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DOCUMENT NUMBER:
DOCUMENT TITLE:
DOCUMENT NOTES:

LOCATION:	VERSION:
DOC TYPE:	STATUS:

EFFECTIVE DATE:	NEXT REVIEW DATE:
RELEASE DATE:	EXPIRATION DATE:

AUTHOR:	PREVIOUS NUMBER:
OWNER:	CHANGE NUMBER:

Aerosol Transmissible Diseases - Laboratory Biosafety Plan

Southern California Region

Aerosol Transmissible Diseases - Laboratory Biosafety Plan

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Our activities include laboratory operations where employees perform procedures that may aerosolize ATPs-L. ATPs-L are pathogens that meet any *one* of the following criteria:

1. The pathogen appears on the list in Appendix D of title 8 CCR 5199.
2. The Biosafety in Microbiological and Biomedical Laboratories (BMBL) recommends biosafety level 3 or above for the pathogen.
3. The biological safety officer recommends biosafety level 3 or above for the pathogen.
4. The pathogen is a novel or unknown pathogen.

Due to this exposure, we are required to establish and implement a written Biosafety Plan that meets the requirements of title 8 CCR 5199.

Our employees do not have direct contact with ATD cases, suspected cases of ATD, or with potentially infected cadavers. Therefore, we are only required to comply with the provisions of subsection (a), subsection (f), all provisions of title 8 CCR 5199 referred to in subsection (f), subsection (i), and subsection (j) and maintain this written Biosafety Plan for Laboratories.

Our employees have direct contact with ATD cases, suspected cases of ATD, or with potentially infected cadavers and, therefore, we also protect them by following the requirements of the other subsections of title 8 CCR 5199, including a written Exposure Control Plan, engineering controls, respiratory protection, medical services, training, and recordkeeping.

Designation of the Biological Safety Officer

Our organization has designated a Biological Safety Officer to be in charge of implementing and overseeing this Laboratory Biosafety Plan. This person is knowledgeable in the subject matter and has the authority to ensure that the various procedures are implemented.

Our Biological Safety Officer is Manager Operations Area Lab (Alexandro Gomez, CLS)

The biological safety officer will conduct a risk assessment in accordance with the methodology included in Section II of the [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#) for each agent and procedure where employees may handle ATPs-L. The biological safety officer will determine and document the safe practices required for each agent and procedure in the Biosafety Plan.

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Job Classifications with Exposure

We have determined that some or all of our employees in the following job classifications have occupational exposure when performing certain tasks and procedures:

Job classifications where all or some employees have occupational exposure	Tasks and procedures where that job classification has occupational exposure
Clinical Laboratory Scientists, Medical Laboratory Technicians, Phlebotomists and Service Representatives	Centrifugation of specimens associated with ATD
Clinical Laboratory Scientists, Medical Laboratory Technicians, Phlebotomists and Service Representatives	Homogenizing, stirring, vortexing, blending
Clinical Laboratory Scientists, Medical Laboratory Technicians, and Phlebotomists	Opening and inoculating culture plates
Clinical Laboratory Scientists, Medical Laboratory Technicians, Phlebotomists and Service Representatives	Pouring liquids
Clinical Laboratory Scientists, Medical Laboratory Technicians, Phlebotomists and Service Representatives	Pipetting
Clinical Laboratory Scientists, Medical Laboratory Technicians, Phlebotomists and Service Representatives	Dropping culture containers
Clinical Laboratory Scientists, Medical Laboratory Technicians, and Phlebotomists	Streaking or spreading inoculum
Clinical Laboratory Scientists, Medical Laboratory Technicians, and Phlebotomists	Breakage of culture containers
Clinical Laboratory Scientists, Medical Laboratory Technicians, Path Tissue Techs, Certified Path Assistants and Phlebotomists	Collecting/manipulating infected body fluids or tissues

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Clinical Laboratory Scientists, Medical Laboratory Technicians, Path Tissue Techs, Certified Path Assistants and Phlebotomists Environmental Services/Housekeeping	Cleaning – blood and body fluid (including spills)
Clinical Laboratory Scientists, Medical Laboratory Technicians, Path Tissue Techs, Certified Path Assistants, Phlebotomists and Technicians/Technologists (ex. Biomedical Engineering)	Instruments/Equipment decontaminating
Clinical Laboratory Scientists, Medical Laboratory Technicians, Path Tissue Techs, Certified Path Assistants and Phlebotomists Technicians/Technologists (ex. Biomedical Engineering, Facilities Engineers)	Instrument/Equipment with potential aerosolizing contaminants such as repairing, replacing, maintaining that may contain or generate aerosolized pathogens
Phlebotomists and Nurses	Specimen collection
Clinical Laboratory Scientists, Medical Laboratory Technicians, Path Tissue Techs, Certified Path Assistants and Phlebotomists	Resuspending packed cells by shaking or mixing
Clinical Laboratory Scientists, Medical Laboratory Technicians, Path Tissue Techs, Certified Path Assistants and Phlebotomists	Sonic disruption of cells

* There are occasions (e.g., disasters or work stoppages) when health care workers who are not listed may be asked to perform duties involving occupational exposure to ATDs. In such instances, appropriate actions will be taken to ensure fulfillment of applicable aspects of this Biosafety plan.

List of ATPs-L

We have determined that ATPs-L are either present or reasonably expected to be present in our laboratory materials. We have established biosafety measures to protect our employees from exposure to these ATPs-L and have listed them in the following table. We will take these measures any time we work with materials containing these ATPs-L.

