



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Vaccine Management Plan Templates

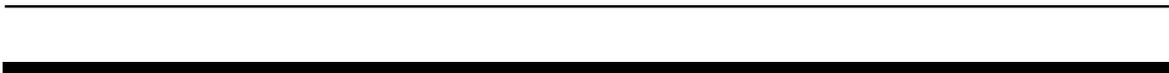


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Contact List

Vaccine Coordinators			
Vaccine Coordinators (Name/Title)	Phone Number (home, cell)	Alternate Phone Number (home, cell)	Email Address
Primary:			
Secondary:			
Alternate (back-up):			
Resources Contact List			
Resources	Phone Number	Email Address	
Local Health Department (LHD)			
DSHS Public Health Region (PHR)			
DSHS Immunization Disaster Response		immdro@dshs.texas.gov	
Additional Resources	Company / Entity Name	Phone Number	Email Address
Electric/Power/ Utility Company			
Refrigerator repair			
Freezer repair			
Data logger repair/recalibration			

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Texas DSHS Immunization Routine Vaccine Storage and Handling Plan

Instructions: All Texas DSHS Immunization enrolled sites are responsible for routine management of vaccine inventory. Once completed, this template will serve as the required *Routine Vaccine Storage and Handling Plan*.

This plan should be reviewed **annually** or whenever there are changes to the signing clinician, vaccine coordinators, or vaccine storage equipment. The most current *Routine Vaccine Storage and Handling Plan* will be reviewed during Texas DSHS Immunization Program Compliance Site Visits (if applicable).

A copy of this plan, along with the Emergency Vaccine Storage and Handling Plan, must be posted on or near all refrigerators and freezers that store vaccine.

Clinic Name:	Clinic Address:
PIN:	Email Address:
Telephone number:	Fax Number:
Signing Clinician or Equivalent:	Primary Vaccine Coordinator:
Back-up Vaccine Coordinator:	Alternate Back-up:
Person(s) Responsible for Monthly Vaccine Count:	Person Responsible for Monthly Vaccine Reporting and Ordering:
Person Responsible for Rotating Vaccine Inventory:	Person Responsible for Receiving and Storing Vaccine Shipments:

Routine Vaccine Storage and Handling Plan reviewed and updated by:

Name:	Title:
Signature:	Date of Last Review:

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Texas DSHS Immunization Procedures for Routine Storage and Handling of Vaccine Temperature Monitoring

- _____ is responsible for monitoring data logger(s) and recording temperatures of all vaccine storage units.
In their absence, _____ is responsible for monitoring and recording temperatures.
- A *Temperature Recording Form* (stock no. EC-105) must be posted on or near all units storing vaccine.
- Current refrigerator/freezer temperatures must be recorded twice daily on the *Temperature Recording Form* (stock no. EC-105).
- Staff are required to record min/max temperatures at least once daily, preferably in the morning.
- Results of each temperature check must be documented on the *Temperature Recording Form* (stock no. EC-105). The time (hour and minute) and the initials of the staff member monitoring/recording the information must be documented on the form.
- Do not round the temperatures up or down – record only the number to the left of the decimal point.
- If an out-of-range temperature is observed, immediately contact your Responsible Entity (RE) (DSHS LHD or PHR) and complete the “Vaccine Storage Troubleshooting Record” on page 3 of the *Temperature Recording Form* (stock no. EC-105).

Vaccine Storage

- Clinics enrolled in the Texas DSHS Immunization Program are required to have the appropriate equipment to store vaccine that will maintain proper temperatures.
- Refrigerator/freezer units must be large enough to hold DSHS and private vaccine during back-to-school or flu season without crowding.

