**I. PURPOSE**

It is the policy of South Texas Dermatopathology to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with federal and state regulations. All human blood and other potentially infectious materials will be treated as if known to be infectious for human immunodeficiency virus (HIV), Hepatitis B virus (HBV), and other bloodborne pathogens. The Exposure Control Plan (ECP) applies to all employees with actual or potential exposure to bloodborne pathogens. This Plan and training is in accordance with 29 CFR 1910.1030.

**II. MATERIALS**

|  |  |  |
| --- | --- | --- |
| **REAGENTS** | **SUPPLIES** | **EQUIPMENT** |
|  |  |  |

**III. PROCEDURE**

# EMPLOYEE EXPOSURE DETERMINATION

Determinations for employee exposure are made for job classifications where occupational exposure to blood or other potentially infectious material (OPIM) occurs, is likely to occur, or is possible to occur.

The Job Hazard Analysis serves as the Risk Exposure Safety Training Analysis and contains a list of all job classifications, the occupational exposure potential to bloodborne pathogens, and proper precautions and personal protective equipment required. The list includes positions for which occupational exposure may occur as a result of duties performed.

1. **RISK EXPOSURE ANALYSIS**
* **Derm and Surgical Specimen Accessioning (HIGH):** Handling specimen vials containing 10% Neutral Buffers Formalin in which a specimen is immersed. Formalin is contaminated with blood and other fluids. PPE: lab coats and gloves.
* **Derm and Margins Grossing (HIGH)**: Dissecting samples at workstation. Employees cut specimens with scalpel into smaller pieces before processing. Although specimens are preserved in formalin and alcohol, a hazardous condition is still present. PPE: lab coats, gloves and safety glasses (with side shields) or safety shield.

**Surgical Specimens grossing: (HIGH):** Dissecting surgical samples at workstation. A large number of these samples are very large in size and although

* they are in formalin, the blood and body fluid levels are high making the highest level bloodborne pathogens contaminants. PPE: lab coats, gloves and safety glasses (with side shields) or safety shield.
* **Frozen “Fresh” Sections (HIGH)**: Sectioning specimens by cryostat. These samples are sent to the laboratory where blood and fluids are still active. The sample has not been in a fixative that might help arrest the pathogen level of the specimen. Samples are embedded in a cryogenic compound, sectioned, stained and coverslipped. PPE: lab coats and gloves. Note: in the case of frozen section of bronchial tissue, additional PPE is mandatory such as a mask and face shield.
* **Frozen Sections (DIF) (HIGH):** Sectioning skin samples by cryostat. Although these samples are normally small and they are immersed in a fixative (Michel’s Medium), the fixative does not contain alcohol or any other chemical that will ensure removal of the pathogen. PPE: lab coats and gloves.
* **Hazardous Solid Waste Disposal (HIGH):** Solid biological waste is discarded by placing the specimen vials and specimen containers in a red biohazard bag. The bag is sealed and placed in a special plastic biohazard container provided by the Waste Management Company. PPE: lab coats and gloves.
* **Specimen Embedding** **(LOW):** Orientation and inclusion of Derms, Margins and Surgical specimen samples in paraffin blocks. All samples at this point of the process have been exposed to additional formalin, alcohol, solvents (such as xylene) and paraffin heated at 61 C for long periods of time. PPE: lab coats or aprons and gloves.
* **Microtomy (LOW):** Derm and Surgical samples embedded in paraffin blocks are sectioned by microtome. All samples at this point of the preparation have been processed in chemical solvents, infiltrated with paraffin and embedded in heated paraffin. PPE: lab coats or aprons and gloves.
* **H&E Staining, Special Stains and Immunohistochemistry (NE**): Histology staining paraffin tissue sections with chemical dyes, alcohol, and solvents. Pathogenicity is non-existing. PPE: lab coats, safety glasses with side shields (if performed on benchtop w/o protective barrier/shield) and gloves used to prevent chemical exposure.
* **Slide Coverslipping (NE):** Placing a clear protective cover over the stained cellular material on the slide.
* **Slide Distribution (NE):** Distribution of slides to Pathologists.

 ***(NE)- Not exposed***

If an employee believes that he or she may be occupationally exposed to bloodborne pathogens and his or her job classification or tasks do not appear on the above mentioned list, the employee should contact his/her manager.

