U.S. EPA DuoDote® Storage and Use Protocol

For EPA Laboratories, On-Scene Coordinators & Emergency Responders

February 2022

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Part 1: Guidelines for Use of DuoDote® Kits

Disclaimer:

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1. Introduction

Nerve agents are some of the most toxic of chemical warfare agents (CWAs). They are hazards in their liquid and vapor states and can cause death within minutes after exposure. Nerve agents inhibit the acetylcholinesterase breakdown of acetylcholine (ACh) in tissue. The inhibitive action results in a cholinergic crisis in the synapses between the nerves that control muscle contraction. If the ACh cannot be broken down, muscles are prevented from relaxing and are effectively paralyzed. Nerve agents are considered to be major military and terrorist threats. Common names for nerve agents include Tabun (GA), Sarin (GB), Soman (GD), Cyclosarin (GF), and Venomous Agent X (VX). Nerve agents are liquids under normal temperature conditions. When dispersed, the most volatile ones constitute both an inhalation and dermal contact hazard.

A DuoDote® kit is a single, dual-chambered auto-injector containing two separate chemical nerve agent antidotes: atropine and pralidoxime chloride. It is intended for use in the event of chemical nerve agent or organophosphorus insecticide exposure.

2. Background

The U.S. Environmental Protection Agency (EPA) established a Task Force comprised of members of the Emergency Response Health and Safety Workgroup, and the CWA Preparedness Workgroup to address health and safety needs related to CWA emergencies. This Task Force included EPA regional On-Scene Coordinators (OSCs), and was led by Safety and Sustainability Division (SSD) members, representatives from EPA's Environmental Response Team (ERT), and the Chemical, Biological, Radiological and Nuclear (CBRN) CBRN Consequence Management Advisory Team (CMAT). In addition, Regional Removal Managers and Safety, Health and Environmental Management Program Managers provided input to the DuoDote® Storage and Use Protocol.

The Task Force determined that one of the health and safety needs is a more comprehensive process for the distribution and management of DuoDote® Auto-Injector kits. EPA intends to maintain a stockpile of DuoDote® kits available for use by EPA-designated personnel responding to incidents involving chemical nerve agents or organophosphorus insecticides. This would include DuoDote® Kits for use by EPA-designated laboratory personnel when working with samples suspected to contain nerve agents or organophosphorus insecticides for each of the EPA CWA laboratories. The EPA DuoDote® Kit stockpile will not be available to EPA contractors.

All EPA contractors are responsible for obtaining their own nerve agent antidote kits, medical clearances, and training sufficient to meet occupational safety and health requirements for DuoDote® kit access and usage from their employer.

2.1. Laboratories Background

The EPA developed the Emergency Response Laboratory Network (ERLN) in 2005 in response to Homeland Security Presidential Directives (HSPD) 7 and 10. The ERLN's primary mission is to integrate the Nation's federal, state, and commercial laboratories for the detection and identification of chemical, biological and radiological threats in environmental matrices to support local and state response decisions. The ERLN is administered out of the Office of Emergency Management (OEM) by CBRN CMAT within the Office of Land and Emergency Management (OLEM) and is comprised of several EPA regional laboratories and two mobile laboratories.

The OEM and the Department of Homeland Security (DHS) began discussions in 2006 to develop a means by which the ERLN could develop and maintain laboratory capability and capacity to perform analysis of environmental samples contaminated with CWA. DHS submitted a Request for Information to solicit federal and state laboratories that had the infrastructure to analyze CWA using analytical methods and dilute CWA standards for instrument calibration and quality assurance. Responding laboratories were evaluated for their potential capability to perform the analysis and their general laboratory facility infrastructure (e.g., adequate analytical instrumentation, accreditations, adequate health and safety protocols, adequate staff, etc.). DHS transferred (through Technology Transfer Agreements) complete administration of the EPA CWA labs to EPA in 2010.

One of the health and safety needs determined for the safe analysis of environmental samples with unknown concentrations of CWA materials is the distribution and management of DuoDote® Kits for each of the CWA laboratories. The EPA will maintain a stockpile of DuoDote® Kits available for use by EPA-designated laboratory personnel when working with samples suspected to contain nerve agents. This protocol, as it is written, supersedes the final version of the National EPA DuoDote® Protocol, Chemical Warfare Laboratory.

2.2. On-Scene Coordinators & Emergency Responders Background

In accordance with CERCLA and Stafford Act requirements, EPA OSCs, Special Teams, and Emergency Response personnel have the potential to respond to terrorist activities and/or organophosphate pesticide manufacturing facility incidents. These kinds of responses may include potential organophosphate or chemical warfare agent exposures. The EPA will maintain a stockpile of DuoDote® Kits available for use by EPA-designated and trained personnel when involved with activities where nerve agents are suspected to be present as per this protocol.

3. Purpose

The purpose of this document is to provide DuoDote® kit acquisition, storage, and use guidelines for EPA CWA Laboratory personnel, OSCs, Special Teams, and Emergency Response personnel agency-wide who have the potential for exposure to chemical nerve agents or organophosphorus insecticides. DuoDote® kit usage is intended for self- or "buddy" administration in the event of exposure from a chemical nerve agent (See Attachment 1). If possible, trained EMS or medical personnel should assess symptoms and administer the DuoDote® kit. Only when EMS support is not available should there be self-administration. The DuoDote® kits are to be used only by trained and medically approved EPA personnel for official duties. The administration of this kit for any other class of hazardous agents (e.g., blister) is not applicable under these guidelines.

4. Participation

EPA employee participation in this program is voluntary. Each EPA region must have a minimum of 10 emergency response participants to qualify for a box of 30 DuoDote® autoinjector kits. The removal manager for each EPA region will work with their OSCs to determine which OSCs to train to use the DuoDote® kit. For CWA laboratories, there is no minimum number

of participants, but all EPA laboratory employees with CWA nerve agent exposure potential are required to be trained and participate in the DuoDote® Program. **EPA employees who have not completed the DuoDote® program training are not allowed to use/administer DuoDote® kits,** and therefore should not be participating in CWA or organophosphorus insecticide agency activities where the potential for an exposure exists.

