Clinical Laboratory Biosafety Risk Management Program Assessment Checklist

LAB ID and LABORATORY NAME:	
ASSESSOR NAME:	**DATE:**

Question	Y	N	NA	Comments
1. ESSENTIAL ELEMENTS FOR MANAGING AN EFFECTIVE BIOSAFETY PROGRAM				
1.1 Responsibility for Managing Biosafety				
Is the laboratory director responsible for ensuring that systems are in place and documented for identifying potential hazards, assessing risks associated with those hazards, and establishing precautions and standard procedures to minimize employee exposure to those risks? Is there a standard operating procedure (SOP) in place to document these?	○	○	○	
Is the laboratory director responsible for providing facilities commensurate with each laboratory's function and the recommended containment level for the agents or materials being handled? Is this written in an SOP?	○	○	○	
Are supervisory staff responsible for the following and are these responsibilities documented? • Conducting, reviewing, and approving risk assessment results. • Developing lab-specific safety plans; • Ensuring completion of initial and refresher training of laboratory workers, and for ongoing monitoring and correction of unsafe practices and conditions within the lab.	○ ○ ○	○ ○ ○	○ ○ ○	
Are employees encouraged to report accidents or incidents and are these reports promoted as nonpunitive and as opportunities for improvement?	○	○	○	
Is compliance with safety policies and completion of safety-related training considered in staff performance evaluations?	○	○	○	

Question	Y	N	NA	Comments
Does the laboratory director have a mechanism in place for ensuring that comprehensive safety policies and procedures are developed, communicated appropriately to affected staff, and readily available?	○	○	○	
Does the senior laboratory management review and approve work practices designed to minimize employee risk?	○	○	○	
1.2 Biosafety Policies and Procedures				
Does each laboratory have a written biosafety manual that identifies the hazards that will or may be encountered, and that specifies applicable practices and procedures designed to minimize or eliminate exposure to these hazards?	○	○	○	
Does the manual include the following elements: • Minimum Biosafety Level 2 (BSL-2) practices and an explanation of standard precautions. • Information on recommended vaccines and the method for obtaining the advice of a medical professional on the advisability of vaccination. • Information on the signs and symptoms of illness, routes of exposure for infectious agents, and the prevention of exposure incidents. • Information on post-exposure prophylaxis (PEP). • Statement that reporting an exposure accident, incident, or near miss does not result in punitive action.	○ ○ ○ ○ ○	○ ○ ○ ○ ○	○ ○ ○ ○ ○	
Does the laboratory have a written Bloodborne Pathogens (BBP) Exposure Control Plan or written biosafety manual that addresses the required elements of OSHA's BBP Standard?	○	○	○	
Does the BBP Exposure Control Plan adequately address compliance with the OSHA BBP Standard?	○	○	○	
Are the requirements for the use of safety-engineered needle products clearly stated and any exceptions justified?	○	○	○	
Does the laboratory have an inventory control program for cultures and stocks of infectious agents?	○	○	○	
Does the laboratory have a Chemical Hygiene Plan (CHP) for handling of toxins of biological origin if these toxins are handled in the laboratory?	○	○	○	
Do laboratory procedures and instructional material clearly define biohazard				

Question	Y	N	NA	Comments
risks and integrate safety practices into performing the tasks where appropriate?	○	○	○	
Are biosafety-related policies and procedures managed in a document control system to ensure that the most current documents are in use and available.	○	○	○	
Does the laboratory have a TB Infection Control Policy?	○	○	○	
1.3 Biosafety Program Implementation and Continuous Improvement				
When accidents, incidents, or near misses are reported, is a root cause analysis conducted and corrective actions identified, documented, and addressed?	○	○	○	
Does management solicit staff input when evaluating safety concerns, performing risk assessments, or when choosing safety products or reviewing a procedure?	○	○	○	
Are self-audits of the biosafety management systems and accident/incident reports performed annually to assess effectiveness and compliance and initiate improved methods and engineering controls as needed?	○	○	○	
2. BIOLOGICAL RISK ASSESSMENT				
Does the laboratory have a standardized process for conducting activity-specific biological risk assessments?	○	○	○	
Does the institution's biological risk assessment process include the following steps: • Identify the hazards associated with a known infectious agent or procedure • Identify the activities that might cause exposure to the agent or material; • Consider the competencies and experience of laboratory personnel performing the various activities; • Evaluate and prioritize risks (i.e., evaluate the likelihood that an exposure would occur and the severity of consequences to both individual and institution if such an infection occurs); and • Select, implement, and evaluate appropriate controls that minimize the risk for employee exposure.	○ ○ ○ ○ ○	○ ○ ○ ○ ○	○ ○ ○ ○ ○	