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Clinical laboratories conduct the majority of their work at BSL-2, including initial processing of clinical specimens for microbiology workup in a biosafety cabinet (BSC). Hence, standard precautions with BSL-2 practice should be used when handling all clinical samples. Exposure risk to ATPs-L is only associated with pre-analytical processing (specimen handling and processing) such as plating and aliquoting from direct clinical specimen. Follow-up culture workup, if appropriate, is performed at the Regional Reference Laboratories.

ATPs-L Known or Expected to be Present in Laboratory Materials	Biosafety Measures
Adenovirus	BSL-2 with standard precautions
Arboviruses, unless identified individually elsewhere in this list	BSL-2 with standard precautions for handling clinical specimens. Tissue culture of arboviruses is not performed.
Arenaviruses	
Bacillus anthracis	
Blastomyces dermatitidis	
Bordetella pertussis	
Brucella abortus, B. canis, B. “maris”, B. melitensis, B. suis	
Burkholderia mallei, B. pseudomallei	
Cercopithecine herpesvirus	
Chlamydia pneumoniae	
Chlamydia psittaci	
Chlamydia trachomatis	
Clostridium botulinum	
Coccidioides immitis, C. posadasii	
Corynebacterium diphtheriae	
Coxiella burnetti	
Cytomegalovirus, human	
Eastern equine encephalomyelitis virus (EEEV)	
Epstein-Barr virus	
Escherichia coli, shiga toxin-producing only	
Francisella tularensis	
Haemophilus influenzae, type b	
Hantaviruses	
Helicobacter pylori	
Hepatitis B, C, and D viruses	
Herpes simplex virus 1 and 2	

BSL-2 with standard precautions for handling clinical specimens.

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Herpesvirus simiae (B-virus)	
Histoplasma capsulatum	
Human herpesviruses 6A, 6B, 7, and 8	
Influenza virus, non-contemporary human (H2N2) strains, 1918 influenza strain, highly pathogenic avian influenza (HPAI)	
Influenza virus, H5N1 - human, avian	
Legionella pneumophila, other legionella-like agents (aerosol generation, large quantities or high concentrations)	
Lymphocytic choriomeningitis virus (LCMV)	
Monkeypox virus (experimentally or naturally infected animals)	
Mycoplasma pneumoniae	
Neisseria gonorrhoeae	
Neisseria meningitidis	
Parvovirus B19	
Prions (bovine spongiform encephalopathy prions, only when supported by a risk assessment)	
Retroviruses, including Human and Simian Immunodeficiency viruses (HIV and SIV) (activities with high potential for aerosol or droplet production, large quantities or high concentrations)	
Rickettsia prowazekii, Orientia (Rickettsia) tsutsuagmushi, R. typhi (R. mooseri), Spotted Fever Group agents (R. akari, R. australis, R. conorii, R. japonicum, R. rickettsii, and R. siberica)	
Rubella virus	
Salmonella spp. other than S. typhi	
Salmonella typhi	
Shigella spp. (aerosol generation or high splash potential)	
Streptococcus spp., group A	
Tick-borne encephalitis viruses	
Vaccinia virus	
Varicella zoster virus	

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Venezuelan equine encephalitis virus (VEEV)	
West Nile virus (WNV)	
Western equine encephalitis virus (WEEV)	
Yersinia pestis	
Crimean-Congo haemorrhagic fever virus	Specimens from patients suspected of hemorrhagic fever viruses should not be processed by the clinical laboratory. Consult local public health lab.
Ebola virus	
Flexal virus	
Guanarito virus	
Junin virus	
Kyasanur forest disease virus	
Lassa fever virus	
Machupo virus	
Marburg virus	
Omsk hemorrhagic fever virus	
Hemorrhagic fever - specimens from cases thought to be due to dengue or yellow fever viruses or which originate from areas in which communicable hemorrhagic fever are reasonably anticipated to be present	Patient's geographic origin may not always be known. Specimens from patients suspected of hemorrhagic fever viruses should not be processed by the clinical laboratory. Consult local public health lab if hemorrhagic fever needs to be ruled out.
Hendra virus	Specimens from patients suspected of Hendra virus should not be processed by the clinical laboratory. Consult local public health lab.
Measles virus	BSL-2 with standard precautions for handling clinical specimens. Consult public health lab for acute cases .
Mumps virus	
Mycobacterium tuberculosis complex (M. africanum, M. bovis, M. caprae, M. microti, M. pinnipedii, M. tuberculosis (aerosol-generating activities with clinical specimens, cultures, experimental animal studies with infected nonhuman primates))	BSL-2 with standard precautions for handling clinical specimens. Cultures are performed at the Regional Reference Laboratories.
Mycobacteria spp. other than those in the M. tuberculosis complex and M. leprae (aerosol generation)	

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Nipah virus	Specimens from patients suspected of Nipah virus should not be processed by the clinical laboratory. Consult local public health lab.
Rabies virus, and related lyssaviruses (activities with high potential for droplet or aerosol production, large quantities or high concentrations)	Specimens from patients suspected of Rabies virus should not be processed by the clinical laboratory. Consult local public health lab.
Rift valley fever virus (RVFV)	Specimens from patients suspected of Rift valley fever virus should not be processed by the clinical laboratory. Consult local public health lab.
Sabia virus	Specimens from patients suspected of Sabia virus should not be processed by the clinical laboratory. Consult local public health lab.
SARS coronavirus (untreated specimens, cell cultures, experimental animal studies)	BSL-2 with standard precautions for handling clinical specimens. Consider BSL-3 practice. Consult local public health lab.
Variola major virus (Smallpox virus) Variola minor virus (Alastrim)	Specimens from patients suspected of Smallpox virus should not be processed by the clinical laboratory. Consult local public health lab.