### ENGINEERING CONTROLS AND WORK PRACTICES

Engineering controls and work practices shall be implemented to prevent or minimize exposure to bloodborne pathogens. The Safety Technician (or designee) is responsible for ensuring that engineering controls and work practices are implemented and updated as necessary.

Engineering controls include:

* General laboratory ventilation.
* Chemical or tabletop fume hoods. Airflow will be monitored while in use and **monthly**; be tested at the time of installation and any time the hood is moved; and at least **annually** thereafter.
* Biological hoods for processing potentially infectious biological material (especially if capable of aerosolizing). Airflow will be monitored while in use and **monthly**; be tested at the time of installation and any time the biological hood is moved; and at least **annually** thereafter.
* Mechanical devices for safely removing contaminated scalpel blades.
* Sharps containers for needles, broken glass, and scalpel blades.

The following work practices will be followed:

* All employees will use **universal precautions** in order to prevent contact with blood or OPIM. All blood and OPIM will be considered infectious regardless of the perceived status of the source.
* After removal of PPE (e.g., gloves, lab coat) used during exposure to blood or OPIM, the employee(s) will wash hands or other exposed skin areas with running water and soap as soon as possible. In the event of a scalpel injury, promote blood flow by squeezing the affected area while flushing with water.
* Hand washing facilities are available throughout the laboratory. They are readily accessible to all employees who may incur exposure to blood or other potentially infectious materials. Soap is provided at each hand washing station.
* If handwashing facilities are not immediately available after exposure, exposed employee(s) will be provided with an antiseptic cleanser with cloth or paper towels or antiseptic towelettes. Exposed employees will wash their hands with running water and soap as soon as possible after using the antiseptic alternatives.
* When skin or mucous membranes are exposed to blood or OPIM, those areas of the body will be washed or flushed with running water as soon as possible after contact.
* In work areas where there is a reasonable risk of exposure to blood or other potentially infectious materials (in the laboratory), employees will not eat, drink, apply cosmetics or lip balm, smoke, or handle contact lenses. Food and beverages shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or bench tops where blood or other potentially infectious materials may be present or stored.
* Mouth pipetting or suctioning of blood or other potentially infectious materials is strictly prohibited.
* All processes and procedures shall be conducted in a matter that will minimize splashing, spraying, splattering and generation of droplets of blood or other potentially infectious materials.
* Shoes will be fluid impermeable material, leather or synthetic, and should cover the entire foot. Shoes with open toes or holes are not acceptable and will not be worn while in the laboratory.
* Wear appropriate clothing at all times in the laboratory. Shorts and skirts are not acceptable attire.
* Do not leave the laboratory work area while wearing PPE that was used in the handling of specimens, stains, or chemicals.

### HOUSEKEEPING—CLEANING AND DECONTAMINATION

All equipment, work areas, and working surfaces will be cleaned and decontaminated immediately or as soon as possible after any spill of blood or OPIM materials, after completion of procedures, and at the end of each shift. See appropriate department logs for the cleaning schedule in their work area.

Decontamination of surfaces, equipment, and work areas will be accomplished by using the following materials:

|  |
| --- |
| 1. **Disinfectants**
 |
| 1. 10 % Bleach or other germicidal product.
 |
| 1. Spray on infected area, let stand for 2-3 minutes, and wipe off completely.
 |
| 1. **Work Surfaces**
 |
| 1. All body fluid spills must be cleaned up immediately and properly disposed of.
 |
| 1. External surfaces of machines and instruments shall be cleaned with 10% bleach solution or equivalent disinfectant when contaminated with blood or body fluids. Internal portions, of before mentioned machines and instruments, shall be disinfected on a regular basis and with disinfectants as recommended by the manufacturer.
 |
| 1. Bins, pails (e.g., specimen bins), cans, and similar receptacles will be inspected and decontaminated on a regularly scheduled basis, and cleaned and decontaminated as soon as possible after visible contamination.
 |

