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# Introduction

At Bioreach Laboratories, the well-being and safety of each employee is a top priority. Management and staff work together to protect all employees from biological hazards. Bioreach Laboratories is committed to providing a safe work environment for its employees. In turn, employees are expected to perform their duties in accordance with its current safe standards and practices. Bioreach Laboratories promotes a safe and healthy workplace by developing effective safety policies and regular training opportunities, tailored to our workplace. This biosafety manual provides laboratory personnel with information about biosafety requirements and injury prevention at the laboratory.

# Scope

This biosafety manual applies to all laboratory employees, contractors and visitors who work in the laboratory and related work areas..

# Responsibilities

Laboratory management and staff have a shared responsibility to inform and to be well informed regarding potential biological hazards in the workplace. Delineation of these responsibilities is described below.

## 3.1. Laboratory Director

Bioreach Laboratories Director has ultimate responsibility for biological safety.

## 3.2. Laboratory Manager or Safety Officer

The Laboratory Manager or Safety Officer serves as an advocate for safety and health of all employees at Bioreach Laboratories. The laboratory manager or Safety Officer ensures employee safety through:

* + Development and implementation of appropriate biological safety guidelines.
	+ Monitoring procurement use and disposal of biological agents.
	+ Assess the risk for biological agents in house and determine the requirements for protective apparel and appropriate equipment.
	+ Conduct or arrange information and training programs for all individuals who maybe potentially exposed to biological hazards.
	+ Perform the appropriate audits and inventory assessments.
	+ Establish emergency response programs.
	+ Determination of compliance with rules and regulations.
	+ Execute the day-to-day administrative responsibilities of the biological safety program.
	+ Maintaining records, including but not limited to training records and Hazard Assessments

The laboratory manager or Safety Officer may delegate responsibility for carrying out day-to-day activities to one or more individuals.

## 3.3. Laboratory Manager

Laboratory Manager is responsible for overseeing daily operations. They shall:

* Follow all guidelines and prudent practices covered in this document
* Ensure that all employees working in the laboratory understand and comply with all guidelines and prudent practices covered in this document
* Ensure that all personnel wear appropriate Personal Protective Equipment (PPE) when working in laboratory areas
* Work in a safe manner as to avoid harm or injury to oneself or another employee
* Report any potentially hazardous workplace conditions to the laboratory manager or Safety Officer

## 3.4. Staff

All staff that work in the lab shall:

* Read and follow all guidelines and prudent practices covered in this document
* Complete the required safety training and remain current with refresher training requirements
* Wear appropriate PPE (lab coat, gloves, closed toe shoes, eye protection) when working in laboratory areas
* Work in a safe, efficient manner as to avoid harm or injury to oneself or other employees
* Report any potentially hazardous conditions within the lab to the supervisor and the laboratory manager or Safety Officer
* Planning and conducting experiments in accordance with the Biological Safety Program guidelines
* Developing good personal work practices and hygiene habits
* Developing and maintaining appropriate Standard Operating Procedures (SOPs) for the safe use of biological agents
* Carrying out regular biological safety and housekeeping inspections
* Complying with all rules, regulations, and instructions pursuant to occupational safety and health standards

# Information and Training

It is the responsibility of the laboratory manager or Safety Officer or designee to implement an information and training program to assure that all individuals at risk are adequately informed of the work done in the Biohazard Work Area (BWA), the risks associated with the work, appropriate laboratory practices and techniques, emergency procedures and compliance. Every employee shall receive biological safety training when beginning work in the BWA. Training shall include health hazards of the agents present in the biohazard work area, measures employees can take to protect themselves and others from these hazards, signs and symptoms associated with exposure to the agents present in the laboratory and location and availability of reference material on biological safety. Every BWA worker shall know the location and proper use of protective apparel and emergency equipment and will have the opportunity to receive first aid training.

Literature about biological safety should be readily available to lab workers and they should be encouraged to use these resources. Employees shall be informed in keeping with requirements of the OSHA Blood borne Pathogens Standard and where applicable, OSHA Right-to-Know Regulations and the OSHA Laboratory Standard. Employee biological safety training records shall include content, trainer, date and be documented on the Biological Safety Training Record form.

The following types of training will be offered, initially:

* Reading Laboratory’s Biological Safety Policy/Manual- Employees will read the manual and sign that they have read and understood it.
* Specific SOP training- Employees will read each laboratory SOP, watch the procedure, perform the procedure with observation, and finally perform the procedure solo with data review. Employees will sign off on the SOP once they are fully trained.
* Medtraining.org safety specific competency assessments are performed annually and documented in the employees Competency assessment documents.