Incoming Materials Containing ATPs-L

All incoming materials suspected of ATPs-L are treated as if they contain the virulent or wild-type pathogen until appropriate procedures are followed to verify that the pathogen has been deactivated or attenuated.

This is the procedure staff will use to communicate that a given pathogen has been deactivated or attenuated: Select Agent Notification and Destruction Refer to [SCPMG-PPP-0500](#)

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Engineering Controls

For any health or safety hazard, engineering controls are always an important method of mitigating the hazard. The following engineering controls are used to minimize exposure to infectious or potentially infectious laboratory aerosols:

Engineering Control	Procedures for use of the engineering control
Certified HEPA-filtered containment equipment (ex. Biological Safety Cabinets)	Refer to SCPMG-PPP-0327 , Hood Scheduled Preventative Maintenance
Safety centrifuges with automatic locking mechanisms or solid lids, bioseal rotors, or safety centrifuge cups	Refer to SCPMG-PPP-0264 , New Equipment in New Laboratories Inventory and Inspection
Ventilation system/Negative pressure laboratories	Refer to RIV-PPP-0442 , Failure of Heating Ventilation and RIV-PPP-1189 Biosafety Level
Laboratory must be designed so that it can be easily cleaned and decontaminated. Laboratory floors, seams, walls, and ceiling surfaces are sealed. Spaces around doors and ventilation. Carpets and rugs are not permitted.	Procedures for use of this control is maintenance to ensure surfaces remain sealed.

Safe Handling Procedures and Prohibited Practices

Another level of protection for our employees is mandatory work practices for safely handling materials that contain ATPs-L. Employees must observe the following procedures when handling such materials:

The Lab Care Delivery System follow universal precautions when handling clinical specimens, all of which may contain potentially infectious materials. Site and activity specific biosafety risk assessment are performed to determine if additional biosafety precautions (such as the need for respiratory protection) are warranted in handling and processing specimens that are suspected or confirmed for high risk pathogens (i.e.,

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Francisella, tularensis, Ebola, avian influenza, MERS coronavirus, SARS coronavirus, SARS-CoV-2 coronavirus, or any infectious agent that has a high potential to cause a disease to individuals and the community), in adherence to the following regulations, including Cal/OSHA's Bloodborne Pathogen Standard ([8 CCR 5193](#)), Personal Protective Equipment ([8 CCR 3380](#)), Respiratory Protection ([8 CCR 5144](#)), and Occupational Exposure to Hazardous Chemicals in Laboratories ([8 CCR 5191](#)) standards. Routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste are followed in accordance with regulatory standards.

Biosafety Level – 2 Standard Microbiological Practices
1. The laboratory supervisor enforces the institutional policies that control safety in and access to the laboratory.
2. The laboratory supervisor ensures that laboratory personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization) and that appropriate records are maintained. Personnel receive annual updates and additional training when equipment, procedures, or policies change. All persons entering the facility are advised of the potential hazards, are instructed on the appropriate safeguards, and read and follow instructions on practices and procedures. An institutional policy regarding visitor training, occupational health requirements, and safety communication is considered.
3. Personal health status may affect an individual's susceptibility to infection and ability to receive available immunizations or prophylactic interventions. Therefore, all personnel, and particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive agents), are provided information regarding immune competence and susceptibility to infectious agents. Individuals having such conditions are encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.
4. A safety manual specific to the facility is prepared or adopted in consultation with the appropriate safety/facility professionals. The safety manual is available, accessible, and periodically reviewed and updated as necessary. a. The safety manual contains sufficient information to describe the biosafety and containment procedures for the organisms and biological materials in use, appropriate agent-specific decontamination methods, and the work performed.

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<p>b. The safety manual contains or references protocols for emergency situations, including exposures, medical emergencies, facility malfunctions, and other potential emergencies. Training in emergency response procedures is provided to emergency response personnel and other responsible staff according to institutional policies.</p>
<p>5. A sign incorporating the universal biohazard symbol is posted at the entrance to the laboratory when infectious materials are present. Posted information includes: the laboratory's Biosafety Level, the supervisor's or other responsible personnel's name and telephone number, PPE requirements, general occupational health requirements (e.g., immunizations, respiratory protection), and required procedures for entering and exiting the laboratory. Agent information is posted in accordance with the institutional policy.</p>
<p>6. Long hair is restrained so that it cannot contact hands, specimens, containers, or equipment.</p>
<p>7. Gloves are worn to protect hands from exposure to hazardous materials.</p> <ul style="list-style-type: none">a. Glove selection is based on an appropriate risk assessment.b. Gloves are not worn outside the laboratory.c. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.d. Do not wash or reuse disposable gloves, and dispose of used gloves with other contaminated laboratory waste.
<p>8. Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated.</p>
<p>9. Persons wash their hands after working with potentially hazardous materials and before leaving the laboratory.</p>
<p>10. Eating, drinking, smoking, vaping, gum chewing, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in laboratory areas. Food is stored outside the laboratory area.</p>
<p>11. Mouth pipetting is prohibited. Mechanical pipetting devices are used</p>
<p>12. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware are developed, implemented, and followed; policies are consistent with applicable state, federal, and local requirements. Whenever practical, laboratory supervisors adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions are always taken with sharp items. These include:</p> <ul style="list-style-type: none">a. Use of needles and syringes or other sharp instruments is limited in the laboratory. Active or passive needle-based safety devices are to be used whenever possible.