Currently, the following EPA regions and CWA Laboratories have agreed to participate in the DuoDote® program. Several regions will have their DuoDote® kits stored in alternate locations:

- Region 1 – Stored in Region 1
- Region 2 – Stored with CBRN CMAT's PHILIS East in Edison, NJ
- Region 3 – Stored with CBRN CMAT's PHILIS East in Edison, NJ (for OSCs); Ft. Meade, MD (for CWA Lab)
- Region 4 – Stored in Region 4
- Region 5 – Stored in Region 5
- Region 6 – Stored in Region 6
- Region 7 – Half stored in Region 5 and half Stored with CBRN CMAT's PHILIS West in Castlerock, CO
- Region 8 – Stored with CBRN CMAT's PHILIS West in Castlerock, CO
- Region 9 – Stored with CBRN CMAT's PHILIS West in Castlerock, CO
- Region 10 – Stored in Region 10 (for OSCs); R10 Laboratory, Manchester, WA (for CWA Lab)
- All 4 Special Teams – Caches stored in both PHILIS locations.

5. Qualifications and Training

EPA is responsible for ensuring employees are adequately trained, with consultation and approval from the Occupational Physician, i.e., the Contract Reviewing Medical Officer (CRMO), in the potential use of a DuoDote® autoinjector. The authorized use of a DuoDote® kit is strictly limited to those EPA personnel who have had training on "self-administration" and "buddy administration". These personnel must have a current medical clearance for field or CWA laboratory work by the Federal Occupational Health (FOH) Reviewing Medical Officer (RMO) prior to administration of these kits. Cholinesterase levels are to be determined as part of the periodic occupational medical surveillance physical examination.

Emergency responders and laboratory personnel participating in the program must complete Occupational Physician/CRMO-approved annual DuoDote® kit training which can be found in FedTalent. Participants must have annual hands-on training with the DuoDote® training kits and review the approved DuoDote® training video. (During FY21, there will be a one-time exception to this requirement, due to SARS-CoV-2, whereby hands-on training was demonstrated via virtual and video training, since participants were not encouraged to travel and congregate during the global pandemic). Training may be conducted as a group or individually but must be recorded in the Field Readiness Module. A standard 90-day grace period for exceeding the one-year mark from when the original training or last annual refresher was completed will be allowed for those personnel who are unable to take the annual training within the required time. EPA contractors are responsible for providing equivalent training materials and may be provided access to the EPA training materials or files necessary to conduct equivalent annual training externally.

If EPA emergency responders are deployed to a CWA event, the site safety officer must provide for additional "just-in-time" site-specific nerve agent antidote refresher training for personnel.

If samples are being sent to an EPA CWA laboratory for a CWA event, the EPA laboratory safety officer must provide for additional "just-in-time" nerve agent antidote refresher training for all EPA CWA laboratory personnel.

6. Roles and Responsibilities

EPA will take responsibility for stockpiling, storage, inventory control, and proper disposal of the DuoDote® nerve agent antidote kits upon expiration. Specific roles and responsibilities are highlighted below.

6.1. Office of Land and Emergency Management

The Office of Land and Emergency Management (OLEM) provides funding and long-term direction to the overall DuoDote® Program.

6.1.1. CBRN Consequence Management Advisory Team

The CBRN CMAT will provide a DuoDote® program manager to manage the overall EPA DuoDote® Program. The CMAT, in collaboration with SSD, will also provide communication to appropriate EPA personnel about the DuoDote® program. To contact the current CBRN CMAT DuoDote® program manager, refer to the **regional job aid or contact the Headquarters EOC**.

6.2. Office of Mission Support

The Office of Mission Support (OMS) will ensure SSD has adequate resources to assist OLEM with administering the DuoDote® Program.

6.2.1. Safety and Sustainability Division

The SSD will assist OLEM and the SHEMP managers with consultation and coordination with the Occupational Physician/CRMO, provide training on use of the DuoDote® kits, participate in future updates to the DuoDote® protocol, and will assist CBRN CMAT and the Regions in procurement and disposal of DuoDote® kits through the Occupational Physician/CRMO. The SSD will maintain occupational physician oversight required for this program, either through direct means or a contract vehicle (CRMO). **When notified that a DuoDote® kit was administered, The SSD will contact the Occupational Physician/CRMO.**

6.3. DuoDote® Program Manager

The CBRN CMAT DuoDote® program manager will be responsible for all program-related aspects of managing the DuoDote® program including: ensuring an annual inventory is completed by coordinating with local SHEMP managers, Removal Managers, CWA Lab Directors, and/or health and safety points of contact (HSPC); sending results of the inventories to the SSD COR national program manager; ensuring that expired kits are sent back to the manufacturer; collecting annual completion of training data from SHEMP managers/HSPCs; and verifying to the SSD COR that training was conducted annually for EPA personnel. Finally, the CMAT DuoDote® program manager, will work with the SSD COR to ensure funding for procurement of the DuoDote® kits.

6.4. Removal/Laboratory Manager and DuoDote® Program Custodian

The Removal/Laboratory Manager shall designate a DuoDote® Custodian at each region/laboratory location that is storing DuoDote® kits. The Custodian shall be a participate in the DuoDote® program and may be a SHEMP manager, an OSC, a health professional, or any other designated EPA employee as determined by management. The selected Custodian is responsible for ensuring:

- That participating employees are completing the DuoDote® training prior to any kits being sent to their location
- All applicable regional/laboratory employees are properly trained annually.

- That the stockpile/inventory of DuoDote® kits are maintained
- The kits are always accessible, stored appropriately, and accounted for and in good condition monthly.
- The monthly inventory verification information is emailed to the DuoDote® Program Manager and the local SHEMP Manager.
- Notification to the SHEMP manager and the DuoDote® Program manager if kits are deployed to the field/incident.
- To Report when a DuoDote® kit is used to the DuoDote® Program Manager, the local SHEMP Manager, and the incident Safety Officer as appropriate.
- To determine if DuoDote® kits need to be deployed based on credible intelligence.

If DuoDote® kits need to be deployed, the proper transference of responsibility to the on-site Safety Officer (or other POC) must occur, including the completion of the chain of custody form (attachment 7). Note: The Custodian may enlist the support of a contractors, grantees, or other designated employees to assist in the duties listed above. The CWA Lab Manager is also responsible for ensuring DuoDote® kits are always accessible during the analysis of unknown CWA samples.

6.5. Site Safety Officer (SO) or Medical Unit Leader (MUL)

When DuoDote® kits are deployed to the field, the Site Safety Officer, Medical Unit Leader or other designated on-site POC will use the chain of custody form (attachment 7) to gain custody/responsibility of DuoDote® kits from the Removal Manager, Custodian, or their designee. The integrity and temperature storage parameters of the kits must be consistently maintained while on a deployment site (section 7), and procedures for their continued custody/surveillance, access and use must be included in the Site Safety Plan or Site Medical Plan. In the deployed environment, kits should be inspected on a weekly basis (per section 9 of this Protocol). When the site work is completed, the Site Safety Officer, Medical Unit Leader or other designated on-site POC will return unused kits back to the Removal Manager, Custodian, or their designee using the custody form (attachment 7). If kits are used or discharged, appropriate notifications must be made (see section 10).