# Risk Assessment (Biosafety Level)

Biological agents are assigned to biosafety levels (BSL) based on the risk they pose to human health and the environment. Factors such as severity of disease caused by the agent, routes of exposure and virulence are used when determining the most appropriate BSL. Before beginning work with a biological agent, the laboratory manager or Safety Officer must review the agent and assess the level of risk posed by the agent to be used in the experimental protocol.

*INITIAL RISK ASSESSMENT 05/21/2023:*

* *Bioreach staff will be working with potentially infectious body fluids, specifically blood and urine.*
* *No Microbiological culturing of any kind is performed at Bioreach Laboratories. Any Microbiological procedures are to be sent to the appropriate reference laboratory.*
* *Exposure to BSL-1 and BSL-2 agents poses the greatest risk to employees at Bioreach Laboratories, specifically blood borne pathogens such as HIV, Hepatitis B and Hepatitis C.*
* *Risk of aerosolization of potentially infectious agents is low due to closed centrifuges and appropriate use of PPE.*
* *Safety training should focus on minimizing the potential for blood borne pathogen exposure including appropriate use of PPE. Shipping of human specimens and safe, efficient, lean laboratory practices. 05/21/2023ls*

## 5.1. Biosafety Level 1 (BSL-1)

BSL-1 is suitable for work involving well-characterized agents not known to cause disease in healthy adult humans. All bacterial, parasitic, fungal, viral, rickettsial and chlamydial agents which have been assessed for risk but do not belong to a higher risk group can be safely handled at BSL-1. BSL-1 practices, safety equipment and facility requirements represent a basic level of containment utilizing standard universal precautions and good laboratory technique.

*BSL-1 practices*: no mouth pipetting, sharps safety, biohazard signs, handwashing, PPE (coat, gloves, lab glasses), daily decontamination of work surfaces, avoid making aerosols, and waste is autoclaved or removed through a biohazardous waste service.

## 5.2. Biosafety Level 2 (BSL-2)

BSL-2 contains a broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity. The primary hazard with these agents is associated with accidental splashes, needle sticks, cuts or ingestion of infectious materials. These agents may be used on the open bench only if potential for producing splashes or aerosols is low. Examples of BSL-2 agents include:

* Bacterial agents such as Chlamydia psittaci, Chlamydia trachomatis, Clostridium botulinum, Clostridium tetani, Corynebacterium diphtheriae, Legionella spp, Neisseria gonorrhoeae, Neisseria meningitides, Salmonella spp, Shigella boydii, Shigella dysenteriae, Treponema pallidum, Vibrio cholera and Vibrio parahemolyticus.
* Viral agents such as cytomegalovirus, Eastern equine encephalitis, Epstein-Barr virus, hepatitis A, B, C, D and E, Herpes simplex viruses, HIV, SIV and vaccinia virus.
* Fungal agents such as Blastomyces dermatitidis, Cryptococcus neoformans, Microsporum spp, Exophiala dermatitidis (wangiella), Fonsecaea pedrosoi, Sporothrix schenkii and Trichophyton spp.
* Parasitic agents such as Crytosporidium spp, Entomeoeba histolytia, Giardia spp, Naegleria fowleri, Plasmodium spp, Strongyloides spp, Tania solium, Toxoplasma spp and Trypanosoma spp

***BSL-2 practices:* BSL-1 practices with additional requirements (refer to sec 11 for details**). Additional requirements: laboratory has self-closing, lockable doors, and restricted access while work is performed. Most importantly care is taken to reduce the production splashing or aerosols. Also, extra care is taken against needle sticks, accidental ingestion, and mucous membrane exposure.

# The Biohazard Work Area

All work with biological agents shall be confined to a specified area known as a Biohazard Work Area (BWA). This may be an entire room, or a portion thereof, set aside for work with these materials. If only a portion of the work area is designated as the BWA, it shall be delineated with floor markings. If the entire area is designated as the BWA, all doors into the BWA shall be properly marked.

## 6.1. Security and Admittance

Due to the potentially infectious nature of materials used in various laboratories, only individuals who complete required initial training and subsequent refresher training should be allowed admittance into the BWA.

Doors to areas which contain biohazard agents are securely locked when the area is not in use. Security of the BWA is provided by combination locks.

## 6.2. Signage

Employers must label biological hazards found in the workplace. Additionally, all laboratory equipment, especially refrigerators and freezers must be labeled with the biohazard symbol. All secondary containers which transport human specimens should have the biological hazard symbol. All biohazardous waste containers must have biohazard warning labels. Any item that contains biohazards should be properly labeled at all times.



## 6.3. Safety Equipment

Appropriate safety equipment is in place, unobstructed and in good working order. Emergency showers and eyewash stations are properly maintained and undergo periodic checks, including monthly inspection and activation by the laboratory manager or Safety Officer or a designee.