Question	Y	N	NA	Comments
• Specify any agent-specific or procedural "triggers" that warrant enhanced precautions.	○	○	○	
Are all risk assessments documented with sufficient detail to capture the hazards and exposure risks associated with each method or procedure, as well as the required necessary level of controls and triggers for enhanced precautions?	○	○	○	
Are there management systems in place to ensure that risk assessments are performed before new procedures are implemented and when procedures are changed?	○	○	○	
Are all laboratories required to review activity-specific risk assessments whenever there are any new or emerging pathogens, changes in personnel, and new technologies introduced into existing procedures?	○	○	○	
3. FUNDAMENTAL SAFETY PRACTICES				
Are there written procedures to deal with specimen receiving, leaking containers, and visible contamination of the outside of containers.	○	○	○	
Are personal precautions such has handwashing, the use of splash guards at workstations, and no sniffing of culture plates strictly enforced.	○	○	○	
Are all surfaces in the laboratory regularly disinfected with an intermediate level disinfectant each day of work?	○	○	○	
Do staff refrain from touching eyes, nose, mouth and lips while in the laboratory.	○	○	○	
Is prohibition of the storage of food or drink in the laboratory enforced?	○	○	○	
Do staff refrain from using cellphone and bringing personal items (purses, backpacks, books, magazines etc.) into the laboratory?	○	○	○	
If there are offices adjacent to laboratories are these offices maintained in a manner that allows for easy disinfection; is PPE removed before entering the office; and are hands washed after working in the office.	○	○	○	
4. ENGINEERING CONTROLS				

Question	Y	N	NA	Comments
4.1 Biological Safety Cabinets (BSCs)				
Does each laboratory have sufficient Class II BSCs (preferably a Class II, Type A2) where needed as determined by each activity-specific risk assessment?	○	○	○	
Are all Class II BSCs tested and certified *in situ* by an accredited field certifier initially, annually, and each time a unit is moved, in accordance with Annex F of ANSI/NSF Standard No. 49?	○	○	○	
Are Class II, Type A2 BSCs connected to the laboratory exhaust system with a thimble (canopy) connection when minute quantities of volatile chemicals or radionuclides are used?	○	○	○	
Do Class II Type A2 BSCs with exhaust canopies/thimble unit connections have flow alarms have flow alarms?	○	○	○	
Is the use of equipment with open flames (e.g., Bunsen burners) prohibited within BSCs?	○	○	○	
Is the use of ultraviolet (UV) lamps in BSCs avoided? If not, are bulbs cleaned routinely and tested biannually to ensure efficacy.	○	○	○	
Are BSCs properly decontaminated before HEPA filters are changed or internal repair work is done?	○	○	○	
Are traps consisting of one or two suction flasks together in series with an in-line HEPA filter used for vacuum-assisted devices within BSCs to prevent contamination of the vacuum pump or house vacuum system?	○	○	○	
Are the in-line HEPA filters assessed and replaced at a frequency appropriate to usage in the laboratory?	○	○	○	
4.2 Centrifuge Safety Cups and Sealed Rotor Heads				
Is all centrifugation performed using centrifuge safety buckets or cups, or sealed centrifuge tubes in sealed rotors as appropriate?	○	○	○	
Are all centrifuges and rotors inspected and maintained (i.e. visual inspection of O-rings and gaskets) following manufacturers' instructions to prevent malfunctions and aerosol generation within the centrifuge?	○	○	○	
Are appropriate plastic centrifuge tubes with seal-forming screw caps used whenever possible?	○	○	○	