6.6. SHEMP Manager

The local SHEMP manager will aid in overseeing the local DuoDote® program and will ensure that EPA employees are properly enrolled in the EPA's Occupational Medical Surveillance Program (OMSP). The SHEMP manager will ensure that the Removal Manager, CWA Lab Manager, HSPC, DuoDote® Program Custodian, or other designated EPA employee, has verified that employees have completed the required DuoDote® training (See Section 5 – Qualifications and Training). The SHEMP manager is also responsible for:

- Ensuring that the monthly inventory report is received and reviewed, and that the kits are accounted for and in good condition
- Notifying the SSD Director who will ensure the Occupational Physician/CRMO is contacted if any DuoDote® kit is deployed to the field, used, discharged, lost, stolen, or requires disposal

6.7. EPA Employees

EPA employees are responsible for completing nerve agent antidote training annually and maintaining a current OMSP clearance. Employees should also notify their supervisor and SHEMP manager of any medical conditions, injuries, illnesses and/or changes that could possibly affect their medical clearance status (prompting an episodic medical clearance reassessment).

6.8. EPA Contractors

All EPA contractors are responsible for obtaining their own nerve agent antidote kits, medical clearances, and training sufficient to meet occupational safety and health requirements for DuoDote® kit access and usage from their employer. On EPA controlled sites, the contractor shall meet the EPA nerve agent antidote training and medical clearance requirements for the use of DuoDote® kits as specified in this document.

6.9. Federal Occupational Health (FOH) Clinics/Health Units

FOH health units are responsible for conducting occupational medical surveillance exams and orchestrating medical clearance review by FOH's RMO. Contact the local SHEMP manager for additional information about enrollment in the OMSP.

6.10. FOH Reviewing Medical Officer (FOH RMO)

The FOH RMO is responsible for providing EPA exam medical reviews and clearances. The FOH RMO is not responsible for providing medical direction for EPA's DuoDote® program (the Contractual RMO provides medical direction for EPA's DuoDote® program).

6.11. Occupational Physician/Contractual Reviewing Medical Officer (CRMO)

The SSD and the Occupational Physician/CRMO are responsible for managing the DuoDote® program, procuring the DuoDote® kits (prescription required) and providing medical consultation services to EPA employees. The CRMO is an occupational physician under contract to EPA for medical consultative support services. The contract for the CRMO is administered by the SSD COR.

The SSD and the Occupational Physician/CRMO will assist the agency in the procurement and distribution of the DuoDote® kits and assist with disposal of the expired DuoDote® stockpile when procurement of new kits is necessary. The Occupational Physician/CRMO will provide EPA expert medical guidance during the development and subsequent alteration of nerve-agent antidote computer-based and lecture-based training materials, and this DuoDote® protocol. The Occupational Physician/CRMO will review the training and inventory records to be certain this protocol is being followed and the supply of DuoDote® kits is adequate.

Where needed, the Occupational Physician/CRMO will provide medical consultation to EPA management during a nerve agent related emergency response, or after DuoDote® kit use. In this role, the Occupational Physician/CRMO may offer ongoing health information to individual employees but will not assume the role of an employee's primary care or treating physician. The workplace response to any medical emergency should focus on alerting 911. If needed, the Occupational Physician/CRMO may serve as liaison between the EPA and the employee's health care provider or local emergency department to ensure that the employee's health needs are met in a timely manner for ongoing care.

6.12. SSD Contract Officer Representative (COR)

The SSD COR is responsible for administering and managing the medical consultation occupational physician contract for EPA. The SSD COR assists EPA in the acquisition of DuoDote® kits and is the liaison between EPA and the Occupational Physician/CRMO ensuring the Occupational Physician/CRMO conducts annual verification of EPA's CWA DuoDote® program.

7. Storage

DuoDote® kits must be stored at room temperature – typically about 25°C (77°F) – and must be protected from freezing. Shelf life is approximately four years, and an expiration date is displayed on each kit by the manufacturer. Follow the manufacturer's guidance and any FDA updates regarding expiration. Re-supply should be planned six months in advance of expiration, or if a response situation presents a current need for resupply. In certain circumstances, DuoDote® kit expiration dates may be extended through the U.S. Food and Drug Administration (FDA). EPA will ensure that documentation is kept with the kits should this happen.

CBRN CMAT will stock DuoDote® kits in select EPA locations and laboratories around the country (see section 4). For long-term storage (i.e., not for immediate use), the kits will be maintained in a climate-controlled room or container until needed for deployment. The climate-controlled long-term storage room or container must have a thermometer or gauge and have a locking mechanism. An inventory sheet with sign-in, sign-out spaces, is also required to record and keep track of the deployment history and stewardship responsibility of DuoDote® kits deployed to the field or the Regions.

When needed, DuoDote® kits may be deployed to incidents, and/or provided to neighboring EPA regions, and outposted OSCs at the request of the OSC or EPA management. Kits must be issued only to trained and designated EPA users. The kits should never be removed from agency surveillance or used for personal purposes outside the agency. The kits are for on-duty staff acting in an official EPA capacity.

DuoDote® kits must be close in proximity and readily accessible (not locked) when the potential exists to use the kits. OSCs must notify their management when checking out DuoDote® kits. The OSC will fill out the Chain of Custody form (Attachment 7) once approval is granted by their manager.

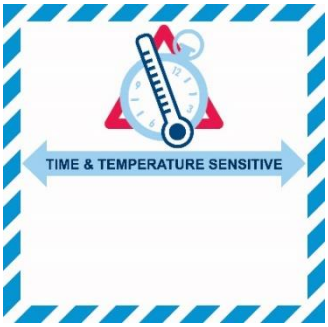
When DuoDote® kits are deployed in the field, they will be stored in durable, waterproof cases. The cases will be appropriately labeled and marked (See Attachment 1). It may not be feasible to store the DuoDote® kits on-site in the emergency response vehicles due to the storage temperature limits. Emergency responders should ensure temperatures of the kits remain at room temperature. The storage recommendations are:

- Per the manufacturer's specifications, store at typical room temperature (70-80°F); excursions are permitted from 59-86°F (15ºC to 30ºC). If DuoDote® kits reach 32°F (frozen) or are left open to direct sunlight, tag the affected DuoDote® kit(s) out of service and contact the DuoDote® Program Coordinator who will consult the SSD and the Occupational Physician/CRMO to determine the disposition of the affected kits.
- Keep from freezing
- Protect from light

8. Shipping/Deployment

According to the International Air Transport Association (IATA) Program for Pharma/Healthcare products, DuoDote® Kits are a pharmaceutical product, since a prescription is needed to purchase the kits. For distribution purposes, the manufacturer has placed each auto-injector inside a separate plastic pouch which is then stored inside a cardboard carton. An individual cardboard carton or a shipping box containing individual cartons of DuoDote® auto-injector kits can be shipped, via standard air transportation. Up to 30 cartons can be added to one shipping box.