The procedure for handling blood or OPIM contaminated waste is:

|  |
| --- |
| 1. **INFECTIOUS / BIOHAZARD WASTE DISPOSAL**
 |
| 1. Disposal of all infectious waste is in accordance with federal, state, and local regulations.
 |
| 1. All regulated medical waste generated is placed in a closable container or combination of containers that are rigid and leak resistant, impervious to moisture, strong enough to prevent tearing or bursting under normal handling, and securely sealed. A biohazard label is affixed to all containers or packages of untreated medical wastes.
 |
| 1. Never place biohazard bags in with regular trash, even if they are not visibly contaminated.
 |
| 1. If it is likely that outside contamination of the container or bag will occur, a second leak-proof container or bag is placed over the outside of the first container. When there is inner and outer packaging, or containers, each container (inside and outside) is labeled “Infectious Waste” or “Medical Waste” or display the universal Biohazard Symbol. Red plastic bags, when used as inner packaging for untreated waste, need no labels. However, the outer packaging or container is identified by the proper label or symbol.
 |
| 1. Biohazard waste containers will be kept in an upright position throughout use and are routinely checked by laboratory staff.
 |
| 1. Contaminated sharps (needles, scalpel blades, microtome blades, and other sharp items) will be discarded immediately or as soon as possible in containers that are :
 |
| * 1. Closeable, puncture resistant, leak proof, red in color or labeled “Biohazard”.
 |
| * 1. Sharps containers are not filled more than 2/3 full. Containers are discarded following site specific policy.
 |
| * 1. Puncture-resistant sharps containers are easily accessible to workers and are located in areas where they are commonly used.
 |
| * 1. Broken glass/slides, glass tubes, and glass pipettes are considered potentially hazardous sharp objects and must be disposed of in an appropriate sharps container.
 |
| 1. Used gloves, clothing protection, and gauze that are not regulated waste and may be discarded in regular trash containers. However, if these items are contaminated with blood or body fluids, they should be discarded in regulated waste containers.
 |
| 1. Biohazard bags will be double knotted when full and the outer container will be sealed shut before transport to prevent spillage, protrusion of contents, or aerosols during handling, storage, transport, or shipping.
 |
| 1. Biohazard containers will not exceed 50 pounds.
 |
| 1. Once sealed, an “Incinerate Only” yellow tag (UN 3291, Regulated Medical Waste, n.o.s.) will be placed on the outer container. These tags are provided by the contracted company and may be obtained in the grossing storage room. Each department will document the following information in the Biohazard Weight Log:
 |
| 1. Date.
 |
| 1. Label # (last 5 letters and numbers of the tag number).
 |
| 1. Contents (department name).
 |
| 1. Weight (not to exceed 50 pounds).
 |
| 1. Initials of employee.
 |
| 1. Name of storage or treatment facility.
 |
| 1. Containers will be transported to loading dock or designated area and removed by the contracted company.
 |
| 1. Records of regulated medical waste shall be maintained for each shipment and shall include the following information listed below. This information shall be maintained for no less than 3 years.
 |
| 1. Amount of waste by number of packages (piece count).
 |
| 1. Date shipped off-site.
 |
| 1. Name of transporter.
 |
| 1. Name of storage or treatment facility.
 |

### SHARPS INJURY PREVENTION

The following sharps safer devices and engineering controls will be implemented:

* Removal of contaminated scalpel blades must be done with the use of mechanical devices provided to the employees.

All employees will comply with the following work practice controls to reduce exposure to sharps:

* Contaminated sharps will not be bent, recapped, or removed.
* Contaminated reusable sharps must be placed in designated reusable sharps containers.
* Any scalpel blade removal must be accomplished by mechanical device or one-handed technique.
* Contaminated broken glassware shall not be picked up directly with hands, use mechanical means such as brush and dust pan or forceps for clean-up.

*Reusable sharps*

Immediately or as soon as possible after use, contaminated reusable sharps will be placed in appropriate containers until properly reprocessed. These containers will be puncture resistant, appropriately labeled or color-coded, and leakproof on the sides and bottom. Reusable sharps that are contaminated with blood or OPIM will not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

## PPE

PPE is provided to employees at no cost to them. PPE will be chosen based on the anticipated exposure to blood or OPIM. The PPE will be considered appropriate only if it does not permit blood or OPIM to pass through or reach the employee’s clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which it will be used.

PPE may consist of:

* Gloves (Nitrile and non-powdered low latex)
* Lab coat/apron
* Face shield
* Goggles or safety glasses with side shields
* Respirator

All PPE will be provided and disposed of by the employer. All repairs and replacements will be made by the employer.