Question	Y	N	NA	Comments
4.3 Sharps				
Have laboratories evaluated and adopted, whenever practical, improved engineering controls (i.e., sharps with engineered sharps injury protection, such as safety needles and safety scalpels) that reduce risks of sharps injuries?	○	○	○	
Are properly labeled, leak- and puncture-resistant sharps containers used for collecting all items defined as regulated sharps (e.g., used disposable needles, syringes, scalpels, blades, Pasteur pipettes, etc.) under the applicable regulated medical waste regulations?	○	○	○	
Are sharps containers located in or near the areas where sharps are used?	○	○	○	
Are sharps containers replaced when disposed sharps reach the fill line or reach ¾ full?	○	○	○	
Are sharps containers designed to be closed securely for transport to decontamination areas?	○	○	○	
Are covered leak-resistant, hard-walled containers used for transporting nondisposable sharps to processing areas for decontamination?	○	○	○	
4.4 Mechanical Pipetting Devices				
Are mechanical pipetting devices with filters used to minimize contamination of the handset?	○	○	○	
If mechanical pipetting devices with filters are used, are filters replaced regularly and whenever they become wet?	○	○	○	
4.5 Automated Equipment Safety Features				
Do automated analyzers have added features (e.g., instrument safety shields and containment devices) to help reduce operator exposures?	○	○	○	
Do automated analyzers have automatic probe wash cycles that eliminate operators from having to wipe sample probes after sampling?	○	○	○	
Are procedures available for minimizing exposure to patient samples through surface contamination, aerosolization, or penetrating injury when performing testing on automated analyzers?	○	○	○	
Are primary containment devices utilized with ELISA plate washers and shakers?	○	○	○	
Are aerosol containment covers placed over ELISA plate washers and shakers to	○	○	○	

Question	Y	N	NA	Comments
minimize aerosol contamination whenever possible?	○	○	○	
5. LABORATORY FACILITIES				
Are all laboratory facilities commensurate with each laboratory's function and the recommended containment level for the agents or materials being handled, based on risk assessment?	○	○	○	
5.1 Biosafety Level 2 Facilities				
Are laboratory doors self-closing?	○	○	○	
Do all laboratories have a sink for handwashing that is located near the exit door?	○	○	○	
Are all laboratories designed so they can be easily cleaned and thoroughly disinfected (e.g., surfaces are smooth and free of cracks or crevices) and free of any carpets or rugs?	○	○	○	
Are materials used in laboratory fixtures and furniture designed for easy cleaning and disinfection, impervious to water, and resistant to solvents?	○	○	○	
Are all chairs used for laboratory work constructed or covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant?	○	○	○	
Are vacuum lines associated with biohazardous procedures protected with liquid disinfectant traps and assessed and replaced at a frequency appropriate to usage in the laboratory?	○	○	○	
If laboratory windows are capable of being opened to the exterior, are they fitted with screens?	○	○	○	
Are all biological safety cabinets located away from doors and windows that can be opened, heavily traveled laboratory areas, fans, room air supply louvers, and other possible airflow disruptions?	○	○	○	
Are eyewash stations installed within each lab and maintained in accordance with the most recent edition of ANSI Z358.1 (e.g., flushed and function checked weekly)?	○	○	○	
Are all laboratories supported by ventilation systems that provide an inward				

Question	Y	N	NA	Comments
flow of air without recirculation to spaces outside of each laboratory?	○	○	○	
If regulated medical waste is autoclaved on site, are all required permits in place and have all autoclave units and cycles been properly validated and verified on an ongoing basis with challenge testing using chemical and/or biological indicators?	○	○	○	
5.2 Biosafety Level 3 Facilities				
Is laboratory access restricted?	○	○	○	
Is the laboratory separated from areas that are open to unrestricted traffic flow within the building?	○	○	○	
Is access to the laboratory through an anteroom with two self-closing doors?	○	○	○	
Does the laboratory have a sink for handwashing which is hands-free or automatically operated and located near the exit door?	○	○	○	
If segregated into different laboratories, is there a sink for handwashing in each zone as determined by risk assessment (i.e., points at which inner gloves might need to be removed and replaced).	○	○	○	
Is the laboratory (including floors, walls, and ceilings) designed so it can be easily cleaned and thoroughly disinfected (e.g., surfaces are smooth and free of cracks or crevices) and free of any carpets or rugs?	○	○	○	
Are floors slip resistant, impervious to liquids, and resistant to chemicals?	○	○	○	
Are all seams of floors, walls, and ceilings sealed to facilitate decontamination?	○	○	○	
If present, are all laboratory windows sealed?	○	○	○	
Are all penetrations (e.g., spaces around doors and ventilation ducts) capable of being sealed to facilitate gaseous or vapor phase decontamination of the lab if that method of decontamination is appropriate based on risk assessment?	○	○	○	
Are materials used in laboratory fixtures and furniture (including chairs) designed for easy cleaning and disinfection, impervious to water, and resistant to solvents?	○	○	○	
Are eyewash stations installed within the lab and maintained in accordance with the most recent edition of ANSI Z358.1 (e.g., flushed and function checked weekly)?	○	○	○	