Under the IATA Program for Pharma/Healthcare products, **shippers must attach a time and temperature (T&T) sensitive label to the outer packaging** (https://www.iata.org/en/programs/cargo/pharma/). A secondary T&T sensitive label may be attached to the inner packaging but is not required. The T&T sensitive label will always reflect the temperature external (or ambient temperature) to the package allowed during transportation and distribution and not the actual product (internal) temperature. The correct usage and affixing the label, does not guarantee that the shipment will always be transported at the required temperature range. It will depend on the booked air carrier service and the airlines/transporter's infrastructure and capabilities.



When deploying DuoDote® Kits, the shipper must legibly write the temperature range of 15º Celsius to 30º Celsius (59º F to 86ºF) on the lower section of the T&T sensitive label. It should always be recorded in Celsius and in English. It is the responsibility of the shipper to ensure that the T&T sensitive label is applied properly for any time and temperature sensitive healthcare cargo shipments booked as such, and that the kits are maintained at the appropriate temperature throughout shipment and storage.

It is highly recommended that, when deploying these kits to the field, an automated temperature logger accompanies them during shipment. The use of an automated temperature logger will then allow effective temperature tracking of the DuoDote® kits while in the field environment.

A standard "Air Waybill" can be utilized for the shipment of the DuoDote® Kits. In preparing the standard Air Waybill for the shipment of the DuoDote® Kits, the temperature range must be added either manually or electronically to the standard Air Waybill. In addition, the Emergency Contact number to be completed on the waybill should be designated as the Shipper's 24-hour contact number in case issues arise with the shipment of the DuoDote® kits.

When shipping DuoDote® Kits to the field, EPA personnel and contractors must use a Chain of Custody (COC) form to maintain a "legal paper trail" and track of all DuoDote® kits from one location to the next (See Attachment 7), Items recorded on the COC should include the DuoDote® Kit Lot Number(s), dates the kits were shipped, the locations the kits were shipped from, dates the kits were received by the recipient(s) and the recipient locations the kits were shipped to. In addition, the shipper must sign the COC form relinquishing the DuoDote® Kits for shipment and the recipient must sign the accompanying COC form, when the kits are delivered to requested location. The COC form will be kept with the DuoDote® kits.

9. Maintenance, Inspection and Disposal

All DuoDote® kits will be inspected and maintained as follows:

- DuoDote® kits are pharmaceuticals. They will be stored in a locked area, inspected, inventoried, and maintained according to the manufacturer's instructions and the requirements listed above.
- Designated staff (e.g., the CWA Lab Director/Lab POC, EPA warehouse manager, Superfund Technical Assessment and Response Team [START] equipment manager, etc.) will complete monthly inspections of the kits at select EPA storage locations (e.g., EPA warehouse, contractor warehouse, EPA laboratories).
- Monthly inspection will verify the number of DuoDote® kits on hand and the condition of the units and ensure that the DuoDote® kits have not exceeded their expiration date. Inspection forms will be completed during the monthly inspection (See Attachment 2).

- Annually, the DuoDote® Program Manager will compile these monthly inspection inventory verification logs and the annual log of up-to-date training of employees authorized to use the DuoDote® kits, and will send this documentation to the SSD COR (who will forward to the Contractual RMO) as well as archive it in accordance with federal requirements.
- **When DuoDote® kits are deployed**, the OSCs, EPA Incident Commanders, Site Safety Officers, Medical Unit Leaders, and designated incident staff (e.g., START contractors, ERRS contractors, Logistics Section Chief) will be responsible for overseeing **weekly inspections of their assigned DuoDote® kits**. All inspections will be documented using the form provided in Attachment 2.
- DuoDote® kits that fail an inspection will be immediately tagged and taken out of service. The individual taking the equipment out of service must immediately notify the regional SSD Manager, Incident Command System (ICS) Safety Officer, and the designated staff of the originating EPA storage location (e.g., EPA warehouse manager, START equipment manager).
- The regional SHEMP Manager or designee, with assistance from CBRN CMAT and SSD, will be responsible for the proper disposal of expired DuoDote® kits through the manufacturer, as well as requesting the procurement of new DuoDote® kits.

10. Reporting and Notification

EPA-designated personnel are responsible for maintaining possession and integrity of the issued kits. Should a kit be lost, stolen, damaged or used, the notification process is similar to a typical safety event. The OSC in the field or CWA lab employee, must notify management and the Regional SHEMP manager (or another designated person), who will then inform the EPA's DuoDote® program coordinator (CMAT). The Regional SHEMP manager will also notify SSD who will inform the Occupational Physician/CRMO. At a minimum, the report should include the name of the person **if used**, the circumstances surrounding the incident (e.g., nature of the exposure, time, event location...etc), the local point of contact's name and phone number and whether any medical attention was required (See Attachment 3, DuoDote® Notification Form). If the kit is stolen, the OSC should notify Federal Protective Service who will work with local jurisdictions on the matter. In the case of disposal or a lost or used kit, fill out Attachment 7 and annotate the specific situation (such as "sent back to manufacturer due to expiration" in the case of disposal).

11. Indications for Use

In the event of life-threatening exposure from organophosphorus nerve agents or insecticides, anyone trained on DuoDote® kits use can administer aid to an exposed person. **Either call emergency medical services to request medical assistance or call 911 (or ensure that someone else is completing this task).** While there are no contraindications to the use of the DuoDote® auto-injector, DuoDote® kits should be used with extreme caution in persons with any underlying health conditions.[1]

When the presence of a nerve agent has not been established, and symptoms of poisoning are *not* severe, DuoDote® should be used with extreme caution in people with heart disease, arrhythmias, recent myocardial infarction, severe narrow angle glaucoma, pyloric stenosis, prostatic hypertrophy, significant renal insufficiency, chronic pulmonary disease or hypersensitivity to any component of the product. **The DuoDote® auto-injector is intended as an initial treatment of the**

[1] Risks include tachycardia, palpitations, premature ventricular contractions, flutter, fibrillation, asystole, and myocardial infarction, severe narrow-angle glaucoma, pyloric stenosis, prostatic hypertrophy, significant renal insufficiency, chronic pulmonary disease, or hypersensitivity to any component of the product. Other cardiovascular adverse reactions have also been reported. Use caution in patients with known CV disease or conduction problems. https://www.meridianmeds.com/products/duodote; https://www.meridianmeds.com/sites/default/files/duodote_presentation_pp-duo-usa-0032.pdf

symptoms of organophosphorus insecticide or nerve agent exposures, followed by immediate and professional medical care.