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<ul style="list-style-type: none">i. Uncapping of needles is performed in such a manner to reduce the potential for recoil causing an accidental needlestick.ii. Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.iii. If absolutely necessary to remove a needle from a syringe (e.g., to prevent lysing blood cells) or recap a needle, a hands-free device or comparable safety procedure must be used (e.g., a needle remover on a sharps container, the use of forceps to hold the cap when recapping a needle).iv. Used, disposable needles and syringes are carefully placed in puncture-resistant containers used for sharps disposal immediately after use. The sharps disposal container is located as close to the point of use as possible. <p>b. Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps.</p>
<p>13. Perform all procedures to minimize the creation of splashes and/or aerosols.</p>
<p>14. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. Spills involving infectious materials are contained, decontaminated, and cleaned up by staff who are properly trained and equipped to work with infectious material. A spill procedure is developed and posted within the laboratory.</p>
<p>15. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method, consistent with applicable institutional, local, and state requirements. Depending on where the decontamination will be performed, the following methods are used prior to transport:</p> <ul style="list-style-type: none">a. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and secured for transport. For infectious materials, the outer surface of the container is disinfected prior to moving materials and the transport container has a universal biohazard label.b. Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations.
<p style="text-align: center;">Prohibited Practices</p>

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1. There will be no eating drinking, smoking, vaping, gum chewing, handling contact lenses, and applying cosmetics or lip balm in laboratory room(s) at any time.
2. Mouth pipetting is prohibited.
3. Do not place your head into the BSC.
4. Cultures and other samples will not be sniffed.
5. Do not overcrowd the BSC or disrupt airflow.

Special Practices
1. Access to the laboratory is controlled when work is being conducted.
2. The laboratory supervisor is responsible for ensuring that laboratory personnel demonstrate proficiency in standard microbiological practices and techniques for working with agents requiring BSL-2 containment.
3. Laboratory personnel are provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.
4. Properly maintained BSCs or other physical containment devices are used, when possible, whenever: <ul style="list-style-type: none">a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating, and harvesting tissues.b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotors or centrifuge safety cups with loading and unloading of the rotors and centrifuge safety cups in the BSC or another containment device.c. If it is not possible to perform a procedure within a BSC or other physical containment device, a combination of appropriate personal protective equipment and administrative controls are used, based on a risk assessment.
5. Laboratory equipment is decontaminated routinely; after spills, splashes, or other potential contamination; and before repair, maintenance, or removal from the laboratory.
6. A method for decontaminating all laboratory waste is available (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).
7. Incidents that may result in exposure to infectious materials are immediately evaluated per institutional policies. All such incidents are

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reported to the laboratory supervisor and any other personnel designated by the institution. Appropriate records are maintained.

Decontamination and Disinfection Procedures

Employees are also at risk of becoming infected with an ATD when coming into contact with surfaces contaminated with ATPs-L. To reduce this risk, we will decontaminate and disinfect laboratory surfaces and equipment using the following procedures: The Laboratory follows ATD ECP decontamination and disinfection procedures. Refer to RIV-PPP-0437 Cleaning Work Areas.

We use the following EPA-registered cleaner(s) or disinfectant(s): household bleach, quaternary ammonium compounds, phenolic compounds, and iodophors.

Decontamination and disinfection will occur according to the following schedule (*e.g., nightly; after every procedure*): before and after use of biological safety cabinet, and before and after every procedure.

The following employees will perform the decontamination and disinfection: Lab Assistant I/II, Clinical Lab Scientist, Lab Technicians, and other personnel that will work in biosafety cabinet or bench.

Personal Protective Equipment

In our laboratory, we require specific personal protective equipment (PPE) to be used when conducting certain procedures with ATPs-L to minimize exposure to infectious or potentially infectious aerosols. To assist us in determining the appropriate PPE, we referred to the BMBL, which identifies the minimum required PPE that must be used in biosafety level 3 laboratories.

Lab coats and gloves will be removed prior to leaving the lab. Body protection is required because many pathogens transmit from being carried on clothing. Eye and face protection are required because many pathogens transmit through contact with eyes and mucous membranes.

We describe our PPE requirements in the following PPE Selection guidance.

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CLINICAL LABORATORY PPE GUIDELINES							
	Required		Primary Physical Barrier	Alternate to Physical Barrier	Last Resort to Primary & Alternate		
	Gloves	Gown/ Disposable Apron with arms	Splash Guard	Face Shield ¹	Eye Protection	Surgical Mask (fluid protective barrier)	Respirator (N95, PAPR, CAPR)
Task/Procedure Outside of a Biological Safety Cabinet (BSC) Involving Potential Occupational Exposure <i>(Tasks performed in a BSC require only gloves and gown)</i>							
Centrifugation of uncapped urine	Y	Y	S	S	S	S	N
Centrifugation of uncapped blood	Y	Y	Y	Y	Y	Y	N
Manual smear prep (blood, CSF, others)	Y	Y	Y	Y	S	S	N
Blood and body fluid aliquoting	Y	Y	Y	Y	Y	Y	N
Manual decanting	Y	Y	Y	Y	Y	Y	N
Manual sample vortexing/mixing/shaking/pipetting	Y	Y	Y	Y	Y	Y	N
Manual sample dilutions	Y	Y	Y	Y	Y	Y	N
Manual sample uncapping	Y	Y	Y	Y	Y	Y	N
Automated capping/decapping	Y	Y	S	S	S	S	N
Loading and unloading of open samples to and from racks and instruments	Y	Y	S	S	S	S	N
Disposal of cuvettes/sample tubes with liquid	Y	Y	S	S	S	S	N
Manual disposal of tips	Y	Y	N	N	N	N	N
Discarding of biological specimens or Other Potential Infectious Material (OPIM) in biohazardous waste containers	Y	Y	S	S	S	S	N
As part of Standard Precautions, workspace that may have been soiled or contaminated should be disinfected after a task or procedure to minimize biohazards exposure.							
Y = Yes, required							
N = No, not required							
S = Suggested after risk assessment determines risk is present							
Footnote:							
¹ Face shield with sufficient width to reach at least the point of the ear and length that extends to the bottom of the chin.							