## 6.4. Storage

Biological agent storage areas are within the confines of the BWA, dedicated solely for the purpose of biological materials containment and are properly labeled. All biological agents are properly stored within containment befitting the inherent risk of the agent. An accurate inventory is maintained for the purposes of hazard assessment and to reduce unnecessary handling. Containers used for storage are closeable or sealable, leak-resistant, disposable or serializable and clearly labeled as a biohazard with a listing of the contents.

## 6.5. Laboratory Audits

Biohazard Work Areas are subject to periodic safety assessments conducted by the laboratory manager or Safety Officer. A general self-audit is completed during monthly Quality Assurance review.

# 7. Biological Safety Guidelines

Exposure to and infection by biological agents occurs through inhalation, ingestion, absorption, or injection. Therefore, measures must be taken to eliminate these routes of exposure through application of work practices, engineering controls and personal protective equipment. The laboratory manager or Safety Officer is responsible for assessing risks posed by the use of biological agents and for incorporating appropriate risk reduction methodologies into experimental protocols.

If handling radioactive specimen, there must be specific policies and procedures in place for the safe handling of specimens that may contain radioactive material.

## 7.1. Safe Work Practices

Containment and technique are the primary factors in working safely with biological agents. Strict observance of standard microbiological practices and techniques is the cornerstone of containment. If standard techniques do not afford the required protection with a given biological agent, it shall be the responsibility of the laboratory manager or Safety Officer to select additional safety precautions to minimize or eliminate risk potentials to the workers.

## 7.2. Personal Responsibility

Individuals are ultimately responsible for their own actions. Personal safety awareness is crucial in settings where the potential for personal harm is present. The employee must possess a thorough knowledge of procedures, surroundings and inherent risks. Prior to initiating a procedure, the employee should thoroughly consider its potential impact on personnel in the surrounding area and perform a hazard assessment.

## 7.3. Routes of Exposure

There are four main routes of exposure that one must try to avoid when working with biohazardous agents in the laboratory. These would include percutaneous injuries, inhaling infectious aerosols, exposure to mucous membranes and ingestion. Any incident or exposure must be reported immediately to your supervisor, and the laboratory manager or Safety Officer.

### 7.3.1. Percutaneous injuries

Percutaneous (through the skin) injuries can result from needle sticks, cuts or abrasions from contaminated items. These exposures are particularly serious because of the potential for immediate entry of the agent into a normally sterile bloodstream. Working with sharps should be avoided. When working with sharps is necessary, all sharps items should be handled and disposed of as noted in the [Waste Management](http://www.safety.duke.edu/SafetyManuals/labmanual/section1.htm#Waste) section of this manual. In the event of a percutaneous injury, follow the safety procedure below.

* **Taking care of the wound immediately after the accident**
	+ Let the wound bleed for a moment
	+ Cleanse thoroughly with water or a saline solution.
	+ Disinfect the wound using an ample amount of soap and water followed by 70% alcohol.
	+ In case of contact with mucous membranes it is important to rinse immediately and thoroughly, using water or a saline solution only, not alcohol.
* **Reporting the incident**
	+ It is important to report the incident immediately to your supervisor or laboratory manager or Safety Officer.
	+ Complete a Bioreach Incident report and forward this to your immediate supervisor.
* **Immediate action (injured person)**
	+ A blood sample should be taken as soon as possible after the injury. It acts as a baseline value in case infection takes place and it becomes necessary to determine whether infection by one of the three viruses occurred at work.
	+ Further blood samples to test for HBV, HCV and HIV are collected after 1, 3, and 12 months.
* **Immediate action (dealing with the potential source)**
	+ If the source of the blood is known the patient must be asked for permission to sample blood for a HCV and HIV test. Patient may refuse this. Employee can seek a Workman’s Compensation insurance claim and visit a healthcare provider if needed.

### 7.3.2. Inhalation of aerosols

### Procedures with a high likelihood of generating aerosols or droplets, should be done using either a certified Class II Biological Safety Cabinet (BSC) or additional precautions to provide a barrier between the specimen and personnel. Examples of these additional precautions include personal protective equipment (PPE), such as a surgical mask or face shield, or other physical barriers, like a splash shield; centrifuge safety cups; and sealed centrifuge rotors to reduce the risk of exposure to laboratory personnel.

### Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs, such as high testing volumes, and the likelihood to generate infectious droplets and aerosols.