12. Signs and Symptoms

The following mnemonics – SLUDGEM, DUMBBELS, and OBSERVE – may be used to help identify the general signs and symptoms of nerve agent exposure:

SLUDGEM

- **S**alivation
- **L**acrimation
- **U**rination
- **D**efecation
- **G**astric pain
- **E**mesis
- **M**iosis

DUMBBELS

- **D**iarrhea
- **U**rination
- **M**iosis
- **B**ronchorrhea
- **B**radycardia
- **E**mesis
- **L**acrimation
- **S**alivation

OBSERVE

- **O**thers affected suddenly
- **B**ody tremors/twitching
- **S**alivation
- **E**ye tearing
- **R**estricted breathing
- **V**omiting
- **E**xcessive sweating

More specific signs and symptoms of mild/moderate and severe nerve agent exposure include:

Mild to Moderate Exposure:

- Miosis (pinpoint pupils)
- Lacrimation (excessive tear production)
- Blurred or dim vision
- Rhinorrhea (excessively runny nose)
- Salivation (excessive); drooling
- Chest tightness or difficulty breathing
- Coughing, wheezing
- Increased airway secretions (bronchorrhea)
- Sweating (increased)
- Muscle twitching (localized)
- Weakness
- Tremors (body-wide)
- Tachycardia or bradycardia (abnormal heart rate)
- Nausea, vomiting, stomach cramps

Severe Exposure:

Any of the symptoms of mild/moderate exposure, plus:

- Convulsions (seizures)
- Muscle twitching (severe and body-wide)
- Bronchorrhea (copious secretions from lungs and airways)
- Difficulty breathing (severe)
- Flaccid paralysis; limpness
- Defecation (involuntary)
- Urination (involuntary)
- Strange or confused behavior
- Loss of consciousness
- Cessation of breathing

Signs and symptoms may vary depending on route of exposure (inhalation or transdermal).
An exposed person may not exhibit all the signs and symptoms in these lists. If the exposed person experiences **two or more MILD/MODERATE symptoms OR one SEVERE symptom,** responders should administer treatment using a DuoDote® kit (See Section 13 for Treatment).

13. Treatment

The nervous system controls bodily functions by secreting chemical transmitters that act as "instructions" to nerves, muscles, and glands at the nerve endings. These neurological instructions come in two forms:

- Stimulate (move or work)
- Relax (stop or rest)

When a toxic nerve agent is present, it interferes with the normal instructions of chemical transmitters that direct the muscle or gland to return to an unstimulated, relaxed state. By interfering with normal chemical checks and balances, toxic nerve agents overstimulate the nerve endings and central nervous system. This overstimulation causes muscles and certain glands to overreact, resulting in SLUDGEM signs and symptoms of nerve agent exposure.

Nerve agent exposure can be reversed with timely use of a DuoDote® kit (See Attachment 4). Each prefilled DuoDote® auto-injector delivers the following as an intramuscular dose:

- 2.1 milligrams (mg) of atropine in 0.7 milliliter (mL) of sterile, pyrogen-free solution containing 12.47 mg glycerin and not more than 2.8 mg phenol, citrate buffer, and water for injection. The pH range is 4.0 to 5.0.

- 600 mg of pralidoxime chloride in 2 mL of sterile, pyrogen-free solution containing 40 mg benzyl alcohol, 22.5 mg glycine, and water for injection. The pH is adjusted with hydrochloric acid. The pH range is 2.0 to 3.0.

Pre-measured doses in auto-injectors should be safe for most adults, barring any underlying medical conditions or vulnerabilities.[2] Auto-injector use is intended to relieve respiratory distress and seizures. However, multiple doses (**no more than three**) may be required to alleviate the symptoms (See Section 5 for Qualifications and Training for Use).

13.1. Application for Mild/Moderate Symptoms

First Dose: In the situation of known or suspected organophosphorus exposure, administer one (1) DuoDote® injection into the *mid-lateral thigh* if the responder experiences **two or more MILD/MODERATE symptoms** of nerve gas or insecticide exposure (See Attachment 4). Seek professional medical care immediately and notify the Safety Officer.

- Trained personnel may administer a single dose of DuoDote® to an individual displaying mild or moderate symptoms. Trained personnel may self-administer a single dose of DuoDote® if experiencing mild or moderate symptoms.
- **After the auto-injector triggers, hold the DuoDote® Auto-Injector firmly in place against the injection site for approximately 10 seconds.**

- **Wait 10 to 15 minutes for DuoDote® to take effect**. If, after 10 to 15 minutes, the responder does not develop any of the SEVERE symptoms listed above, no additional DuoDote® injections are recommended, but **professional** medical care must be sought immediately.

- **Additional Doses:** If, at any time after the first dose, the responder **develops any of the SEVERE symptoms**

[2] According to the manufacturer, there are no contraindications to the use of DuoDote® kits. Cardiovascular risks include tachycardia, palpitations, premature ventricular contractions, flutter, fibrillation, asystole, and myocardial infarction. Other cardiovascular adverse reactions have also been reported. Use caution in patients with known CV disease or conduction problems. https://www.meridianmeds.com/sites/default/files/duodote_presentation_pp-duo-usa-0032.pdf#page=3&zoom=100,0,0

listed above, **administer two (2) additional DuoDote® injections in rapid succession**, and immediately seek **professional** medical care.

13.2. Application for Severe Symptoms

If a patient has any of the **SEVERE** symptoms listed above (See Section 11), immediately administer **three** (3) DuoDote® injections into the patient's mid-lateral thigh in rapid succession (consecutive injections), and immediately seek **professional** medical care.