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Other procedures for using the PPE:

General Guidelines for the Use of Gloves in the Laboratory:
Keep hands away from face and PPE being worn.
Change gloves periodically, when gloves become soiled or torn.
Limit surfaces touched in the patient environment.
Gloves will not prevent needle sticks or other puncture injuries.
Check gloves for visible tears before use.
Do not reuse disposable nitrile gloves.
Double glove when cleaning spills.
Regularly perform hand hygiene.
Always clean hands after removing gloves.
Discard contaminated gloves in a biohazard bag immediately after use.

General Procedure for Removing PPE in the Laboratory:
Gloves: <ul style="list-style-type: none">• Outside of gloves are contaminated. Grasp the outside of the glove with the opposite gloved hand; peel off.• Hold the removed glove in the gloved hand. Slide the fingers of the ungloved hand under the remained glove at the wrist. Peel the second glove off over the first glove. Discard into an appropriate lined waste bin.
Gown/Fluid repellent coverall: <ul style="list-style-type: none">• Gown/Fluid repellent coverall front and sleeves are contaminated. Unfasten neck, then waist ties.• Remove using a peeling motion; pull gown/fluid repellent coverall from each shoulder towards the same hand.• Gown/Fluid repellent coverall will turn inside out. Hold removed gown/fluid repellent coverall away from body, roll into a bundle and discard into an appropriate lined waste bin or linen receptacle.
Eye Protection (Goggles/Face Shield): <ul style="list-style-type: none">• Outside of goggles or face shield are contaminated. Handle only by the headband or the sides. Discard into a lined waste bin or place into a receptacle for reprocessing/decontamination.
Respirator: <ul style="list-style-type: none">• Front of respirator is contaminated – DO NOT TOUCH. Unfasten the ties – first the bottom, then the top. Pull away from the face without touching front of respirator.• Discard disposable items into an appropriate lined waste bin.

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<ul style="list-style-type: none"> For reusable respirator – place in designated receptacle for processing/decontamination.
Perform hand hygiene immediately on removal.
All PPE should be removed before leaving the area and disposed into designated waste bin.

Respiratory Protection Requirement

We have conducted a risk assessment and determined that during some operations or under certain conditions, our employees must wear respiratory protection, as described in the following table:

Condition or Operation Requiring Respiratory Protection	Type of Respiratory Protection Required (e.g., N95, PAPR, supplied-air)
Working with clinical specimens with suspected or confirmed airborne transmitted infections or pathogens outside of BSC	NIOSH approved particulate respirators (ex. N95 respirator, PAPR)
Entering an airborne infection patient isolation room	N95 or PAPR
Repairing, replacing, or maintaining air systems or equipment that may contain or generate aerosolized pathogens	Since KP considers this a High Hazard Procedure, we require PAPR/CAPR
Cleaning of large spills containing potential ATPs-L outside of the BSC	N95 or PAPR

Employees who are required to wear respirators will be covered under our written Respiratory Protection Program, in accordance with title 8 sections 5199 and 5144. We provide our employees with medical evaluations to determine whether they are medically fit to wear a respirator, fit tests to ensure that the chosen respirators provide a good seal, and training to ensure that employees understand how to properly use and care for their respirators. See our Respiratory Protection Program for details.

Emergency Procedures for Uncontrolled or Untreated Releases

We provide training to and communicate with our employees to minimize the occurrence of accidents. However, sometimes uncontrolled or untreated releases, such as spills of cultures, may still occur inside or outside our laboratory facility.

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We have established these emergency procedures for uncontrolled releases inside the laboratory facility:

Emergency Procedures for Uncontrolled Releases Inside the Laboratory Facility
The first essential practice is to avoid inhaling any airborne material by holding the breath and leaving the laboratory.
Make all personnel in the laboratory aware of the release and instruct them to stay away from the area, or, if there is a health threat, to vacate the area. <ul style="list-style-type: none">a. If laboratory personnel believe there is an immediate or significant long-term health hazard threat, they should initiate evacuation by pulling the fire alarm.b. If the release is contained in a small area within a laboratory and there is no immediate or significant long-term health hazard threat, the lab manager will determine if the release is an incidental release or an emergency response. If the release is an incidental release, lab will follow clean up procedure. If the release is an emergency, lab will initiate and follow notification protocol.
Block off the spill area if possible.
If clothing is known or suspected to be contaminated, exit the lab and remove the clothing with care, folding the contaminated area inward.
Discard the clothing into a bag. Wash all potentially contaminated areas as well as the arms, face, and hands. Shower if facilities are available.
Notify the supervisor, lab manager or designee.
Reentry into the laboratory should be delayed and allow 60 minutes for aerosols to settle. Occupants may not reenter the building until emergency responder authorized reentry.
If the emergency involves personal injury, call 911.
Be sure to state the type of contaminant (biological or chemical); state the name of the agent on the victim.
The caller should remain available to brief emergency responders on the type of contamination and proper procedures for handling the material.

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If laboratory personnel experience potential exposure symptoms, follow workplace safety injury/illness reporting protocol.

We follow these emergency procedures for untreated releases outside the laboratory facility:

Emergency Procedures for Untreated Releases Outside the Laboratory Facility

If the release is not confined to the laboratory in which it occurs (e.g. aerosol release to the hallway), or there is any doubt regarding a potential health threat, notify appropriate authorities and describe the incident.

Take interim measures if safely possible, before the hazardous materials response team arrives, such as blocking the affected area.

Seek outside assistance from trained emergency responders.