### 7.3.3. Mucous membrane

Exposure of mucous membranes to infectious agents can lead to occupationally acquired infections. Muco-cutaneous exposures can result from splashes to the eyes, nose or mouth or by inadvertent inoculation via contaminated hands. Laboratory glasses should always be worn in the laboratory. [Face protection](http://www.safety.duke.edu/SafetyManuals/labmanual/section1.htm#Face%20Protection) and/or the use of a biosafety cabinet should always be used if splash or splatter is unavoidable.

### 7.3.4. Ingestion

Accidental ingestion of biohazardous materials can result from improper personal hygiene. Food and drink are prohibited in all areas of the laboratory. Additionally, hands must always be washed before leaving the laboratory and immediately if visible contamination occurs.

## 7.4. Human blood, blood products, tissues and body fluids

In 1991, the Occupational Safety and Health Administration (OSHA) publicized a standard to minimize the risk for occupational exposure to blood borne pathogens (i.e., HIV, Hepatitis B). The regulation, titled Occupational Exposure to Bloodborne Pathogensmandates several provisions for those working with materials that are human-derived such as human blood, blood products, other bodily fluids and any unfixed tissues.

Bloodborne pathogens are infectious agents from human blood that can cause disease in humans. The pathogens of primary concern for laboratory workers are the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Workers and employers can reduce the risk of handling human blood and blood products through engineering controls and work practices to reduce the chance of exposure to these biohazards.

### 7.4.1. Universal Precautions  Universal precautions are defined as handling all human blood, body fluids and tissues as if they are infectious. This calls for the use of appropriate protective measures to reduce or eliminate the risk of occupational exposure.

### 7.4.2. Human Immunodeficiency

Human Immunodeficiency Virus (HIV) targets the immune system, weakening the body’s defense against infections and some types of cancer. As HIV destroys and impairs the function of immune cells, infected individuals gradually become immunodeficient. Immune function is typically measured by CD4 cell count. The most advanced stage of HIV infection is acquired immunodeficiency syndrome (AIDS), which can take 2 to 15 years to develop. AIDS is defined by the development of certain cancers, infections, or other severe clinical manifestations observed only in immunocompromised patients.

The symptoms of HIV vary depending on the stage of infection. HIV-positive individuals tend to be most infectious a few months after the initial infection. They may be unaware of their status until the later stages of the illness. Symptomatic individuals may experience an influenza-like illness including fever, headache, rash or sore throat, shortly after the infection.

As the infection progresses, an individual can develop other signs and symptoms, such as swollen lymph nodes, weight loss, fever, diarrhea and cough. Without treatment, they may develop severe illnesses such as tuberculosis, cryptococcal meningitis, and cancers such as lymphomas and Kaposi's sarcoma, among others.

HIV infection is often diagnosed through rapid diagnostic tests (RDTs), which detect the presence or absence of HIV antibodies. Most often these tests provide same day test results.

Percutaneous injury is the most likely route of infection for healthcare personnel. Exposure to HIV is mitigated by proper laboratory work practices. The HIV virus is readily inactivated by approved disinfectants. Hand hygiene, safe handling of sharps, proper waste disposal, and surface disinfection are strongly recommended.

### 7.4.3. Hepatitis B

**Hepatitis B virus (HBV)** can cause chronic hepatitis, putting infected individuals at high risk of death from cirrhosis and liver cancer. A vaccine against hepatitis B has been available since 1982. The vaccine is 90% effective in preventing infection and the development of chronic disease and liver cancer. The OSHA bloodborne pathogens standard states that employers must offer the Hepatitis B vaccine to all employees at risk of infection through their work activities at no cost to the employee. Additionally, they must offer an HBV titer after the vaccination course or in previously vaccinated employees as well as booster vaccination if the titer out of the protective range. The Hepatitis B vaccination series consists of 3-4 shots in a 6-month period.

The hepatitis B virus can survive outside the body for at least 7 days. It is 50-100 times more infectious than HIV. During this time, the virus can still cause infection if it enters the body of an unvaccinated person. The incubation period of the hepatitis B virus is 75 days on average but can vary from 30 to 180 days. The virus may be detected within 30 to 60 days after infection and can persist and develop into chronic hepatitis B.

#### 7.4.3.1. Hepatitis B Vaccination

Hepatitis B vaccination is strongly encouraged for all workers who handle human blood or human blood products. All laboratory employees that work with human blood or human blood products or have a potential for contact with blood or blood products will be provided with the Hepatitis B vaccine at no cost to them.

### 7.4.4. Hepatitis C

**Hepatitis C** **virus (HCV)** can cause both acute and chronic hepatitis infection, ranging in severity from a mild illness lasting a few weeks to a serious, lifelong illness.

Hepatitis C virus (HCV) causes both acute and chronic infection. Acute HCV infection is usually asymptomatic and is only very rarely associated with life-threatening disease. About 15–45% of infected persons may clear the virus within 6 months of infection without any treatment.

