

# LABORATORIES ADMINISTRATION

## Procedure-specific Biological Risk Assessment: ELISA | EIA (Virology & Immunology)

The Maryland Department of Health – Laboratories Administration’s Laboratory Risk Assessment is intended to guide laboratory staff through the risk assessment process for the work they regularly perform. Throughout this process, a mindset of “what COULD go wrong” should be maintained. The goal of the risk assessment process is to identify and minimize all potential risks that may adversely affect 1) the health and safety of laboratory staff, 2) the health and safety of non-laboratory staff, 3) the health and safety of the general public, and 4) the quality of work being performed. For additional information on biosafety and the risk assessment process, please refer to the Biosafety Risk Assessment SOPM.

This risk assessment is developed for the enzyme-linked immunosorbent assay (ELISA) and the enzyme immunoassay (EIA). ELISA/EIA are plate-based assay technique designed to detect and quantify specific antibodies produced against infectious pathogens. In the assay, antigen of interest (e.g. Zika, Hepatitis, etc.) is immobilized by direct adsorption to the assay plate or by first attaching a capture antibody to the plate surface. Detection of the antigen can then be performed using an enzyme-conjugated primary antibody (direct detection) or a matched set of unlabeled primary and conjugated secondary antibodies (indirect detection). Maryland Department of Health Laboratories Administration routinely use ELISA/EIA to confirm presence of specific pathogens in patient’s specimen. The washer and plate reader used in this assay are provided by Bio-Tek and the pipettes are purchased from Gibson/Rainin/MLA.

This risk assessment addresses enhanced precautions, including personal protective equipment (PPE), for handling specimens from patients who may be at risk of having infection from various pathogens. Additional potential hazards and mitigations should be added by your laboratory depending on the pathogen and according to the testing performed.

Laboratory Unit	Accessioning, Virology and Immunology
Date of Assessment	September 11, 2017
Name of Organism(s)/Agent(s)	List of organisms are in Appendix A

Laboratory Risk Management Worksheet: ELISA-EIA					
Laboratory Section and/or Procedure: Procedure-specific Risk Assessment for ELISA-EIA				Date Prepared: September 11, 2017	
Prepared by: Dr. Ami Patel			Title/Position: PHLS GIII   Biosafety Officer		
Phase of Testing   Procedure   Division	Risk Component   Potential Hazards   Errors	Initial Risk Level	Control Measures	Implementation / Additional information	Responsible staff and When Will it be Done
Pre-analytical  Receiving clinical specimens and or isolates  Accessioning	Aerosols, surface contamination (bench top), broken package, broken specimen tubes, leakage of specimen tubes - may cause exposure to blood, bloodborne pathogens (BBP's), toxins and or infectious pathogens. Sharps hazard - broken/cracked tubes. Chemical hazard - 70% ethanol and or 10% bleach - cause skin irritation, ingested or inhaled causes burns	High	<ul style="list-style-type: none"> <li>• PPE: lab coat, single gloves, and safety glasses</li> <li>• Accessioning must be performed in BSC for respiratory specimens tested for flu and Bordetella pertussis (Phase I) and all other non-serology, clinical specimens (Phase II).</li> <li>• Double bag leaking and/or broken specimen container in plastic bags with absorbent material inserted between the bags</li> </ul>	Risk level after control measures: Medium. All staff are trained and competent in the procedures described in the Sample Accessioning SOP and follow established laboratory practices. <ul style="list-style-type: none"> <li>• Disinfect work surface and change gloves after handling leaking/broken specimen</li> <li>• After appropriate holding time, discard double bagged broken/leading specimens in a sharps container</li> <li>• After completion of work, disinfect work-stations (BSC and bench-top) with 10% bleach solution followed by 70% ethanol</li> </ul>	Laboratory Supervisor, Laboratory Manager and Division Chief