The emergency PPE will be stored in this location: Laboratory & Pathology Department Supply Racking System & Riverside Medical Center – 4th floor

The following supplies and equipment will also be used in emergency response involving ATPs-L: extra gloves, closed front gowns and shoe covers, respirators (employee must have received prior fit testing and training), Tyvek coveralls, First Aid Kit, emergency eye wash, biological spill kits

We will also report such incidents to the local health officer using the following links:
[Public Health Reporting v.3 \(policytech.com\)](https://www.policytech.com/public-health-reporting-v3)
<https://www.ruhealth.org/public-health/disease-control/communicable-disease-reporting>

Contact information for the local health officer: Riverside Public Health Officer
[Public Health Reporting v.3 \(policytech.com\)](https://www.policytech.com/public-health-reporting-v3)
<https://www.ruhealth.org/public-health/disease-control/communicable-disease-reporting>

Person designated to contact the local health officer: Director of Infection Prevention & Control Department.

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During such emergencies, it may be necessary to coordinate response with outside agencies. We have established the following procedures to coordinate with other agencies: Contact Duty Officer at Riverside County Public Health – Emergency Management Department. Contact info: 951-830-8041.

Medical Services

Due to our employees' exposure to ATPs-L, we provide medical services to prevent them from becoming infected and also to provide medical care after exposure incidents. These are provided at no cost to our employees.

Vaccinations

Vaccinations are a safe and effective way to prevent the spread of vaccine-preventable diseases. Therefore, we offer our employees all appropriate vaccinations in accordance with the BMBL for the specific laboratory operations performed at our facility.

We make the following vaccinations available to our employees, based on the aerosol transmissible pathogens-laboratory they work with that are capable of becoming aerosolized through our laboratory procedures: For ATD prevention, provide to all susceptible health care workers with occupational exposure all vaccine doses listed as recommended in Cal/OSHA ATD Standard's 8 CCR 5199 Appendix D. See pertinent Employee Health Guidelines. This includes but not limited to MMRV for all health care workers based on the laboratory baseline and Meningococcal vaccinations for Bacteriology health care workers with potential for exposure. Employees in laboratory operations outside of health care settings, and within the scope of subsection (f) of the ATD Standard, shall be provided with vaccines in accordance with the BMBL for the specific laboratory operations. The requirements in subsection (h)(5) of the ATD Standard became effective on September 1, 2010.

We send our employees to the following medical provider for vaccinations: Employee Health Services

The laboratory follows the procedures described in the Vaccinations section of the site ATD ECP. [Aerosol Transmissible Exposure Control Plan v.8 \(policytech.com\)](https://policytech.com)

We will offer the vaccinations to occupationally exposed employees after providing the required training (*see the "Training" section of this program below*) within 10 working days of initial assignment to duties where they have occupational exposure.

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We will offer the vaccination unless any of the following three conditions exists:

1. The employee has previously received the recommended vaccination and is not due to receive it again.
2. A PLHCP has determined that the employee is immune in accordance with applicable public health guidelines.
3. The vaccine is contraindicated for medical reasons.

We will make additional vaccine doses available to employees within 120 days of the issuance of any new applicable public health guidelines recommending the additional dose.

We do not require our employees to participate in a prescreening serology program prior to receiving a vaccine, unless applicable public health guidelines recommend this prescreening prior to administration of the vaccine.

We train our employees on the benefits of receiving vaccinations and strongly encourage them to get vaccinated. However, employees have the option to decline receiving some of the recommended vaccinations. If an employee declines a vaccination, they must sign the appropriate declination form. This form will be kept in their employee file.

If an employee declines any vaccination, we will have them sign a declination containing the following wording, completed with the name of appropriate disease or pathogen:

Vaccination Declination Statement

I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring infection with (*name of disease or pathogen*). I have been given the opportunity to be vaccinated against this disease or pathogen at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring (*name of disease*), a serious disease. If in the future I continue to have occupational exposure to aerosol transmissible diseases and want to be vaccinated, I can receive the vaccination at no charge to me.

(End of declination statement.)

If the employee initially declines a vaccination but at a later date, while still covered under the standard, decides to accept the vaccination, we will make the vaccination available within 10 working days of receiving a written request from the employee.

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(*check if applicable*) Our employees work with strains of seasonal influenza. If the available influenza vaccination covers the particular strain of influenza, then we will provide the vaccine to those employees who have occupational exposure. The vaccination is provided at no cost to them during the period designated by the CDC (*flu season*), which generally begins in October and can last through as late as May.

We send our employees to: Employee Health Services and anywhere flu vaccine is offered to receive the seasonal influenza vaccine.

We also train our employees on the benefits of receiving the influenza vaccine and strongly encourage them to receive it. However, employees have the option to decline the vaccination. If an employee declines the seasonal influenza vaccination, we will have the employee sign the following declination and keep it in their employee file. This will be done each flu season as long as the employee has occupational exposure.

Seasonal Influenza Vaccination Declination Statement

I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring seasonal influenza. I have been given the opportunity to be vaccinated against this infection at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at increased risk of acquiring influenza. If, during the season for which the CDC recommends administration of the influenza vaccine, I continue to have occupational exposure to aerosol transmissible diseases and want to be vaccinated, I can receive the vaccination at no charge to me.

(End of declination statement.)

If the employee later decides to accept the influenza vaccination and the vaccine is still available, then we will provide it to the employee within 10 days of receiving a written request from the employee.

If any applicable vaccine is not available due to shortages or other reasons, we will document our efforts made to obtain the vaccine in a timely manner and inform the employees of the status of vaccine availability, including when the vaccine is likely to become available.