Question	Y	N	NA	Comments
Are all biological safety cabinets located away from doors, heavily traveled laboratory areas, room air supply louvers, and other possible airflow disruptions?	○	○	○	
Are all vacuum lines protected with HEPA filters or their equivalent and assessed and replaced at a frequency appropriate to usage in the laboratory?	○	○	○	
Is all equipment that may produce infectious aerosols contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged to the laboratory?	○	○	○	
Are all HEPA filters associated with primary barrier devices tested or replaced at least annually?	○	○	○	
Is single-pass air (i.e., 100% air supplied and exhausted without recirculation) provided?	○	○	○	
Is the lab designed with a ducted air ventilation system that provides sustained directional airflow by drawing air into the laboratory from “clean” areas toward “potentially contaminated” areas?	○	○	○	
Is the air ventilation system designed and initially verified by a qualified individual such that under failure conditions, there is no reversal of air which originates within the BSL-3 that travels all of the way outside the containment boundary (Note: The BSL-3 anteroom is considered to be within the containment boundary).	○	○	○	
Is a visual monitoring device provided at the laboratory entry which confirms directional airflow?	○	○	○	
Does the lab have local visual/audible alarms to notify personnel of airflow disruption?	○	○	○	
Is the laboratory building exhaust air HEPA filtered or dispersed away from occupied areas and from building air intake locations?	○	○	○	
Do building HEPA filter housings have gas-tight isolation dampers and decontamination ports, or bag-in/bag-out capability with appropriate decontamination procedures?	○	○	○	
Does the HEPA filter housing allow for leak testing of each filter and assembly?	○	○	○	
Are the HEPA filters and housing certified at least annually?	○	○	○	

Question	Y	N	NA	Comments
Is there a method (e.g., autoclaving, chemical disinfection, etc.) for decontaminating all BSL-3 laboratory waste available within the laboratory or facility?	○	○	○	
Is there a protocol in place to assure that autoclaved waste is not removed from the laboratory until the successful run is verified with a biological indicator?	○	○	○	
Are any required permits in place for BSL3 autoclaves and have all autoclave units and cycles been properly validated and verified on an ongoing basis with challenge testing using chemical and/or biological indicators?	○	○	○	
Is the facility designed appropriately to accommodate required procedures, based on risk assessment, for decontaminating large pieces of equipment before removal from the laboratory?	○	○	○	
Have all necessary facility enhancement (e.g., shower-out capabilities, HEPA filtration of laboratory exhaust air, access control devices, etc.) for environmental and personal protection been considered and integrated into the facility design based on risk assessment?	○	○	○	
Are the BSL-3 facility design, operational parameters, and procedures verified by qualified individuals and documented prior to operation and at least annually thereafter? For testing and performance of BSL3 ventilation systems, refer to ANSI/ASSE Z9.14-2014: *Testing and Performance Verification Methodologies for Ventilation Systems for BSL-3/ABSL-3 Facilities*[1]?	○	○	○	
6. PRE-ANALYTIC PROCESSES (SPECIMEN COLLECTION AND MANAGEMENT)				
If laboratory staff perform phlebotomy, are procedures in place to minimize sharps injuries?	○	○	○	
Are applicable patient care and infection control policies and procedures followed in patient drawing areas?	○	○	○	
If a pneumatic tube system is used to transport specimens, are procedures available and followed for use and decontamination of the system?	○	○	○	
Does the laboratory provide guidance on specimen collection that includes information on the required specimen containers and how to package and send specimens to the laboratory to minimize leakage?	○	○	○	