Pre-analytical  Transfer of specimen and or samples  Accessioning	Aerosols, spills, splashes, breakage or dropped specimen container - may cause exposure to toxins and or infectious pathogens. Sharps hazard - broken/cracked tubes. Chemical hazard - 70% ethanol and or 10% bleach - cause skin irritation, ingested or inhaled cause burns	High	<ul style="list-style-type: none"> <li>● PPE: lab coat, gloves, and safety glasses</li> <li>● Place specimens in leak proof, durable and clearly labelled containers</li> <li>● A cart must be used to transport all containers to the testing areas</li> <li>● For dropped specimen tubes, treat the scenario as a spill - refer to spill response section for details</li> </ul>	<p>Risk level after control measures: <b>Low.</b></p> <ul style="list-style-type: none"> <li>● Weekly decontaminate container(s), racks, and cart by spraying with 70% ethanol</li> <li>● Autoclave as appropriate</li> </ul>	Laboratory Supervisor, Laboratory Manager and Division Chief
Pre-analytical  Triage, transfer of specimen between testing areas, storage  Virology and Immunology	Aerosols, surface contamination, breakage, accidental spill or dropped specimen - may cause exposure to blood, bloodborne pathogens (BBP's), toxins and or infectious pathogens. Sharps hazard - broken/cracked tubes. Chemical hazard - 70% ethanol and or 10% bleach - cause skin irritation, ingested or inhaled causes burn	High	<ul style="list-style-type: none"> <li>● PPE: lab coat, gloves, and safety glasses</li> <li>● Use separate container to sort/transfer the rack containing specimens – container should be shatter and leak proof, durable and clearly labelled</li> <li>● Place all containers on a cart – transport of specimen between testing areas should involve use of a cart and specimen should be taken to their assigned area of the laboratory.</li> <li>● For dropped specimen tubes, treat the scenario as a spill - refer to spill response section for details</li> </ul>	<p>Risk level after control measures: <b>Low.</b></p> <p>All staff are trained and competent in the procedures described in the ELISA-EIA SOP and follow established laboratory practices.</p> <ul style="list-style-type: none"> <li>● All specimen tested for arbovirus panel should be handled in BSC and heat inactivated prior to testing (Note: Not all specimens are heat inactivated).</li> <li>● Pipette tips with barrier filters should be used while handling inactivated samples.</li> <li>● Leaked specimen tubes should be handled in a BSC - use appropriate disinfectant to wipe exterior of specimen tube, wrap the tube with absorbent material and put in a biohazard bag.</li> <li>● Disinfect the area/container where leaked tube was placed.</li> <li>● After completion of work process, container(s), racks, and cart should be</li> </ul>	Laboratory Supervisor, Laboratory Manager and Division Chief

				decontaminated with appropriate disinfectant.	
Analytical  Preparation of specimen for testing  Virology and Immunology	Aerosols, accidental spill, dropped specimen - specimen centrifugation, transfer of specimen to microfuge tubes for inactivation (if applicable), specimen inactivation (if applicable), specimen dilution (if applicable). Chemical hazard - 70% ethanol and or 10% bleach - cause skin irritation, ingested or inhaled causes burn	High	<ul style="list-style-type: none"> <li>• PPE: lab coat, gloves, and safety glasses. Sleeves and double gloves while handling arbovirus specimen under a BSC.</li> <li>• All procedures involving vortex and centrifuge shall be conducted under BSC. In exceptional cases, if work is conducted on bench top, specimen tubes should be placed in centrifuge buckets to contain/limit aerosol risk.</li> <li>• Use of pipette tips with barrier filters is highly recommended for handling serology specimen.</li> <li>• For accidental spill/break in specimen tube on benchtop, wrap the specimen tube with disinfectant soaked absorbent material, put in secondary container to contain the spill. Refer to spill response section for details</li> <li>• In case of accidental discharge of pipette tip outside of waste container and or spills, disinfect pipettes and contaminated area with appropriate disinfectant.</li> <li>• Disinfect benchtop area with appropriate disinfectant</li> </ul>	<p>Risk level after control measures for samples not processed in BSC: <b>Medium</b>. For samples processed in BSC: <b>Low</b></p> <p>All staff are trained and competent in the procedures described in ELISA-EIA SOP and follow established laboratory practices.</p> <ul style="list-style-type: none"> <li>• Pathogens tested for EIA/ELISA are highly infectious. Pathogens with known aerosol transmission route (arboviruses) must be manipulated in a BSC until inactivated. Other pathogens can be tested on benchtop.</li> <li>• Transmission route depend on the pathogen and therefore specimen must be manipulated following standard BSL-2 practices.</li> <li>• Standard BSL-2 PPE should be worn at all times. No exposed skin while working with pathogens</li> <li>• Bring necessary materials into the BSC or on bench top prior to beginning work to avoid unnecessary movement.</li> <li>• If BSC is used, keep materials on sides to ensure proper air flow and limit traffic around BSC</li> </ul>	Laboratory Supervisor, Laboratory Manager and Division Chief