*PPE Precautions*

All employees using PPE must observe the following precautions:

* Wash hands immediately or as soon as possible after removal of gloves or other PPE.
* Remove PPE before leaving the work area and after it becomes contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.
* Used PPE may be disposed of in appropriate containers.
* Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
* Must be worn at all times when the employee has cuts, scratches or other breaks in the skin and is handling infectious or potentially infectious material, regardless of the likelihood of direct exposure.
* Never wash or decontaminate disposable gloves for reuse.
* Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.

### ***Gloves***

Gloves will be worn where it is reasonably anticipated that employees will have hand contact with blood, OPIM, non-intact skin, and mucous membranes. Nitrile and non-powdered low latex gloves are readily available to all staff in various sizes.

*Contaminated Glove Removal*

1. Partially remove the first glove by pinching at the wrist and pulling inside out. Be careful to touch only the outside of the glove.
2. Remove the second glove by pinching the exterior with partially removed glove.
3. Pull the second glove inside out towards the fingertips.
4. Grasp both gloves with your free hand, touching only the clean interior surfaces.

*Latex Allergy*

Latex allergy occurs when the body’s immune system reacts to proteins found in natural rubber latex. Latex is most often associated with disposable gloves but may be found in other products throughout the laboratory and in normal daily life. Latex allergy can be a more serious allergic reaction. It usually begins within minutes of exposure but can sometimes occur hours later. It produces varied symptoms, which commonly include runny nose, sneezing, itchy eyes, scratchy throat, hives, and itchy burning sensations. However, it can involve more severe symptoms including asthma marked by difficult breathing, coughing spells, and wheezing; cardiovascular and gastrointestinal ailments; and in rare cases, anaphylaxis and death.

If an employee is allergic to the natural rubber latex (NRL) protein:

* Avoid, as far as feasible, exposure to the protein and only use nonlatex (e.g., nitrile) gloves. Nitrile gloves do not sensitize employees to natural rubber products.
* Make sure that other staff members in the laboratory wear nonlatex or reduced protein, powder-free latex gloves.

## LABELS

Warning labels will be affixed to containers of regulated waste, refrigerators, and freezers containing blood or OPIM and other containers used to store, transport, or ship blood or OPIM.

*Labeling exemptions*

Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of this Plan. Individual containers of blood or OPIM that are placed in a labeled container during storage, transport, shipment, or disposal are not required to be labeled. Blood or OPIM waste that has been decontaminated does not need warning labels.

*Label specifications*

Labels will be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color. They will be affixed as close as possible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal. Red bags or red containers may be substituted for labels. Labels required for contaminated equipment will meet the same specifications for containers and will also state which portions of the equipment remain contaminated.

Example of label:



**BIOHAZARD**

Management is responsible for ensuring that warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify their Designee if they discover blood or OPIM contaminated waste containers, refrigerators containing blood or OPIM, or contaminated equipment without proper labels.

## HEPATITIS B VACCINATION

Aurora Diagnostics will provide information to employees regarding hepatitis B vaccinations, addressing safety, benefits, efficacy, methods of administration, and availability.

The hepatitis B vaccination series is available at no cost after initial employee orientation and within 10 days of initial assignment to all employees identified in the exposure determination section of this ECP.

Vaccination is encouraged unless:

* Documentation exists that the employee has previously received the series.
* Antibody testing reveals that the employee is immune.
* Medical evaluation by a medical practitioner shows that vaccination is contraindicated.

Vaccination will be provided in accordance with the recommendation of the United States Public Health Service.

*Declination of the vaccine*

If an employee declines the vaccination, the employee must sign a declination form. Employees who decline may request and obtain the vaccination at a later date at no cost. Signed declination forms are kept in the employee’s confidential employee medical file in Human Resources.

# EXPOSURE INCIDENT MANAGEMENT

## ***Exposure Incident Report***

The employee will be sent to an off-site, medical provider for treatment, evaluation and follow up. Baseline and follow-up testing will not be conducted on site by the employer. Any incident that results in occupational exposure to blood or OPIM will be reported immediately to Management. An Accident/Injury Investigation Report must be completed by each person exposed to blood or OPIM. The report will include the name of the person exposed, the time and date of the incident, and details as to what/how the exposure occurred. All completed reports are kept in Human Resources.