Question	Y	N	NA	Comments
Does the laboratory have policies and procedures for inspecting incoming specimens and for handling leaking specimen containers?	○	○	○	
Are gloves and other required PPE available and worn by phlebotomists and specimen receiving and processing personnel?	○	○	○	
Are engineering controls available when using centrifuges to prepare specimens for testing?	○	○	○	
7. MICROBIOLOGY LABORATORY				
Is basic PPE provided for all personnel working in the laboratory? (basic PPE includes gloves, laboratory coats or gowns, protective eyewear or face protection, etc.	○	○	○	
If a procedure is inducing aerosols, is a risk assessment being performed to determine whether the procedure should be performed in a BSC (or what other measures are required to control the risk)?	○	○	○	
Is there a policy in place for decontaminating surfaces after completion of work?	○	○	○	
Is there a biological safety cabinet available for aerosol generating procedures (as determined by risk assessment)?	○	○	○	
If there is a pneumatic tube system, is there a decontamination protocol?	○	○	○	
If gloves are worn for routine plate reading is there a policy for removal when work is completed and before touching other surfaces?	○	○	○	
8. CORE LABORATORY (HEMATOLOGY, COAGULATION,				
Have biological risk assessments been conducted for the laboratory procedures in which potential infectious specimens are handled in accordance with Section 2?	○	○	○	
Are procedures in place to prevent exposure to spills, sample trays, sample probes, and contaminated areas around the analyzers i.e. use of splash shields when opening specimen tubes?	○	○	○	
Are procedures for instrument decontamination available and in use?	○	○	○	

Question	Y	N	NA	Comments
Is adequate PPE available when using instruments that cause spray ionization?	○	○	○	
Are chemistry analyzers, hematology and other instruments regularly cleaned and maintained according to manufacturer's recommendations ensuring protection of the operator?	○	○	○	
Are procedures in place to contain aerosols and droplets generated by flow cytometers?	○	○	○	
Are procedures available and followed to disinfect microscope knobs or microscope stages routinely?	○	○	○	
9. IMMUNOHEMATOLOGY/BLOOD BANK LABORATORY				
Have biological risk assessments been conducted for the laboratory procedures in which potential infectious specimens are handled in accordance with Section 2?	○	○	○	
Are procedures available for work practices and work practice controls to mitigate potential exposures when working on unfixed specimens on an open bench (e.g. slide preparation, manual cell washing, and plasma extraction)?	○	○	○	
Are blood bank refrigerators cleaned and disinfected regularly as per the disinfection schedule (as per the Bloodborne Pathogens Exposure Control Plan?	○	○	○	
Are procedures available for safely dispensing blood and blood products?	○	○	○	
Are blood and blood components discarded in compliance with federal, state and local regulations?	○	○	○	
10. ANATOMIC PATHOLOGY AND CYTOLOGY LABORATORY				
Are efforts made to reduce the risk of exposure to *M. tuberculosis* and CJD in formalin-fixed tissue?	○	○	○	
Is fresh tissue examined in a BSC using appropriate PPE?	○	○	○	
Is the cryostat located in a closed room and are procedures in place to protect against aerosols?	○	○	○	
Is decontamination of the cryostat performed as per manufacturer's instructions[2] to remove shavings and disinfect surfaces as per the disinfection				

Question	Y	N	NA	Comments
schedule? Are stainless steel mesh gloves are used while cleaning the microtome knifes?	○	○	○	
Are cytology guards against blood and body fluids present? These guards should work by processing large-volume body fluids so that the risk from splash and spills are reduced.	○	○	○	
Are air-dried slides treated as infectious until they are fixed and stained by appropriately validated methods?	○	○	○	
11. POST-ANALYTIC PROCESSES: STORAGE AND TRANSPORT OF POTENTIALLY INFECTIOUS SUBSTANCES				
Does the laboratory have a specimen retention policy that includes biosafety considerations for retained materials?	○	○	○	
Is there a written SOP for storage and inventory of infectious substances?	○	○	○	
Does the laboratory have at least two employees who are certified in packing and shipping IATA Division 6.2 (Category A) infectious substances and other infectious samples to meet regulatory requirements for sending out infectious disease testing (e.g. testing for Ebola Virus Disease)?	○	○	○	
Have staff who package and ship infectious substances (category A and B) been initially certified as per IATA to ship these materials, and have they been recertified as required?	○	○	○	
Are shipping records maintained and available?	○	○	○	
12. MANAGEMENT OF REGULATED WASTE				
Is there a written regulated waste management plan?	○	○	○	
Is there a contingency waste management plan in the circumstance that waste removal companies refuse to transport specific medical waste?	○	○	○	
Does the management plan include a waste reduction/minimization program?	○	○	○	
Have applicable state/local requirements been referenced in the plan?	○	○	○	
Have all types of regulated waste generated in the laboratory been identified?	○	○	○	
For each identified waste category, has specific guidance been provided in the				