- **No more than three doses of DuoDote® should be administered. Emergency medical response personnel may be provided additional autoinjectors during the response, if requested. Generally, atropine alone is the primary agent required for ongoing treatment of severe nerve agent poisoning.**

- **After the auto-injector triggers, hold the DuoDote® Auto-Injector firmly in place against the injection site for approximately 10 seconds.**

- Close supervision of all individuals exposed to nerve agent is indicated for at least 48 to 72 hours.

13.3. Post-Treatment Actions

The following should be conducted post treatment with a DuoDote® kit:

- Once a DuoDote® injection is administered, the responder will notify site and/or laboratory personnel of the danger. All activities should stop, and the site or laboratory should be evacuated until the site is reassessed.
- The laboratory worker, responder (and buddy) should egress from the contaminated area and await expedited decontamination before advancing for further medical evaluation. Removal of outer PPE and/or clothing can reduce 80-90% of physical contamination in almost all cases.[3]
- Once decontaminated, the treated employee will be transported to the nearest Emergency Medical Facility for further medical evaluation.
- Every attempt should be made to send the used DuoDote® Auto-Injector with the treated employee to the treatment facility. It should be in the original pouch with the needle bent back.
- Notifications must be made to the EPA Regional Removal Manager or Laboratory Director as appropriate, and the SHEMP Manager (See **Attachment 3** for the proper documentation and notification protocol). The EPA Injury and Illness Reporting and Workers Compensation Process must be started as soon as feasibly possible.

[3] ECBC, 2013. Updated Guidelines for Mass Casualty Decontamination During a HAZMAT/Weapon of Mass Destruction Incident, Volumes I and II. ECBC-SP-036. Page 3.

13.4. Inadvertent Injection

In cases where DuoDote® is inadvertently administered to people who are not poisoned with nerve agent or organophosphorus insecticide, the following:

- Effects on their ability to function normally may occur.
- Atropine 2 mg IM, roughly the equivalent of one DuoDote® autoinjector, when given to healthy male volunteers, is associated with minimal effects on visual, motor, and mental functions, though unsteadiness walking and difficulty concentrating may occur. Atropine reduces body sweating and increases body temperature, particularly with exercise and under hot conditions.
- Atropine 4 mg IM, roughly the equivalent of two DuoDote® autoinjectors, when given to healthy male volunteers, is associated with impaired visual acuity, visual near point accommodation, logical reasoning, digital recall, learning, and cognitive reaction time. Ability to read is reduced or lost. Subjects are unsteady and need to concentrate on walking. These effects begin about 15 minutes to one hour or more post-dose.
- Atropine 6 mg IM, roughly the equivalent of three DuoDote® autoinjectors, when given to healthy male volunteers, is associated with the effects described above plus additional central effects including poor coordination, poor attention span, and visual hallucinations (colored flashes) in many subjects. Frank visual hallucinations, auditory hallucinations, disorientation, and ataxia occur in some subjects. Skilled and labor-intense tasks are performed more slowly and less efficiently. Decision making takes longer and is sometimes impaired.

Staff who are mistakenly injected with DuoDote® should avoid potentially dangerous overheating, as well as vigorous physical activity. They should not operate motor vehicles or hazardous equipment and should seek medical attention as soon as feasible.

Part 2: Instructions for the Use of the DuoDote® Auto-Injector

IMPORTANT: Do Not Remove Gray Safety Release until ready to use.

CAUTION: Never Touch the Green Tip (Needle End)!

DuoDote® kits can be self-administered by a responder or a responder can administer DuoDote® to an affected buddy. The ten steps for use include (See Attachments 1 and 4 for more details):

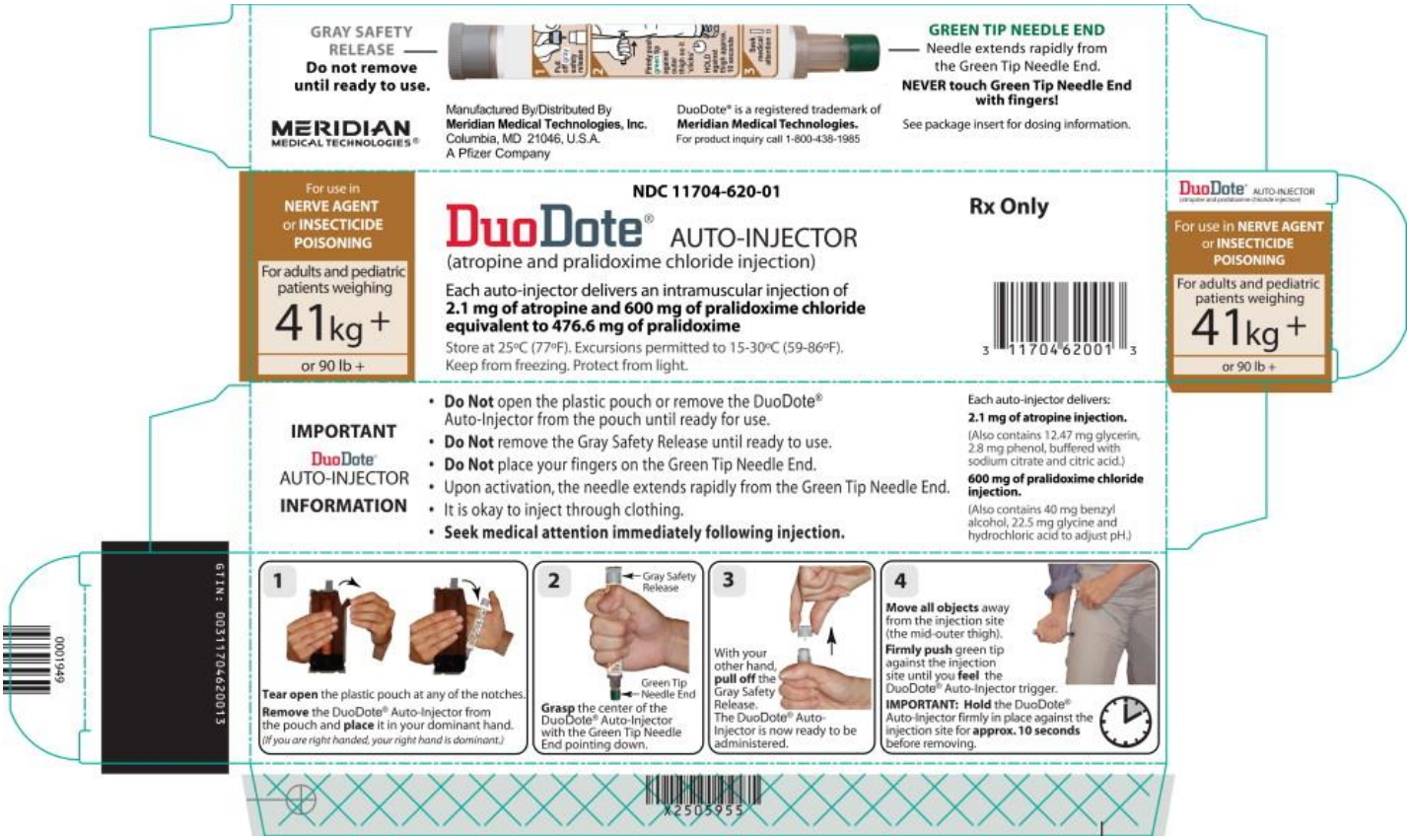
1) Either call to request medical assistance through the Command Post or call 911 or ensure that someone else is completing this task.
2) Tear open the plastic pouch at any of the notches. Remove the DuoDote® Auto-Injector from the pouch.
3) Place the DuoDote® Auto-Injector in your dominant hand. (If you are right-handed, your right hand is dominant.) Firmly grasp the center of the DuoDote® Auto-Injector with the Green Tip (needle end) pointing down.
4) With your other hand, pull off the Gray Safety Release. The DuoDote® Auto-Injector is now ready to be administered.
5) The injection site is the mid-outer thigh area. The DuoDote® Auto-Injector can inject through clothing. **However, make sure pockets at the injection site are empty.**
6) Swing and firmly push the Green Tip straight down (a 90° angle) against the mid-outer thigh. Continue to firmly push until you feel the DuoDote® Auto-Injector trigger.