<p>Analytical ELISA-EIA testing Virology and Immunology</p>	<p>Aerosols, accidental spill, dropped specimen, dropped plates/strips - specimen addition to coated plate/strips, washes, addition of STOP solution, plate reading, removal and disposal of plate/strips. Chemical hazard - 70% ethanol and or 10% bleach - cause skin irritation, ingested or inhaled causes burn</p>	<p>High</p>	<ul style="list-style-type: none"> <li>● PPE: lab coat, gloves, and safety glasses. Sleeves and gloves while handling arbovirus under a BSC prior to inactivation. Post inactivation, regular PPE – lab coat, gloves, and safety glasses required while handling specimen.</li> <li>● For accidental spills/dropped specimen on benchtop, wrap the specimen tube with disinfectant soaked absorbent material, and transfer it to biohazard container. Refer to spill response section for details</li> <li>● In case of accidental discharge of pipette tip outside of waste container and or spills, pick up pipette tips with disinfectant soaked absorbent material and transfer to biohazard container. Disinfect pipettes and contaminated area with appropriate disinfectant.</li> <li>● After washes, remaining buffer should be removed by wrapping absorbent material around the plate or strips and gentle tapping on absorbent material.</li> <li>● After completion of the procedure, absorbent material/pad from BSC or bench top should be put in biohazard bag.</li> <li>● Disinfect benchtop area with appropriate disinfectant</li> </ul>	<ul style="list-style-type: none"> <li>● Minimize the use of sharps and where applicable use tips with barrier filters</li> <li>● When making specimen aliquot tube wipe outside of tubes prior to removing from BSC.</li> <li>● Dispose all pipette tips and other disposables in clearly marked biohazard waste container</li> <li>● Decontaminate surface area of bench top and BSC after completion of work process, with appropriate disinfectant</li> <li>● Specimen container, equipment, and all materials must be decontaminated prior to removing from BSC or benchtop.</li> <li>● ELISA plates/strips should be carried in a secondary container to and from the plate reader to avoid spills.</li> <li>● ELISA kit contains chemicals that may be reactive with certain disinfectants. Please refer to MSDS or package insert of each assay kit prior to use.</li> <li>● Disinfectants such as sodium hypochlorite should be used to clean spills.</li> </ul>	
<p>Analytical Specimen retention</p>	<p>Specimen retention - loss of samples; Waste disposal - contamination of</p>	<p>Medium</p>	<ul style="list-style-type: none"> <li>● Use appropriate laboratory protocol for laboratory sample inventory</li> <li>● Disinfect outside of waste containers prior to removal from the</li> </ul>	<p>Risk level after control measures: <b>Low.</b></p> <ul style="list-style-type: none"> <li>● Autoclave all PPE used in specimen handling waste and testing</li> </ul>	

Virology and Immunology	waste container surfaces.		laboratory - 10% bleach disinfectant, 20 minutes contact time, followed by wiping down all surfaces with 70% ethanol.		
-------------------------	---------------------------	--	---	--	--

### **Spill Clean-Up:**

#### **Inside a Biological Safety Cabinet (BSC) (Reference Laboratories Administration Safety Manual 2.6.1 Biological Spills inside a BSC)**

**Response:** Remain calm. Alert co-workers in the immediate area. Remove contaminated PPE, turn exposed area inward and put item in biohazard waste container. Inform Supervisor and Safety & Security Officer (SSO) call 443-681-3792 immediately. Have a biological spill kit ready prior to beginning of clean-up process.

#### **Spills Clean-up**

- Leave the BSC turned on.
- Put on, don new PPE.
- Use tongs or forceps for sharp objects, and dispose items into a sharps container.
- Work carefully, starting at the edges and working towards the center, cover the area with absorbent materials.
- Select appropriate disinfectant and pour material onto the spill area. A germicidal disinfectant such as a 0.04 % solution Lophene or a fresh 1:10 dilution of sodium hypochlorite (household bleach) should be used in wiping down all accessible cabinet surfaces.
- Allow at least 30 minutes of contact time with the germicide before removing items from the cabinet. NOTE: spills that contain organic material, such as blood or feces, will interfere with the microbicidal activity of many agents by acting as physical barrier. As a result, these spills may require preliminary wiping in order to reduce the organic load prior to disinfection.
- If the catch basin is contaminated contact the SSO for further instructions on decontamination process
- If the spill overflows into the interior of the cabinet, inform the immediate supervisor and the SSO. This requires a Biological Safety Cabinet certification technician to perform the decontamination.
- All items within the cabinet should be placed in autoclave cans for transport to the autoclave. Items that cannot be autoclaved, such as viable cultures to be retained, should be wiped carefully with the disinfectant.
- Run the cabinet for 15 minutes after cleanup is completed, and before routine use is resumed.
- Discard clean-up materials and PPE, into biohazard waste bag or container.