Our procedure for communicating vaccine availability status to our employees in these circumstances is:

Buy to Pay/Demand Planning communicates vaccine availability information (shortages, info. on supply availability) to both National and Regional Pharmacy leaders. These

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leaders in turn provide the information to regional executive leadership who then work with regional Communications to develop appropriate messaging to employees regarding vaccine availability or options when the need for the vaccine is widespread (e.g., seasonal influenza, COVID-19). When vaccine unavailability impacts only a limited number of employees, communication regarding vaccine availability will be provided to these employees by local Employee Health Services.

Our procedure for documenting the unavailability of a recommended vaccine is: KP Demand Planning will check on the availability of the vaccine at least every 60 calendar days and will document unavailability via the creation and issuance of Drug Shortage Alerts. This documentation will include the department determining that the vaccine was not available, the name of the vendor providing the vaccine availability information, and the date of the alert. KP Demand Planning will maintain records of vaccine unavailability for three years.

Latent TB Infection Assessment

See site ATD ECP, LTBI Assessment section, for lab procedures and [SCAL Annual TB Screening policy, #EHS 1001](#).

In the event of a TB conversion, we will also record the case on the Cal/OSHA Form 300 Log of Work-Related Injuries and Illnesses by placing a check in the “respiratory condition” column and entering “privacy case” in the space normally used for the employee’s name. We will also investigate the circumstances of the conversion and correct any deficiencies in the procedures, engineering controls, or PPE that were involved.

List the job titles and roles of staff involved in investigating the circumstances of the conversion and correcting deficiencies (e.g., *biological safety officer, infection prevention officer, employee health coordinator, safety manager*): Employee Health Services, Infection Prevention and Control, Workplace Safety, EH&S.

We will also document the investigation using the following procedure: Laboratory follows the same procedure for investigating and documenting the investigation of LTBI conversions as described in the Exposure Incidents section of the site ATD ECP [Aerosol Transmissible Exposure Control Plan v.8 \(policytech.com\)](#)

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Exposure Incidents

An “exposure incident (*laboratory*)” is defined as a significant exposure to an aerosol containing an ATP-L, without the benefit of applicable exposure control measures. A “significant exposure” is an exposure to a source of ATPs-L in which the circumstances of the exposure make the transmission of a disease sufficiently likely that the employee requires further evaluation by a physician or other licensed health care provider (PLHCP).

In the event of an exposure incident (*laboratory*), we will offer medical services to our employees who were exposed to the ATPs-L and conduct an incident investigation using procedures described in this section of this Biosafety Plan.

In order to notify our employees who were exposed to the ATP-L, we will first conduct an analysis of the exposure scenario to determine which of our employees had significant exposure. This analysis will be completed within a timeframe reasonable for the specific disease.

The person responsible for conducting this analysis is: Laboratory Area Operations Manager, Biosafety Officer and Infection Prevention and Control. The laboratory follows exposure incident procedures described in the site ATD ECP [Aerosol Transmissible Exposure Control Plan v.8 \(policytech.com\)](#)

Our procedures for conducting this analysis are as follows (*e.g., review ATP-L virulence, interview employee or review biosafety procedures*): The laboratory follows the procedures described in the site ATD ECP for exposure incident analysis, documentation of the analysis, notification of significantly exposed employees, provision of post-exposure medical evaluation to significantly exposed employees, documenting determinations that an employee does not require post-exposure follow up, and related requirements.

Other resources for exposure follow up include: Infectious Hazard Policies - [Mycobacterium Tuberculosis Exposure Follow-up Policy, #EHS2008](#); [Exposure to Rubella, Rubeola, Mumps, and Varicella Policy, #EHS2002](#); [ParvoVirus B19 Exposure Follow-Up Policy, #EHS2009](#); [Pertussis Exposure Policy, #EHS2010](#); [Off-Work Orders for Communicable Illnesses Policy, #EHS2014](#)

Investigation of exposure incidents (*laboratory*) is necessary to determine what happened, so that we may correct any deficiencies in the procedures, engineering

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controls, or PPE that were involved to prevent reoccurrence. After ensuring that the exposed employees receive required medical evaluations and follow-up, we will also investigate the exposure incidents to determine the cause and to revise existing procedures in order to prevent recurrence of the incidents.

Our procedures for investigating exposure incidents (*laboratory*) are as follows (*e.g., interview employees, inspect equipment involved, determine if biosafety procedures were followed*): The Laboratory follows the procedures in the ATD ECP Evaluation of Exposure Incidents section and the [Comprehensive Incident Reporting and Analysis System \(CIRAS\)](#) process.

Our procedures to evaluate exposure incidents to determine causation and identify ways to prevent future exposures are as follows: [Aerosol Transmissible Exposure Control Plan v.8 \(policytech.com\)](#) We interview exposed employees to understand the circumstances of the exposure and identify possible actions to prevent future incidents. We review pertinent procedures and make changes as needed to improve the effectiveness of these procedures. We conduct investigations with participation from exposed employees when possible, as well as others performing similar work. We inspect equipment that may have been involved in the exposure incident and interview personnel and subject matter experts (*e.g., Engineering, vendors*) who can speak to maintenance and repair procedures in place or needed, and whether equipment was functioning properly.

List the job titles and roles of staff involved in the investigations and correction of deficiencies (*e.g., biological safety officer, infection prevention officer, employee health coordinator, safety manager*): Laboratory Area Operations Manager, Biological Safety Officer and others identified as required. Other parties may include but are not limited to Infection Prevention and Control, Employee Health Nurse, Environmental Health and Safety Manager, Workplace Safety Specialist, Labor Partners.

Communication of Hazards and Employee Training

We provide training to our employees who have occupational exposure to ATP-L, as listed at the beginning of this biosafety plan. This training will be provided to each employee in those job categories when they are initially assigned to tasks where they may have occupational exposure and at least annually thereafter, within 12 months of the previous training.