IMPORTANT: After the auto-injector triggers, hold the DuoDote® Auto-Injector firmly in place against the injection site for approximately 10 seconds.

7) Remove the DuoDote® Auto-Injector from the thigh and look at the Green Tip (see Attachment 1). If the needle is visible, the drug has been administered. If the needle is not visible, check to be sure the Gray Safety Release has been removed, and then repeat above steps beginning with Step 4, but push harder in Step 5.
8) After the drug has been administered, carefully push the needle against a hard surface to bend the needle back against the DuoDote® Auto-Injector.
9) Put the used DuoDote® Auto-Injector back into the plastic pouch, if available. Leave used DuoDote® Auto-Injector(s) with the patient to allow other medical personnel to see the number of DuoDote® Auto-Injector(s) administered.
10) Immediately move yourself and the patient away from the contaminated area.

NOTE: Administer additional dose (up to three total doses can be administered) if moderate or severe signs and symptoms indicate.

Attachment 1. DuoDote® Auto-Injector Package Instructions



Attachment 2. DuoDote® Kit Inspection Form

Each DuoDote® kit must be inspected monthly. Please submit the form to the designated CWA Lab Director or Removal Manager as appropriate, and SHEMP manager.

DATE	INSPECTOR	LOT NUMBER	EXPIRATION DATE	EXPIRED Y / N	GOOD CONDITION / STORED PROPERLY / PROPER TEMPERATURE (~77°F) Y / N

Attachment 3. DuoDote® Kit Notification Form

This form is used in the event a DuoDote® kit is used, discharged, lost, stolen, or requires disposal. The CWA Lab Director or Removal Manager as appropriate will ensure that the SHEMP manager is notified using this form. When a DuoDote® Kit has been used, discharged, damaged, lost, stolen, or requires disposal it is necessary to notify the SHEMP manager within 24 hours. The SHEMP manager will notify the SSD Director or SSD COR who will contact the Occupational Physician/CRMO. **Please provide the following information:**

Date of use discharge damage or loss: _____ Number of DuoDote® kits: _____

Time of use discharge damage or loss: _____

Reason for DuoDote® Notification: (please check one)

❑ Self-Administered ❑ Stolen (Attach Police Report) ❑ Damaged

❑ Administered to Patient ❑ Disposal Required ❑ Lost

Brief description of the incident:

_____

_____

_____

_____

Adverse reactions to administration:

_____

_____

_____

_____

Name of person completing form: _____

Name of reporting agency: _____

Contact phone number: _____

Signature of person completing form: _____

Attachment 4. Pictorial Field Guide for DuoDote® Auto-Injector Use

1)	• **Before administering care to the injured person, assess the scene and the person to ensure it is safe to proceed**. • If the person is awake and responsive, obtain consent. • Tell the person your name, describe the type and level of training, state what you think is wrong and what you plan to do. Ask permission to provide care. • If the person is unresponsive, shout to get the person's attention and tap their shoulder. Proceed with care after 5-10 seconds. • Tear open the plastic pouch at any of the notches. • Remove the DuoDote® Auto-Injector from the pouch.	
2) 3)	• Place the DuoDote® Auto-Injector in your dominant hand. • Firmly grasp the center of the DuoDote® Auto-Injector with the **Green Tip** (needle end) pointing down. • With your other hand, pull off the Grey Safety Release, taking care never to touch the **Green Tip.** • Keep fingers clear of both ends of the auto-injector. • You are now ready to inject.	
4) 5)	• The injection site is the mid-outer thigh area. • You <u>can</u> inject through clothing, but make sure that pockets are empty. • Swing and firmly push **Green Tip** straight down (at a 90º angle) against mid-outer thigh, continuing to push firmly until you feel the auto-injector trigger. • After the DuoDote® Auto-Injector triggers, hold it firmly in place against the injection site for 10 seconds.	 
6) 7) 8) 9)	• After injecting, remove the DuoDote® Auto-Injector from thigh and inspect the Green Tip; if the needle is visible, then the injection was successful. • If the needle is not visible, make sure the Gray Safety Release is removed and repeat the preceding injection steps. • Push the exposed needle against a solid surface until it bends back, then put the used auto-injector back in the plastic pouch. • Keep used auto-injector(s) with the responder so other medical personnel will be aware of how many injections were administered. • Immediately move away from the contaminated area, decontaminate skin and clothing, and seek professional medical treatment.	
10)	• Administer additional dose **(up to three)** if moderate or severe signs and symptoms indicate.	