#### **Spills Outside a BSC (Reference Laboratories Administration Safety Manual 2.6.2 Biological Spills in the laboratory)**

**Response:** Remain calm. Alert co-workers in the immediate area. Remove contaminated PPE, turn exposed area inward and put item in biohazard waste container. Wash hands with disinfectant soap and evacuate. Inform Supervisor or Division Chief, Principle Investigator and SSO immediately. Call 3911 if necessary to reach key personnel. Allow 30 minutes for any aerosol resulting from the spill to settle before beginning the clean-up process. SSO, or designee, and Lab Director will determine if BSL-2 Open Lab will need to be shut down. Have a biological spill kit ready prior to beginning of clean-up process.

### Spill Clean-Up

- SSO will assist with clean-up lab employee with clean-up.
- Don appropriate PPE.
- Assess splash and spill area.
- Select appropriate disinfectant and pour material onto the spill area. A germicidal disinfectant such as a 0.04 % solution LopHene or a fresh 1:10 dilution of sodium hypochlorite (household bleach) should be used in wiping down all accessible cabinet surfaces.
- Flood the spill area with additional disinfectant and/or wipe down the area with new paper towels soaked with disinfectant.
- Allow at least 30 minutes of contact time.
- Use tongs or forceps for sharp objects, and dispose items into a sharps container.
- Work carefully, starting at the edges and working towards the center, cover the area with absorbent materials.
- Continue to disinfect bench tops, bench legs, chairs, equipment floor in the splash area with additional disinfectant and/or wipe down the area with new paper towels soaked with disinfectant.
- Discard clean-up materials and PPE, into biohazard waste bag or container.

### **Risk Management Worksheet**

<b>To be completed by laboratory staff during and/or after they perform work with control measures in place</b>		<b>Yes</b>	<b>No</b>
1. Are the planned control measures sufficient and effective in minimizing the level of risk?			
2. Have there been any changes to the planned control measures?			
3. Are any changes and/or additional control measures required in the future?			
Details:			
<b>Risk Management Worksheet Authorization (to be signed by Unit Supervisor and Division Manager/Chief)</b>	Review completed by:	Position/Title:	
	Signature:	Date:	
	Review completed by:	Position/Title:	
	Signature:	Date:	

## Appendix A

[illegible]



### Risk Assessment - Appendix B

Biological Safety Risk Assessment Checklist	
Item	Response
1. Indicate the biosafety level (BSL) established in each Unit and required PPE. (BSL-1, BSL-2, Enhanced BSL-2, BSL-3, N/A)	BSL-2: Accessioning BSL-2: Virology and Immunology BSL-3: Virology and Immunology for triplex (Zika, Dengue, CHIK) until samples are heat-treated
2. Is there potential for aerosol generation?	Yes (Pipetting, Centrifugation, manipulation of specimen, dilution, opening/closing collection tubes and micro centrifuge tubes)
3. Equipment such as centrifuges, incubators, freezers involved in the use and storage of infectious materials have biosafety labels affixed?	No. Laboratories (open and closed) are labelled with biohazardous warning label at each entrance
4. Buckets with safety caps/cups or aerosol tight rotor lids used when centrifuging infectious materials?	Yes
5. Is health monitoring performed in each Unit?	Please refer to current MDH Laboratory Safety Manual
6. Are vaccines recommended for work in each Unit?	Please refer to current MDH Laboratory Safety Manual
7. Are sharps used?	Accessioning: No Virology and Immunology: No
8. Does work include a Biological Safety Cabinet?	Accessioning: Will be introduced during Phase II process of accessioning samples Virology and Immunology: Only for endemic arbovirus and arbovirus triplex panel Class II BSCs are certified annually