The remaining 55–85% of infected persons will develop chronic HCV infection. Of those with chronic HCV infection, the risk of cirrhosis of the liver is between 15–30% over 20 years.

The incubation period for hepatitis C is 2 weeks to 6 months. Following initial infection, approximately 80% of people are asymptomatic. Acutely symptomatic individuals may exhibit fever, fatigue, decreased appetite, nausea, vomiting, abdominal pain, dark urine, grey-colored feces, joint pain and jaundice.

Because acute HCV infection is usually asymptomatic, few people are diagnosed during that stage. Chronic HCV infection is often undiagnosed because the individuals can remain asymptomatic for decades until symptoms develop which are secondary to the serious, primary liver damage caused by HCV

There is no vaccine for hepatitis C, therefore infection prevention is the first line of defense against exposure in health-care settings and in higher risk populations. Hand hygiene, safe handling of sharps, proper waste disposal, and surface disinfection are strongly recommended.

### 7.4.5. Blood and Body Fluid Exposure Reporting

All occupational exposures to potentially infectious materials are to be reported immediately to the supervisor. A direct supervisor will discuss with the employee the appropriate follow up to the exposure which may require immediate medical attention. It is important that exposures are reported as soon after the incident as possible because some post exposure treatments are considered time sensitive.

## 7.5. Biological Agents Registration and Inventory

No biological agents are ordered or stored in house other than blood and urine.

# 8. General Laboratory Practices and Techniques

**For Specific Biosafety Levels Work Practices refer to sec 11**

## 8.1. Personal Protective Equipment

Personal protective equipment (PPE) suitable for the inherent risks of the biological agent shall be made available to all employees without cost to them. Prior to assignment of PPE, a workplace hazard assessment shall be completed, and a copy held on file for inspection. Appropriate PPE may include eye and face protection, protective clothing, gloves, footwear and respiratory equipment as the nature of work dictates. When protective clothing is required for work with biological agents, it should be donned before handling potentially hazardous biological materials. PPE should be removed and left in the laboratory before leaving for non-laboratory areas such as cafeteria, rest rooms and offices. If a gross contamination of the PPE should occur, the equipment should be immediately removed and replaced. It is the responsibility of each employee to wash, clean and store PPE in accordance with regulations and company procedures. It is the responsibility of the laboratory manager or Safety Officer to ensure that PPE is used correctly.

### 8.1.1. Face Protection

When splash or splatter of infectious substances or other biological materials is anticipated, appropriate face protection should be worn if work is performed outside a biological safety cabinet. Such equipment would include but is not limited to goggles, side-shielded safety glasses and chin length face shields.

### 8.1.2. Eye Protection

Laboratory glasses protect eyes against splash or splatter from infectious substances. Regular prescription glasses without side-shields are not acceptable. Staff who wear prescription eyewear can obtain corrective laboratory glasses at no cost through USA Safety.

### 8.1.3. Lab Coats and Gowns

Long sleeved lab coats or gowns should be worn to protect skin and street clothes from contamination while processing samples. In circumstances when splash or splatter is anticipated, the garment must be resistant to liquid penetration. A cuffed lab coat or gown should be worn when working with potentially infectious materials. If a reusable lab coat, which must be laundered off site by a laundering service, gets splashed or infected it must be disinfected and disposed of in the biohazardous waste.

### 8.1.4. Gloves

Gloves should always be worn inside the laboratory and especially when handling biological materials. Disposable gloves can provide an adequate barrier between the laboratory worker and most biohazardous materials. Disposable gloves are not to be used for touching “clean” surfaces such as telephones. At the Laboratory only non-latex gloves should be worn and should never be worn outside the lab. Latex and/or powdered gloves are not used in the laboratory because they can cause the development of allergies. Allergies to nitrile are uncommon, but they are possible. Always let your laboratory supervisor know if you are sensitive to these materials.

### 8.1.5. Respirators

No BSL-3 practices or procedures are performed at Bioreach Laboratories. Respirators or any other BSL-3 practices are not required. Routine safety policy review will amend this policy if needed.

### 8.1.6. Disposable Booties/ Shoe-covers

When significant splash and splatter are anticipated, booties/ shoe-covers should be considered. Prior to exiting the laboratory, these must be removed and disposed of properly.

## 8.2. Work practice Controls

### 8.2.1. Eating, Drinking, Smoking, Applying Cosmetics and Handling Contact Lenses

Eating, drinking, smoking, applying cosmetics and handling contact lenses is prohibited in work areas in which potentially infectious materials are being manipulated. Food and drink must not be stored in refrigerators in which laboratory materials are kept.