## ***Post-Exposure Evaluation and Follow-up***

A confidential medical evaluation and follow-up will be conducted by a licensed health care professional or service. After initial first aid or medical attention, the following activities will be performed:

* Document the routes of exposure and how the exposure occurred.
* Identify and document the source individual (unless the identification isn’t feasible or prohibited by state or local law).
* Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual’s test results were conveyed to the employee’s healthcare provider.
* If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
* Ensure that the exposed employee is provided with the source individual’s test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
* After obtaining consent, collect exposed employee’s blood as soon as feasible after exposure incident, and have blood tested for HBV and HIV serological status. If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

## ***Administration of Post-Exposure Evaluation***

The employee should provide the healthcare professional performing the post-exposure evaluation with:

* A copy of 29 CFR 1910.1030 “Bloodborne Pathogen Standard.”
* A copy of the Accident/Injury Investigation Report if available.
* A description of the employee’s job duties relevant to the exposure incident.
* A description of route(s) of exposure.
* Circumstances of exposure.
* If possible, results of the source individual’s blood test (State specific requirements regarding source patient consent should be applied).
* Relevant employee medical records, including vaccination status.

TCD will obtain and provide the employee with a copy of the evaluating healthcare professional’s written opinion within 15 days of the completion of the evaluation. Human Resourceswill record all percutaneous injuries from contaminated sharps in a Sharps Injury Log.

# EMPLOYEE TRAINING

All employees who have occupational exposure to bloodborne pathogens will receive training on the epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers, at a minimum, the following elements:

* An explanation of the OSHA bloodborne pathogen standard.
* An explanation of our ECP and how to obtain a copy.
* An explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident.
* An explanation of the use and limitations of engineering controls, work practices, and PPE.
* An explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE.
* An explanation of the basis for PPE selection.
* Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge.
* Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM.
* An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available.
* Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident.
* An explanation of the signs and labels and/or color coding required by the standard and used at this facility.
* An opportunity for interactive questions and answers.

# RECORDKEEPING

## ***Medical Records***

Medical records are maintained for each employee with occupational exposure in accordance with the employee exposure and medical records regulation. Human Resources are responsible for maintenance of the required medical records. These confidential records are retained for at least the duration of employment plus 30 years.

Employee medical records are provided upon request to the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to:

Director of Human Resources

Aurora Diagnostics, LLC

11025 RCA Center Drive, Suite 300

Palm Beach Gardens, Florida 33410

### ***Sharps Injury Log***

In addition to the OSHA recordkeeping requirements, all percutaneous injuries from contaminated sharps are also recorded in a Sharps Injury Log. All incidents will include at least:

* The date of the injury
* The type and brand of the device involved (syringe, suture needle)
* The department or work area where the incident occurred
* An explanation of how the incident occurred

The Sharps Injury Log is reviewed as part of the annual program evaluation and maintained for at least 5 years following the end of the calendar year covered. If a copy is requested by anyone, it will have all personal identifiers removed from the report.

*Universal precaution*—an approach to infection control whereas all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

*Bloodborne pathogen*—microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) which causes acquired immune deficiency syndrome (AIDS).

*Exposure incident*—a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral (i.e., needlestick) contact with blood or other potentially infectious materials that results from the performance of an employee’s duties.

*Occupational exposure*—reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties. “Good Samaritan” acts, such as assisting a co-worker with a nosebleed are not considered occupational exposure.

*Other potentially infectious materials (OPIM)*—body fluids visibly contaminated with blood, including saliva in dental procedures, semen, vaginal secretions, amniotic fluid, and other such material where it is difficult to differentiate between body fluids.

*Percutaneous injury—* exposure by injection or absorption through the unbroken skin.

*Personal protective equipment (PPE)*—protective covering for the head, eyes, and hands such as lab coat/apron, gloves and a face mask/shield.

*Sharps*—any object that can penetrate the skin, including needles, scalpels, microscope slides, broken glass, and broken capillary tubes

**IV. QUALITY CONTROL**

 N/A

**V. CALCULATIONS/CALIBRATION**

 N/A

**VI. INTERPRETATIONS**

 N/A

**VII. METHOD PERFORMANCE SPECIFICATIONS**

 N/A

**VIII. REFERENCES**

1. Bloodborne Pathogens, 29 CFR 1910.1030 (2012).

**IX. RELATED DOCUMENTS**

1. Sharps Injury Log (F-1) *E: 4/16/13*

**X. DOCUMENT HISTORY (For Media Lab Migration)**

 N/A