Chemical Safety		
Item	Response (Yes)	Response (No)
1. Proper labeling: All containers labeled with the name of chemical?	Yes	
2. Fire Department Permit posted on the laboratory door?	Refer to Facility Manager and Tenant Handbook	
3. Updated chemical inventory?	Yes	
4. Material Safety Data Sheets/Safety Data Sheets accessible to staff?	Yes	
5. Incompatible chemicals segregated?	Yes	
6. Flammable liquids stored: rated chemical cabinets?	Yes	
7. Flammable liquids stored: stored in flammable-rated refrigerators/freezers?	Yes	
8. Excessive chemicals stored in chemical storage room?	Yes	
9. Compressed gas cylinders properly stored in laboratory?	N/A	
10. Chemicals stored at eye-level?	Yes	
11. Acids and bases stored:	Yes	
a. Cabinet?	Yes	
b. Labeled area?	Yes	
c. Free from metals?	Cabinet is metal	
12. Chemical fume hoods:	Yes	
a. Certified within past year?	Yes	
b. Sash closed when not in use?	Yes	
c. Exhaust air not blocked by large equipment or containers?	No	
d. Used for hazardous/toxic or flammable procedures?	No	
Comments:		

Personal Protective Equipment		
Item	Response (Yes)	Response (No)
1. Laboratory staff aware of personal protective equipment (PPE) requirements for this laboratory	Yes	
2. Laboratory staff/employee aware of occupational health information?	Please refer to current MDH Laboratory Safety Manual	
3. Does staff receive annual PPE competency assessments?	Yes	
4. PPE Care:		
a. Appropriately stored in laboratory?	Yes	
b. Inspected prior to use and in good condition?	Yes	
c. Worn in laboratory area?	Yes	
5. PPE Required :		
a. Facial shields/eye protection/splash guards?	Yes	
b. Disposable aprons, laboratory coats?	Yes	
c. Appropriate gloves?	Yes	
d. Double gloves required for work under the BSC	Yes	
e. Cryo or autoclave gloves?	Yes	
6. Closed-toe shoes that cover entire foot worn in laboratory?	Yes	
Comments:		

Emergency Preparedness		
Item	Response (Yes)	Response (No)
1. Emergency contact information posted?	Yes	
2. First aid kit maintained?	Yes	
3. Biological spill kit maintained?	Yes	
4. Staff aware of occupational injury procedures?	Yes	
Comments:		

<b>Documentation and Training –</b>		
<b>Item</b>	<b>Response (Yes)</b>	<b>Response (No)</b>
1. Employee(s) completed right-to-know training?	Yes	
2. Employee(s) completed unit-specific training?	Yes	
3. Employee(s) read and understand safety and health plans?	Yes	
4. Door sign up-to-date and posted?	Yes	
5. Laboratory microwaves and refrigerators labeled with “Not for Food or Drink – Biohazard”?	Laboratories (open and closed) are labelled with appropriate signage at the entrance	
Comments:		

<b>Waste Management -</b>		
<b>Item</b>	<b>Response (Yes)</b>	<b>Response (No)</b>
1. Chemical waste containers:		
a. Labeled with chemical name and percent of each chemical?	Yes	
b. Properly sealed?	Yes	
c. In good condition for transport?	Yes	
2. Biohazard waste containers?	Yes	
3. Broken glass placed in appropriate receptacle?	Yes	
4. Sharps container	Yes	
Comments:		

<b>Engineering Controls</b>		
<b>Item</b>	<b>Response (Yes)</b>	<b>Response (No)</b>
1. Laminar Flow Hoods	Yes	
2. Transport Containers	Yes	
Comments:		

References:

At Risk Employees: (Laboratories Administration Safety Manual, section 12.0)		
Unit Name:		
Name	Signature	Date
Unit Name:		
Name	Signature	Date

<b>Read &amp; Signed by</b>		
<b>Unit Name:</b>		
<b>Testing Personnel – Printed Name</b>	<b>Signature</b>	<b>Date</b>

This risk assessment should be reviewed annually or after any major changes (e.g., new facility, new employees, new technology, new method, changes in information for organism/agent, etc.). Reviews have been carried out on the following dates. Minor changes should be recorded under Amendments. Major changes require a new risk assessment to be performed.

Prepared by:			
	Printed Name	Signature	Date

Reviewed by:			
	Printed Name	Signature	Date

Approved by:			
	Printed Name	Signature	Date

Revised by:			
Version	Changes made	Printed Name & Signature	Date

Reviewed by:			
Version	Printed Name	Signature	Date

Approved by:			
Version	Printed Name	Signature	Date