**Biohazardous Agent Reference Document (BARD) and**

**Information for Healthcare Providers in the Event of an Exposure**

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| The BARD is an additional guidance tool. It is not a substitute for a risk assessment, biosafety training, lab-specific training, SOP as required by the IBC or a formal [IBC master protocol registration](https://www.uvm.edu/rpo/biosafety-oversight). This document must be readily available in the laboratory, and it is the responsibility of the Laboratory Supervisor or Principal Investigator to ensure that all personnel have read and understood the information. The BARD is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Please bring this IBC-approved BARD with you to the UVMMC Emergency Department if there has been an exposure and someone requires medical assistance. INSTRUCTIONS for BARD Preparation1. Complete the blue Information for Healthcare Providers section.
2. Review the standard information contained in the green section of this document.
3. Add/revise information that is specific to your work in the laboratory (such as strain-specific information). Please be sure that the track changes function is turned on to indicate any changes that you make.
4. Submit the BARD along with your IBC master protocol registration or amendment.
5. Once approved by the IBC, all personnel must review this BARD. The PI will attest during the submission of the registration or amendment to add new personnel that each lab member has read and understands the material.
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| **Information for Healthcare Providers**Dear Healthcare Provider, This individual works in a UVM research laboratory and has been exposed to a pathogen or toxin. Information about the materials this person may have been exposed to is listed below. You may also find useful additional information in subsequent pages of this reference document. |
| **Pathogen Name:** | Diphtheria toxin (DT) |
| **Pathogen/Toxin Classification:** |  |
| **List All Strains Used in the Laboratory:** |  |
| **List Resistant Genes Known to be Encoded:** |  |
| **Modes of Transmission *(mucous membranes, needle stick, inhalation)*:** | Inhalation, ingestion, mucous membrane contact, percutaneous |
| **Known Medical Precautions and Treatment** |

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| **Prophylaxis** | Booster dose of diphtheria toxoid |
| **Vaccines** | Vaccination with booster recommended every 10 years (typically combined with tetanus & pertussis vaccines as TDaP and administered to young children) |
| **Treatment and/or Post-exposure Intervention** | Administer antitoxin, treat symptomatically |
| **Surveillance** | Monitor for clinical disease symptoms  |
| **Additional Medical Precautions (immunosuppression, pregnancy, allergies)** |  |

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| **Health Hazards** |
| **Host Range** | Humans. Rarely: cows, cats, horses |
| **Signs and Symptoms** | Cranial, motor, and sensory nerve palsies, fever, localized irritation, seizures, myocarditis, endocarditis, organ necrosis, death. |
| **Toxic Dose** | In mice: 0.01 micrograms/kg (intravenous) or 1.0 micrograms/kg (subcutaneous, intraperitoneal) |
| **Incubation Period** | 2 – 4 days for clinical disease |
| **Exposure Procedures** |
| **Mucous membranes** | Immediately flush eyes, mouth or nose for 15 minutes at eyewash station, seek medical attention. |
| **Other exposures** | Wash area with soap and water, seek medical attention.  |
| **Medical Follow-Up** | Contact UVMMC Infectious Disease Dept. directly at **(802) 847-2700** for immediate assistance. Bring this document with you if seeking medical care. |
| **Reporting** | Report all exposures or near misses to:1. Your immediate Supervisor
2. SOS at 802-656-2560 and ask to have the EH&S team paged
3. Risk Management: <https://www.uvm.edu/riskmanagement/incident-claim-reporting-procedures>
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| **Laboratory Hazards** |
| **Laboratory Acquired Infections** | 33 cases of lab-acquired diphtheria infections reported as of 1976 |
| **Sources** | Lyophilized toxin, exudates or secretions of the respiratory system, wounds, blood, or skin of infected animals  |
| **Characteristics** |
| **Morphology** | Bacterial exotoxin that inhibits protein synthesis in eukaryotic cells |
| **Strain Specific Characteristics**  | Natural source is *Corynebacterium diphtheria*  |
| **Containment Requirements** |
| **BSL - 2** | Preparation/dilution of the agent, work with clinical specimens and cultures known or suspected to contain the agent |
| **BSL - 3** |  |
| **ABSL - 2** | Administration of the agent to an animal model. Use mechanical or anesthetic restraint for injections. |
| **ABSL - 3** |  |
| **Aerosol generating activities** | Centrifugation, homogenizing, vortexing or stirring, pipetting, pouring liquids, filling or expelling syringes |
| **Primary containment device (BSC)** | Use a biosafety cabinet for preparing stocks, and for all manipulations of DT |
| **Personal Protective Equipment (PPE)** |
| ***Minimum PPE Requirements*** | Nitrile gloves, lab coat, appropriate eye/face protection |
| ***Additional Precautions*** ***(Risk assessment dependent)*** | Sharps use strictly limited. Store DT locked up. Due to risk of inhalation, respirators may be required when working with DT. Medical clearance, fit testing and training is required annually per UVM’s Respiratory Protection Program.  |
| **Viability** |
| **Disinfection** | Freshly prepared 10% bleach with a 30 minutes contact time |
| **Inactivation** | Autoclaving at 121°C for 1 hour liquid cycle |
| **Survival Outside Host** | Stable at room temperature and normal pressures |
| **Spill Clean-Up Procedures** |
| **Small Spill** | Notify others working in the lab. Allow aerosols to settle. Don appropriate PPE. Cover area of the spill with paper towels and apply approved disinfectant, working from the perimeter towards the center. Allow 30 minutes of contact time before clean up and disposal. Dispose in double biowaste bags and biobox. |
| **Large Spill** | **Inside of a lab:** Call UVM Service Operations at 656-2560 and ask to speak to a dispatcher. Ask them to page Risk Management and Safety. **Outside of the lab:** Pull the nearest fire alarm and evacuate the building. Wait out front of the building for emergency responders to arrive. |
| **References** |
| **Canadian PSDS** | <https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/corynebacterium-diphtheriae.html> |
| **BMBL** | <https://www.cdc.gov/biosafety/publications/bmbl5/> |
| **CDC Guidelines**  | <https://www.cdc.gov/diphtheria/>  |
| **Applied Biosafety** | Johnson B, Mastnjak R, Resnick IG. 2001. Safety and Health Considerations for Working with Biological Toxins. Applied Biosafety. 6 (3): 117-135 |