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This is how we ensure employees receive their initial training: See site ATD ECP, Training section. All employees receive initial training with regard to ATPs-L BSP (e.g. KPLearn, site-specific new employee orientation training).

This is how we ensure employees receive their annual training: See site ATD ECP, Training section. All employees receive annual refresher training with regard to ATPs-L BSP (e.g. KPLearn, site-specific new employee orientation training).

If an employee misses their scheduled training, we will ensure that they receive a make-up training using the following procedure: The Laboratory follows local protocol for providing make-up training to employees who miss either their scheduled initial or annual training through <https://www.medtraining.org/>

(Check one of the following three boxes, as applicable.):

The trainings are provided in-person and questions are answered during the training by the instructor, who is knowledgeable in the subject matter as it relates to our workplace, and who is also knowledgeable in our Biosafety Plan.

The trainings are provided online but we have ensured that all required topics are covered and that interactive questions are answered within 24 hours by a person knowledgeable in the subject matter as it relates to our workplace, and who is also knowledgeable in our Biosafety Plan: The persons or departments assigned to answer questions related to the training are: Laboratory & Pathology Department, Infection Prevention and Control, Environmental Health and Safety, and Employee Health Services.

The trainings are provided by another method, including an opportunity for interactive questions that will be answered either immediately or within 24 hours.

Trainings will include the following topics:

1. An accessible copy of the regulatory text of this standard and an explanation of its contents.
2. A general explanation of ATDs including the signs and symptoms of ATDs that require further medical evaluation.
3. An explanation of the modes of transmission of ATPs-L and applicable source control procedures.

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4. An explanation of the employer's Biosafety Plan, and the means by which the employee can obtain a copy of the written plan and how they can provide input as to its effectiveness.
5. An explanation of the appropriate methods for recognizing tasks and other activities that may expose the employee to ATPs or ATPs-L.
6. An explanation of the use and limitations of methods that will prevent or reduce exposure to ATPs or ATPs-L including appropriate engineering and work practice controls, decontamination and disinfection procedures, and personal and respiratory protective equipment.
7. An explanation of the basis for selection of personal protective equipment, its uses and limitations, and the types, proper use, location, removal, handling, cleaning, decontamination and disposal of the items of personal protective equipment employees will use.
8. A description of the employer's TB surveillance procedures, including the information that persons who are immune-compromised may have a false negative test for LTBI.
9. Training meeting the requirements of section 5144(k) of these orders for employees whose assignment includes the use of a respirator.
10. Information on the vaccines made available by the employer, including information on their efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge.
11. An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident, the medical follow-up that will be made available, and post-exposure evaluation.
12. Information on the employer's surge plan as it pertains to the duties that employees will perform. As applicable, this training will cover the plan for surge procedures for handling of specimens, including specimens from persons who may have been contaminated as the result of a release of a biological agent, how to access supplies needed for the response including personal protective equipment and respirators, decontamination facilities and procedures, and how to coordinate with emergency response personnel from other agencies.

Obtaining Active Involvement of Employees in Reviewing and Updating the Biosafety Plan

As part of our annual review process to update our Biosafety Plan, we obtain the active involvement of employees, not just managers and supervisors. Active involvement means more than merely having a form available that employees can fill out at their leisure.

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These are our procedures to obtain the active involvement of employees, with respect to the procedures performed in their respective work areas or departments. The Laboratory follows various methods including actively asking employees for input in meetings, soliciting during annual trainings, putting employees on the committee to annually review and update the plan.

Review of Plans for Facility Design and Construction

The biological safety officer(s) will review the plans for any new facility design and construction prior to the start of the work if it may affect the control measures for ATPs-L. This will allow us to notice any design element that may interfere with our present control measures before it is installed, so we can have it changed before it is too late.

This review will also be done if we move into a new laboratory facility.

These are our procedures to ensure that the biological safety officer reviews facility plans: We follow the PCRA and ICRA construction plans for all renovations and construction projects. [Infection Control Risk Assessment \(ICRA\) Construction v.3 \(policytech.com\)](https://policytech.com)

Inspection of Laboratory Facilities

Regular inspections of our laboratory facilities must be performed so that hazards may be found and corrected in a timely manner. Our inspections include an audit of our biosafety procedures as well as a physical inspection of the facilities and equipment.

We perform these inspections with the following frequency (*at least once per year*): inspections are performed twice a year or as needed by department.

These inspections will be conducted by: Laboratory & Pathology, Environmental Health and Safety, Infection Prevention and Control, Facilities Engineering.

This person will document the hazards found during the inspections and the corrective action taken for each hazard using the following procedures: communication to corresponding departments through KP Rounding portal.

Hazards will be corrected by following the procedures in our Injury and Illness Prevention Program for hazard correction, including correcting imminent hazards immediately, if possible.

Signature Manifest

Document Number: RIV-PPP-1196

Revision: 01

Title: Aerosol Transmissible Diseases- Laboratory Biosafety Plan

Effective Date: 31 Dec 2024

All dates and times are in Pacific Standard Time.

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Laboratory Manager Approval

Name/Signature	Title	Date	Meaning/Reason
Mary Grace Garcia (O115955)	ASST DIR OPER AREA LAB	31 Dec 2024, 10:35:11 AM	Approved
Alexandro Gomez (L231977)	Area Lab Manager	31 Dec 2024, 11:20:07 AM	Approved

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
Annaleah Raymond (Q741709)	Laboratory Operations Director	31 Dec 2024, 11:30:48 AM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Taira (P161328)	CLIA Director	31 Dec 2024, 12:12:09 PM	Approved