### 8.2.2. Long Hair Tied Back

If hair is longer than shoulder length, it should be worn in a hair elastic. Unrestrained hair can potentially be contaminated by biohazardous material while working.

### 8.2.3. No Working Alone

Since accidents are unexpected by definition, coworkers should always be present in the laboratory. Your immediate supervisor should know when you are working alone.

### 8.2.4. Mobile Phone Caution

Mobile phones are allowed in the laboratory, if they are worn under the coat. However, PPE must be removed, and hands washed before handling them.

### 8.2.5. Proper Personal Attire

Employees should wear close-toed shoes and long pants when working in the laboratory.

### 8.2.6. Headsets Worn

Headphones, ear buds, and blue tooth headsets are allowed in the laboratory, However, employees should be alert when working in the laboratory and be mindful that these accessories can be easily contaminated with biohazards within the laboratory. Gross neglect of headset contamination issues or communication issues may result in changes in policy.

### 8.2.7. Handwashing

Hands should be washed as soon as possible when they come in contact with potentially infectious materials. A vigorous handwashing with a mild soap for 20 full seconds is appropriate. Hands should also be washed as soon as feasible after gloves are removed and before exiting the laboratory. See Bioreach Hand Hygiene Policy for complete procedural details.

### 8.2.8. Housekeeping

Good housekeeping in laboratories can reduce the risk of accidents occurring. Work benches should be kept as clutter-free as feasible and aisles should always be free of trip hazards. Empty shipping containers should be disposed of promptly and not be allowed to accumulate in the laboratory. Benches should be wiped down with an approved disinfectant at least once a day and immediately after a spill of potentially infectious materials.

**8.2.9. Pipetting**

Pipetting infectious agents can lead to personnel exposures by inhalation, contact or ingestion if not performed properly. The following safety precautions are to be followed when pipetting in the laboratory:  1) Never mouth pipette. Pipetting aids should always be used, 2) Place absorbent paper on benchtops to reduce the risk of aerosols being generated by accidental dripping of infectious materials from pipette tips and 3) Place disposable pipettes into biohazard boxes which have been lined with a biohazard bag, and are then disposed of by Stericycle.

**8.2.10. Sharps**

The use of needles, glass pipettes, glass slides and cover slips, scalpels and lancets should be avoided whenever possible. Appropriate precautions should be taken to avoid percutaneous injuries. These items should be disposed of immediately after use by placing them in an appropriate puncture proof container. Bending, recapping, or clipping of needles is prohibited. If recapping is necessary, a mechanical device or the one-handed scoop method must be used. Plasticware should be used whenever possible, such as plastic graduated cylinders, funnels, etc.

# 9. Decontamination

The purpose of decontamination is to make a hazardous material safe for further handling. A decontamination procedure can range from sterilization to simple cleaning with soap and water. **All products listed on List N (Disinfectants for Coronavirus (COVID-19) by EPA can be used to kill the coronavirus SARS-CoV-2 (COVID-19) when used according to the label directions.**

## 9.1. Liquid Disinfection

Many types of liquid disinfectants are available under a variety of trade names. The most practical use of liquid disinfectants is for surface decontamination. Agents included in the category include but are not limited to quaternary ammonium compounds, phenolic compounds, halogens, aldehydes, alcohols and amines. A tuberculocidal disinfectant or diluted bleach should always be used for decontamination when human materials are handled.

**NOTE:** When bleach is used for the decontamination of spills, a fresh solution (at least 10% bleach) must be prepared. Bleach solutions used for routine surface decontamination must be made up at least weekly. Each solution container must be labeled with either a make-up or an expiration date. Prepared 10% Bleach solutions are good for 1 week at room temperature.

## 9.2. Categories of biological waste and acceptable treatments

Only those individuals who have successfully completed Bioreach Laboratories Biological Safety Training Program are allowed to handle biohazardous waste. Universal and Standard Precautions and proper PPE are vital to safe handling of such waste. Individuals working with biological agents or potentially infectious material must properly dispose of such waste in accordance with all pertinent regulations, including but not limited to the OSHA Bloodborne Pathogens Standard.

### 9.2.1. Mixed Waste

Creation of mixed wastes, biological waste and hazardous materials/bio-waste should be avoided whenever possible.

### 9.2.2. Sharps

This category includes needles, syringes with attached needles, capillary tubes, slides and cover slips, scalpel blades, and broken glassware that is contaminated with biological material. These items should be placed in a puncture-resistant container (sharps container). Place the sharps container in the regulated medical waste for disposal.