Question	Y	N	NA	Comments
plan regarding its:				
• On site management?	○	○	○	
• Off site management?	○	○	○	
Is regulated waste segregated to prevent unauthorized access?	○	○	○	
Is there a system identified for responding to regulated waste incidents?	○	○	○	
Do regulated waste management processes meet applicable regulations and guidelines?	○	○	○	
12.1 Decontamination of medical waste before transport and disposal				
Have employees engaged in waste decontamination and treatment processes been trained, and do they demonstrate requisite competencies?	○	○	○	
Have employees been trained not to mix regulated waste and other non-regulated wastes (i.e. radioactive or hazardous chemical)?	○	○	○	
Is regulated waste accumulated in color coded containers, bearing the word, “Biohazard”, the universal biohazard symbol, and any other appropriate marking/labeling in accordance with the site’s management plan?	○	○	○	
12.2 Management of discarded cultures and stocks				
Are discarded cultures and stocks from BSL-3 labs placed into closed, leakproof, containers marked with the word, “Biohazard” and autoclaved on site?	○	○	○	
Are BSL-2 discarded cultures and stocks either autoclaved on site or otherwise decontaminated through a validated technology or approved vendor?	○	○	○	
Are discarded cultures and stocks that are treated on-site outside of the laboratory secured in durable, leakproof containers before being moved?	○	○	○	
Has a risk assessment been conducted to determine if discarded cultures and stocks from BSL-2 labs can be treated off-site?	○	○	○	
Are discarded cultures and stocks from BSL-2 labs treated off site packaged in regulated waste shipping containers in accordance with applicable standards?	○	○	○	
12.3 Discarding a select agent				
Do CDC Forms 4b’s reference the destruction of the sample?	○	○	○	
Have all select agents or toxins identified been properly transferred to a				

Question	Y	N	NA	Comments
registered laboratory within 7 days after identification and/or properly destroyed by on-site autoclaving or overnight immersion in a 1:10 bleach solution[3]?	○	○	○	
12.4 Autoclave Safety				
For at least every 40 hours of operation, are biological indicators used to ensure proper autoclave performance?	○	○	○	
Is autoclave indicator tape applied to bags in each load to confirm achievement of required sterilization temperature?	○	○	○	
Are only bags approved for autoclaving in use to package waste loads?	○	○	○	
Are elbow-length autoclave gloves available and used to remove loads from the autoclave?	○	○	○	
Has staff been trained in the safe and proper use of autoclaves?	○	○	○	
13. LABORATORY EQUIPMENT HAZARDS				
Is appropriate PPE worn when using laboratory instrumentation that may produce aerosols or droplets?	○	○	○	
Are any appropriate engineering control in use when using laboratory instrumentation that may produce aerosols or droplets?	○	○	○	
13.1 Water Baths and Water (humidification) pans in CO2 Incubators				
Are disinfectants, fungicides, or algaecides added to water?	○	○	○	
Is the temperature raised to 90 degrees C. for 30 minutes once a week?	○	○	○	
Are bath pan lids and incubator doors kept closed?	○	○	○	
Are baths cleaned immediately after any spills or breakage?	○	○	○	
Are baths and pans regularly emptied and cleaned (even if disinfectants added to water)?	○	○	○	
13.2 Centrifuges and cytocentrifuges				
Is staff trained in the safe use and associated hazards of centrifuges (by type) as per their operation manual?	○	○	○	
Have unit-specific competency assessments been completed for all staff using				

Question	Y	N	NA	Comments
these units?	○	○	○	
Have risks been considered for the use of any older units which lack interlock mechanisms?	○	○	○	
Is an operations manual accessible for each unit?	○	○	○	
Is appropriate clearance provided when using any high speed and ultracentrifuges: as per manufacturer's recommendations?	○	○	○	
For any high speed and ultracentrifuges: Are comprehensive user logs in use and maintained for each unit?	○	○	○	
Are "O" rings and gasketed safety cups in use?	○	○	○	
Are rotors containing infectious specimens loaded/unloaded in a BSC?	○	○	○	
Are rotors annually stress tested?	○	○	○	
Is a complete certified analysis done annually on all rotors?	○	○	○	
Are rotors retired as per manufacturer's recommendations?	○	○	○	
Are rotors stored in a clean, dedicated space?	○	○	○	
Are centrifuges and rotors used and maintained as per the operations manual?	○	○	○	
Are units cleaned after each shift and after any spill?	○	○	○	
Are centrifuge spill kits available?	○	○	○	
Are detailed procedures in place to deal with specimen tube breakage within screw-capped canisters or buckets?	○	○	○	
Are units maintained as per manufacturer's recommendations?	○	○	○	
13.3 ELISA Plate Washers in Microbiology				
Are gloves worn when handling ELISA plates?	○	○	○	
Are ELISA plate washers and the surrounding areas disinfected at the end of each day used?	○	○	○	
Are covers in place over ELISA plate washers?	○	○	○	
If covers are not utilized or available for the plate washer, is shielding or a biosafety cabinet used to contain the plate washer?	○	○	○	
Is waste from the washer disinfected or is disinfectant added to the waste container?	○	○	○	