Attachment 5. Acronyms and Abbreviations

ACh	Acetylcholine
AChE	Acetylcholinesterase
CBRN	Chemical, Biological, Radiological, and Nuclear
CMAT	CBRN and Consequence Management and Advisory Team
COR	Contracting Officer Representative
CWA	Chemical Warfare Agent
EMS	Emergency Medical Services
EPA	U.S. Environmental Protection Agency
ERRS	Emergency and Rapid Response Services
ERT	Environmental Response Team
FDA	U.S. Food and Drug Administration
FOH	Federal Occupational Health
GA	Tabun
GB	Sarin
GD	Soman
GF	Cyclosarin
HSPC	Health and safety point of contact
ICS	Incident Command System
MG	Milligram
ML	Milliliter
OLEM	Office of Land and Emergency Management
OMS	Office of Mission Support
OMSP	Occupational Medical Surveillance Program
OSC	On-Scene Coordinator
CRMO	Contract Reviewing Medical Officer
SHEMP	Safety, Health and Environmental Management Program
SOG	Standard Operating Guidelines
SSD	Safety and Sustainability Division
START	Superfund Technical Assessment & Response Team
T&T	Time and Temperature
VX	Venomous Agent X

Attachment 6. Glossary

Acetylcholine: A neurotransmitter active in the transmission of nerve impulses

Acetylcholinesterase: An enzyme that occurs chiefly in cholinergic nerve endings and promotes the breakdown of acetylcholine

Acute: Having a sudden onset, sharp rise, and short course; characterized by sharpness or severity of sudden onset

Airway secretions: Respiratory mucus (bronchial, pulmonary)

Blurred vision: A lack of sharpness of vision resulting in the inability to see fine detail or in objects appearing out of focus

Bradycardia: A slower than normal heart rate, usually defined as fewer than 60 beats per minute

Bronchorrhea: The excessive discharge of mucus from the air passages of the lung

Chest tightness: An unpleasant sensation of tightness, heaviness, or pressure in the chest; pain or discomfort that occurs between the upper belly area and the lower neck

Cholinergic crisis: A clinical condition that develops as a result of overstimulation of nicotinic and muscarinic receptors at the neuromuscular junctions and synapses. This is usually secondary to the inactivation or inhibition of acetylcholinesterase (AChE), the enzyme responsible for the degradation of acetylcholine (ACh). Symptoms include cramps, increased salivation, lacrimation, muscular weakness, paralysis, muscular fasciculation, diarrhea, and blurry vision

Convulsion: An abnormal violent and involuntary contraction or series of contractions of the muscles

Copious: Excessive or large amounts

Cough: A rapid expulsion of air from the lungs, typically in order to clear the lung airways of fluids, mucus, or other material

Defecation: Elimination of wastes and undigested food, as feces, from the rectum

Diarrhea: Unusually loose or watery stools

Difficulty breathing: Also called shortness of breath or dyspnea; the sensation of being unable to get enough air; often described as an intense tightening in the chest, air hunger, breathlessness; or a feeling of suffocation

Dimness of vision: The partial loss of sight, especially in one eye, without detectable disease of the eye

Drooling: Saliva trickling from the mouth

Emesis: An act or instance of vomiting

Flaccid paralysis: Weakness or loss of muscle tone; may affect muscles of the respiratory tract and pharyngeal (throat) region; paralysis in which muscle tone is lacking in the affected muscles and in which reflexes are decreased or absent

Gastric pain: Pain or discomfort in the abdomen; also called abdominal pain or stomachache

Generalized: Affecting the whole of the body, or the whole of a part of the body (for example, generalized abdominal pain).

Involuntary: Done without conscious control

Lacrimation: The secretion of tears, especially when abnormal or excessive; teary eyes; watery eyes

Limpness: Floppiness; *See also* flaccid paralysis

Localized: Restricted or limited to a specific body part or region

Loss of consciousness: Inability to respond to people, stimuli, and activities; interruption of awareness of oneself and one's surroundings; also called unconsciousness, coma, comatose state, or fainting (when brief in duration)

Miosis: Excessive smallness or contraction of the pupil of the eye; pinpoint pupils

Muscle twitching: The simultaneous contraction of contiguous groups of muscle fibers; fasciculation

Nausea: Stomach distress with distaste for food and an urge to vomit

Nerve agent: A toxic, usually odorless organophosphate (such as sarin, tabun, or VX) that is used as a chemical weapon in gaseous or liquid form, disrupts the transmission of nerve impulses, and may cause breathing difficulties, coughing, vomiting, muscle weakness or paralysis, convulsions, coma, and death

Pinpoint pupils: *See* miosis

Restricted breathing: *See* difficulty breathing

Runny nose: Excess drainage, ranging from a clear fluid to thick mucus, from the nose and nasal passages; rhinorrhea

Salivation: The flow of saliva, especially in excess

Secretion: A substance, such as saliva, mucus, tears, bile, or a hormone, that is secreted by the body

Seizure: A sudden attack (as of disease), especially the physical manifestations (such as convulsions, sensory disturbances, or loss of consciousness) resulting from abnormal electrical discharges in the brain

Stomach cramp: A sudden, tight feeling in the muscles of the abdomen (belly)

Strange or confused behavior: Confusion; disturbance of consciousness characterized by inability to engage in orderly thought or by lack of power to distinguish, choose, or act decisively

Special Teams: refers to EPA's Environmental Response Team (ERT); CBRN Consequence Management Advisory Team (CMAT), Radiological Emergency Response Team (RERT), or National Criminal Enforcement Response Team (NCERT)

Sweating, excessive: Hyperhidrosis; overproduction of sweat

Tachycardia: A rapid or irregular heart rate, usually defined as greater than 100 beats per minute.

Teary eyes / eye tearing: *See* lacrimation

Tremor: A trembling or shaking, usually from physical weakness, emotional stress, or disease

Urination: The discharge of urine from the body; the act or process of urinating

Vomiting: The act or instance of disgorging the contents of the stomach through the mouth; emesis

Weakness: A decrease in muscle strength; a feeling of body fatigue or tiredness; asthenia

Wheezing: Breathing with difficulty, usually with a whistling sound.

Attachment 7. DuoDote® Kit Chain of Custody Record

COC No.:
Carrier:

DuoDote™ Kit Lot Number:		**Shipped From:**	**Date Shipped:**	**Shipped To:**	**Date Received**:
DuoDote™ Kit Lot Number:		**Shipped From:**	**Date Shipped:**	**Shipped To**:	**Date Received:**
Special Instructions:					
Relinquished by:	**Agency/Company:**	**Date/Time**:	**Received by**:	**Company**:	**Date/Time:**
Relinquished by:	**Agency/Company:**	**Date/Time:**	**Received by:**	**Company:**	**Date/Time**:
Relinquished by:	**Agency/Company**:	**Date/Time:**	**Received by**	**Company:**	**Date/Time:**

Note: This Chain of Custody Form is formatted and saved as a PDF. If you do not possess a copy of the PDF version, please reach out to the National DuoDote® Program Manager for a copy.