### 9.2.3. Pipette Tips

Pipette tips used to process human body fluids, should be placed in a “pipette tip” biohazard bag in a lab-bench stand. Once filled, these bags should be placed in the regulated medical waste for disposal. Non-infectious pipettes do not need to be placed in biohazard bags and can be disposed of in the non-hazardous waste. Non-infectious pipette tips should be placed in the regulated medical waste.

### 9.2.4. Specimens of human blood

These items should be discarded in a biohazard bag then placed in the regulated medical waste box for disposal.

### 9.2.5. Solid Waste

This category includes disposable gloves, gauze, paper wrappings, parafilm, etc., that are minimally contaminated. Gloves, wipes, bandages that are not visibly soiled with body fluids can be placed in the regular trash.

# 10. Emergency Preparedness

## 10.1. Splashes to Eyes

* **Flush your eye with water.**
	+ Aim the water over your affected eye(s). Hold the lids of your affected eye or eyes open for at least 20 minutes.
* **Wash your hands with soap and water.**
	+ Thoroughly rinse your hands to be sure no chemical or soap is left on them.
* **Remove contact lenses.**
	+ If they don’t come out during the flush.
* **Caution**
	+ Don’t rub the eye — this may cause further damage.
	+ Don’t put anything except water or contact lens saline rinse in the eye.
	+ And don’t use eye drops unless instructed by emergency personnel.
* **Seek emergency medical assistance**
	+ Call 911, if an emergency or have the laboratory supervisor call 911.
	+ The Laboratory Supervisor or Safety Officer can arrange for you to be transported.

## 10.2. Emergency Spill/Release

Procedures shall be made for spills or releases with clear designation made between small and large spills or releases. Spills greater than 1 liter are considered large spills. SDSs are available for all chemicals used in the lab. An emergency contact list of personnel will be posted on the door of the BWA.

## 10.3. Biohazard Spill Kits

A biohazard spill kit shall be available in each area where the potential for spills or releases of a biohazardous substance is seen. These kits should include such items as:

* Suitable disposable gloves (double thickness suggested)
* Disinfectant spray (commercially produced or 10% bleach solution)
* Sharps container for needles and other sharps
* Containers for contaminated broken glass
* Paper toweling or disposable sponge material

## 10.4. Biohazard spill clean-up Procedure

A spill control plan must be available in the laboratory. The following procedures should be followed to insure proper spill clean-up.

### 10.4.1. Spill Involving Blood or Body Fluids:

* Wear disposable gloves.
* Absorb fluids with disposable towels.
* Clean area of all visible fluids with detergent (soap/water).
* Decontaminate area with a freshly prepared 1:10 dilution of bleach: water if surface is porous.
* If surface is hard and smooth use a 1:100 dilution of bleach.
* Place all disposable materials into a plastic leak-proof bag.

### 10.4.2. Spill Involving Concentrated Microorganisms Requiring Biosafety Level 2: No Microorganisms or stocks are to be stored in the clinical Laboratory.

## 10.5. Emergency Care

Work-related accidents and injuries, no matter how small, must be reported to your supervisor or the laboratory manager or Safety Officer as soon as possible. Any illness or health condition *suspected* of being related to your work environment must also be reported. When necessary, an occupational physician will be contacted for evaluation and/or treatment. Workman’s Compensation Insurance claim must be completed for any work-related injury requiring medical attention.

# 11. Laboratory Biosafety Level Criteria and Practices

The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community. Standard microbiological practices are common to all laboratories. Special microbiological practices enhance worker safety, environmental protection, and address the risk of handling agents requiring increasing levels of containment.

## 11.1. Biosafety Level 1

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard laboratory practices. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must have access to supervisory staff either in presence, or by phone contact.

The following standard practices, safety equipment, and facility requirements apply to BSL-1.

**A. Standard Microbiological Practices**

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.

2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.

 3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.

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

5. Sharps must be handled safely. Sharps pose the greatest risk of exposure at Bioreach Laboratories. Sharps, such as needles, scalpels, pipettes, and broken glassware must be placed into sharps containers immediately after use or upon breakage of equipment such as glass ware. Broken glassware should be removed via brush and dustpan. Do not handle broken glassware directly.

6. Perform all procedures to minimize the creation of splashes and/or aerosols.

7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.

8. Decontaminate all potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport.

a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.

b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.

9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present.

10. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur.

**B. Safety Equipment (Primary Barriers and Personal Protective Equipment)**

1. Special containment devices or equipment, such as BSCs, are not generally required.

2. Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.

3. Wear protective eyewear when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Persons who wear contact lenses in laboratories should also wear eye protection.

4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Wash hands prior to leaving the laboratory.