Question	Y	N	NA	Comments
13.4 Identification, blood culture, and PCR instruments				
Is Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases (https://www.asm.org/index.php/guidelines/sentinel-guidelines) in accordance with ASM algorithms being conducted?	○	○	○	
Is a biosafety cabinet and appropriate PPE utilized for preparation of samples to load into automated systems when specimens are suspected to contain a high risk agent such as Brucella?	○	○	○	
Are bacterial identification and antimicrobial susceptibility instruments, blood culture instruments, and PCR instruments cleaned/disinfected as per manufacturer's guidance?	○	○	○	
Is a biosafety cabinet and appropriate PPE utilized when a slow growing organism is detected?	○	○	○	
Are procedures in place in the instruments manuals for routine and emergency instrument cleaning?	○	○	○	
13.5 Rapid Test Kits				
Are discarded rapid test kits managed as regulated waste?	○	○	○	
Are rapid test kits only used in a designated area of the laboratory as determined by a risk assessment?	○	○	○	
Are absorbent pads used on work surfaces in the designated area?	○	○	○	
14. MANAGEMENT OF BIOLOGICAL RELEASES, EXPOSURE INCIDENTS, OR ACCIDENTS				
Is a biosafety spill kit available in all laboratory work areas?	○	○	○	
Do all laboratory workers receive appropriate training so that they can respond to spills in their work area?	○	○	○	
Does the laboratory safety manual contain a detailed spill response plan?	○	○	○	
Is appropriate PPE available for clean-up of spills?	○	○	○	
Does the laboratory follow the institutions policy to report accidents or incidents in the laboratory?	○	○	○	
Are exposures, accidents and near misses documented?	○	○	○	

Question	Y	N	NA	Comments
Are there instructions for first aid, specific treatment, prophylaxis and counseling in the laboratory safety manual?	○	○	○	
When an accident or near miss occurs, is the event reviewed to determine root cause factors that can be remedied or removed to prevent future events?	○	○	○	
15. OCCUPATIONAL HEALTH				
Is there a clear 24/7 system for reporting accidents or incidents (e.g., near misses) that all employees are aware of?	○	○	○	
Is a medical evaluation performed on employees working in a BSL3 laboratories as determined by your laboratory policy?	○	○	○	
Is occupational health/employee health services notified upon any work related illness or injury?	○	○	○	
Is occupational health/employee health services notified upon any exposure to any infectious agents or specimens that may contain infectious agents?	○	○	○	
Is medical surveillance performed to detect symptoms or biomarkers if exposed to a known agent?	○	○	○	
Are exposures in the laboratory reported immediately to a supervisor?	○	○	○	
Are laboratorians trained to report any potential symptoms of infection by agents to which they may have been exposed to their health care provider?	○	○	○	
Are laboratorians trained to recognize symptoms of agents to which they may commonly be exposed in the laboratory?	○	○	○	
Are accident reports routinely completed by laboratory staff even when minor accidents/incidents occur?	○	○	○	
Does the laboratory have a medical surveillance program in accordance with OSHA Bloodborne Pathogens Standard requirements?	○	○	○	
Are local or state health departments contacted when a significant exposure occurs for consultation and investigation?	○	○	○	
Are appropriate immunizations offered to all laboratory staff?	○	○	○	
Is pre-placement and medical counseling offered to laboratory staff that may be pregnant or immunocompromised?	○	○	○	

