtOH and vortex.
2. Centrifuge and pour off the supernatant
3. Use a fine tip pipettor to remove the remainder of EtOH and air dry pellet for 5 minutes.
4. Add silica beads and acetonitrile.
5. Use racking technique to mix.
6. Vortex.
7. Add formic acid and vortex.
8. Centrifuge.
 | * Exposure to small volumes of chemicals.
* Minimal biological risk from production of aerosols after heat inactivation.
 | Low | **Required:**[ ]  Follow written procedures.[ ]  Wear appropriate PPE: (no respirator necessary) lab coat, gloves and eye protection.[ ]  Follow chemical hygiene plan.**Additional Protection – Preferred:**[ ]  Perform a viability check to validate organisms are non-viable after heat activation process as part of MALDI-TOF assay validation.  | Low |
| **Comments:** |
| [ ]  **Spotting organism onto target** | 1. Spot low risk pathogen growth directly onto MALDI target, or extracted high risk pathogen onto MALDI target and allow to air dry.
2. Overlay with matrix.
3. For extended direct spotting only, overlay with formic acid.
 | * Very little risk of chemical exposure due to minimal amounts of chemicals.
* Small risk of aerosol production when spotting target.
 | Low | **Required:**[ ]  Follow written procedures.[ ]  Wear PPE: (no respirator necessary) lab coat and gloves.[ ]  Follow chemical hygiene plan.**Additional Protection – Preferred:**[ ]  Spot target in a BSC.[ ]  Wear additional eye protection.**Additional Protection - Alternative:**[ ]  Wear a face shield or work behind a safety shield when spotting target. | Low |
| **Comments:** |

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| **MALDI-TOF Assays: (continued)** |
| **Procedure** | **Process Step** | **Potential Hazards** | **Initial Risk Level** | **Control (Mitigation)** | **Residual Risk Level** |
| [ ]  **Analyze Target** | 1. Carry target inside a plastic carrier to the MALDI-TOF analyzer.
2. Place target in instrument.
3. Analyze target.
 | * Very little risk of chemical exposure due to minimal amounts of chemicals.
* Small risk of aerosol production during ionization process.
 | Low | **Required:**[ ]  Follow written procedures.[ ]  Wear PPE: (no respirator necessary) lab coat and gloves.[ ]  Follow chemical hygiene plan.**Additional Protection – Preferred:**[ ]  Wear additional eye protection. | Low |
| **Comments:** |
| [ ]  **Clean Target** | 1. Use 70% EtOH and 80% trifluoroacetic acid to clean MALDI plate.
 | * Moderate risk of exposure to chemicals.
 | Moderate | **Required:**[ ]  Work in Fume hood.[ ]  Wear PPE: (no respirator necessary) lab coat and gloves.[ ]  Follow chemical hygiene plan.**Additional Protection – Preferred:**[ ]  Wear additional chemical resistant gloves, apron. | Low |
| **Comments:** |