In addition, BSL-1 workers should:

 a. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.

b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.

c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

**C. Laboratory Facilities (Secondary Barriers)**

1. Laboratories should have doors for access control.

2. Laboratories must have a sink for hand washing.

3. The laboratory should be designed so that it can be easily cleaned.

4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.

a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.

b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

5. Laboratories windows that open to the exterior should be fitted with screens.

## 11.2. Biosafety Level 2

BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that:

1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures;

 2) access to the laboratory is restricted when work is being conducted; and

3) all procedures in which infectious aerosols or splashes may be created are conducted with physical containment equipment such as Hemoguard topped blood tubes or Tube capping plexiglass shields.

**A. Standard Microbiological Practices-same as BSL-1**

**B. Special Practices**

1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.

2. Laboratory personnel must be provided medical surveillance, as appropriate, and offered available immunizations for blood borne pathogens.

3. A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.

4. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.

5. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.

6. Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.

a. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.

b. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.

7. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents must be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment should be provided, and appropriate records maintained.

8. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted using a physical containment device.

**C. Safety Equipment (Primary Barriers and Personal Protective Equipment)**

Appropriate personal protective equipment, or other physical containment devices must be used whenever working with blood or body fluids.

1. Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving for non-laboratory areas, e.g., cafeteria, library, and administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.

2. Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or before reuse. Persons who wear contact lenses in laboratories should also wear eye protection.

3.. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-2 laboratory workers should:

a. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.

b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.

c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

**D. Laboratory Facilities (Secondary Barriers)**

1. Laboratory doors should be self-closing and have locks in accordance with the institutional policies.

2. Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.

3. The laboratory should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.

4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.

a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.

b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

5. Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.

6. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.

7. Vacuum lines should be protected with liquid disinfectant traps.

8. An eyewash station must be readily available.

9. A method for decontaminating all laboratory wastes should be available in the facility (e.g., contracted waste company, autoclave, chemical disinfection, or other validated decontamination method).

# 12. Worker’s Compensation

Laboratory maintains Worker’s Compensation insurance for all employees.

## 12.1. Injuries Covered

All work-related injuries and illnesses are covered under the Worker’s Compensation system (including injuries resulting from cuts, falls, breaks, etc. as well as injuries from repetitive motion, cumulative trauma disorders, etc.).

## 12.2. Making a Claim

* If you are injured while on-the-job, you are responsible for notifying your manager/supervisor by the next workday.
* Laboratory is dedicated to ensuring that the injured employee receives proper medical care and treatment by qualified medical providers.
* Human Resources or the laboratory manager or Safety Officer will arrange for proper medical treatment in the event an employee is injured on the job.
* You must fill out a workman’s compensation insurance form.
* Notify the Human Resources Department at your earliest convenience any time you receive work-related medical treatment.
* For any questions about the Worker’s Compensation system, please contact the Human Resources Department or your manager/supervisor.

# 13. Shipping and Receiving Biological Agents

Laboratory personnel shipping and/or receiving biological agents must comply with regulations publicized by the U.S. Department of Agriculture (USDA) to regulate importation and interstate shipment of human body fluids. U.S. Department of Transportation (DOT) regulations cover all aspects of shipping biological agents and regulated medical wastes, including packaging, labeling and other shipping requirements. All personnel who ship and/or receive human blood/body fluids, must be trained prior to engaging in such activities.

# 14. Limitations and Disciplinary Actions

The Biological Safety Manual has been written to set forth rules and guidelines for the safe use of biological materials in the laboratory. It is not a comprehensive set of guidelines and the laboratory manager or Safety Officer may at his or her discretion modify or establish additional procedures to aid in maintaining a safe and healthy environment.

Failure to comply with the procedures outlined in this manual or with procedures established by the laboratory manager or Safety Officer may result in disciplinary action.

# 15. References and Citations

1. *Biosafety in Microbiological and Biomedical Laboratories*; 4th ed., CDC/NIH, 1999
2. *Occupational Exposure to Bloodborne Pathogens*, Final Rule; 29CFR 1910.1030, OSHA, 1991
3. <https://www.cdc.gov/hepatitis/hbv/bfaq.htm>
4. https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF

# 16. Additional References

1. *Biological Safety: Principles and Practices*; Fleming D, Hunt D, 3rd ed., ASM, 2000
2. *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets*; 2nd ed., CDC/NIH, 2000
3. *North Carolina Administrative Code* 10G.1201-.1207, General Statute 130A-309.26, 1990
4. *Occupational Health and Safety in the Care and Use of Research Animals*; NRC, 1997
5. *2005 Dangerous Good Regulations; International Air Transport Association*, 46th Ed.
6. *Possession, Use, and Transfer of Select Agents and Toxins*; USDHHS, 42 CFR Part 73, 2002
7. *North Carolina Administrative Code* G.S. 130A-149, Biological Agent Registry, 2002