Question	Y	N	NA	Comments
Is there a system in place for immediate correction of issues that cause an accident?	○	○	○	
Is there a procedure to handle suspect work related illnesses?	○	○	○	
Does the laboratory have a TB medical surveillance program?	○	○	○	
Does the laboratory have a respirator program that includes training and medical evaluation?	○	○	○	
16. BIOSAFETY TRAINING AND COMPETENCY ASSESSMENT				
To confirm that items in the list below are accomplished, training and competency documentations must be done/completed at least annually as well as when new changes are implemented on all appropriate staff to prove such actions were done/completed/up to date.				
Are the training and competency requirements documented in the biosafety plan?	○	○	○	
Is completion of training and competency documented?	○	○	○	
Is there documentation that the staff has read and understood the Biosafety Manual?	○	○	○	
Does the cover page contain all appropriate signatures? (Lab Director, Division Manager, etc.)	○	○	○	
Have appropriate drills been conducted to test the Biosafety Manual?	○	○	○	
Have staff been trained on agent specific risks?	○	○	○	
Are staff that perform molecular amplification trained to use a uni-directional workflow with sample preparation, amplification, & product detection in separate areas?	○	○	○	
Is there knowledge on how to report accidents/illnesses related to lab duties?	○	○	○	
Per job duties, have staff been trained on the handling testing equipment/supplies in the laboratory?	○	○	○	
Is there training on how to use the biological safety cabinet?	○	○	○	
17. Compliance with Select Agent Regulations				

Question	Y	N	NA	Comments
Is the Federal Select Agent Program immediately notified when a select agent or toxin requiring immediate notification is identified from a specimen presented for diagnosis or verification?	○	○	○	
Is a completed APHIS/CDC form 4 submitted to the Federal Select Agent Program within 7 days for each select agent or toxin identified from a specimen presented for diagnosis or verification?	○	○	○	
If the laboratory is not registered with the Federal Select Agent Program, are all materials containing select agents or toxins transferred to a registered laboratory or destroyed?	○	○	○	
Is an APHIS/CDC form 2 submitted to the Federal Select Agent Program for prior authorization of all transfers of select agents or toxins?	○	○	○	
Is the Federal Select Agent Program immediately notified following any theft, loss, or release of a select agent or toxin?	○	○	○	
Is an APHIS/CDC form 3 submitted following all instances of theft, loss, or release of a select agent or toxin? (E.g. A release would include any instance of a sample being handled outside of primary containment and subsequently testing positive for the presence of a select agent or toxin).	○	○	○	
18. PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES				
Does the laboratory have a Continuity Of Operations Plan (COOP)?	○	○	○	
Does the laboratory have documented plans in the event of a naturally occurring or terrorism related event in the biosafety or emergency response manual or as part of a lab or institutional COOP?	○	○	○	
Does the laboratory have their local or state PHL contact information in case of a naturally occurring or terrorism related event?	○	○	○	
Does the laboratory have hard copy back-up information such as laboratory protocols and plans?	○	○	○	
Does the laboratory maintain an adequate supply of PPE and supplies?	○	○	○	
Does the laboratory maintain an appropriate number of staff for packing and shipping infectious substances with current certifications?	○	○	○	

Question	Y	N	NA	Comments
Are laboratory staff cross trained in other laboratory activities in the event of a surge testing situation?	○	○	○	
Does the laboratory participate in drills or exercises designed to mimic a public health emergency (i.e. pandemic influenza, Ebola, bioterrorism event)?	○	○	○	
Are these drills or exercises documented and are plans modified to address any areas of concern that are discovered during the event?	○	○	○	

ADDITIONAL NOTES:

References:

1. ANSI/ASSE Z9.14-2014: *Testing and Performance Verification Methodologies for Ventilation Systems for BSL-3/ABSL-3 Facilities*
2. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition, Clinical Laboratory Standards Institute, M29-A4 (May 2014).
3. Guidelines for Safe Work Practices in human and Animal Medical Diagnostic Laboratories – Recommendations of a Centers for Disease Control and Prevention-convened Biosafety Blue Ribbon Panel. MMWR Supplement/Vol. 61 (January 2012).
4. Biosafety in Microbiological and Biomedical Laboratories, US Department of Health and Human Services, Public Health Service (Centers for Disease Control and Prevention and National Institutes of Health), 5th Edition (February 2007)
5. Federal Select Agent Program 7 CFR Part 331(Centers for Disease Control and Prevention with the United States Department of Agriculture)
6. Federal Selection Agent Program 42 CFR Part 173 (Centers for Disease Control and Prevention with the United States Department of Agriculture)