- In order of preference, DSHS recommends the use of a:
 - 1) pharmaceutical, purpose-built unit,
 - 2) stand-alone refrigerator and stand-alone freezer, or
 - 3) household combination unit, using only the refrigerator section unless the refrigerator and freezer compartments have separate thermostat controls (they must have separate exterior doors). A stand-alone freezer must be used when using a combination unit for refrigerated vaccine.
- Small combination refrigerator-freezer units outfitted with a single external door (dorm-style) are **never** allowed for the storage of vaccine.
- The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C) for vaccine viability.
- The freezer compartment must maintain temperatures between -58°F and +5°F (-50°C and -15°C).
- Place water bottles (labeled "Do Not Drink") on the top shelf, under the cold air vent, on the floor of the unit, in the door, along both sides of the walls, and at the back of the refrigerator.
 - Water bottles are not recommended for certain pharmaceutical and purpose-built units. Follow the manufacturer's guidance in those instances.
- Place frozen water bottles along both sides of the walls, at the back, on the floor, and in the door of the freezer.
- The ultra-cold freezer must maintain temperatures between -112°F and -76°F (-80°C and -60°C).
- Diluents that are not packaged with vaccine may be stored outside of the storage unit or in the door of the refrigerator. DO NOT freeze diluent.
- Do not store food or drinks in the same refrigerator or freezer as vaccine.
- Do not store lab specimens on the same shelf or above vaccine. Store specimens below vaccine or in a separate storage unit.
- Refrigerators and freezers storing vaccine must be plugged directly into a wall outlet with a plug guard installed. Multi-strip outlets are not allowed.

Vaccine Shipping and Receiving Procedures

- _____ is responsible for receiving and storing vaccine shipments. In their absence, _____ is responsible for receiving and storing vaccine shipments.

- Staff must ensure that an accurate shipping address and delivery hours are entered into the Vaccine Allocation Ordering System (VAOS) or Electronic Vaccine Inventory (EVI) system.
- Staff must always accept vaccine shipments in a timely manner. Never refuse or return vaccine shipments without specific instructions from DSHS.
- Texas DSHS Immunization Unit recommends all sites have a protocol to ensure the vaccine is stored immediately and appropriately upon arrival. The following steps must be taken when a vaccine shipment arrives:
 - Check the vaccine received against the packing list to verify all vaccines have been received.
 - Verify the packing list against the order placed in VAOS/EVI once the vaccine has been properly stored. Receive the order in VAOS/EVI.
 - Ensure adequate diluent is included for vaccines requiring reconstitution.
 - IMMEDIATELY contact the DSHS if vaccine or diluent was ordered and not received.
 - Place vaccine in the appropriate storage unit immediately.
 - Ensure vaccines with longer expiration dates are stored behind shorter-dated vaccines. This ensures short-dated vaccine is used first.
 - If the data logger or temperature monitoring strip in the package indicates or if staff suspect that the cold chain has been compromised, staff should immediately:
 - Place the back-up data logger probe in the shipment, near the vaccine, and put the lid back on it, to gain the current temperature. Check it frequently to see when the temperature stabilizes.
 - Store questionable shipments appropriately, until official word is received from vaccine distributor.
 - If applicable, contact DSHS to inform of the temperature excursion during shipping and the viability determination made by the manufacturer.

Vaccine Ordering Procedures

- _____ is responsible for ordering vaccine.
- All vaccine orders are submitted in VAOS/EVI (unless internet access is unavailable).
- Staff are required to enter in VAOS/EVI all vaccines received, doses transferred, expired/wasted vaccine, doses administered, and a physical count of all DSHS vaccines in their inventory each month regardless of whether an order is placed.
- Staff are responsible for contacting DSHS to update provider information, including delivery address, days and hours available to receive vaccine shipments, and primary and back-up contact information.

Inventory Control including stock rotation

- _____ is responsible for managing DSHS vaccine inventory.
- _____ is responsible for reporting vaccine received, vaccine transferred, vaccine loss, and physical count in VAOS/EVI each month.
- Vaccine with the shortest expiration date must be used first.
- Staff should to notify DSHS 60-90 days prior to the vaccine expiration date.

Vaccine Loss (expired, spoiled, and wasted vaccine)

- Staff are required to follow the procedures listed below when a vaccine loss occurs:
 - _____ is responsible for completing and submitting the *Vaccine Loss Report* (VLR) in VAOS/EVI.
 - Separate expired/spoiled vaccine from the other vaccine in the storage unit immediately. Label "DO NOT USE" and call the manufacturer for further guidance. If instructed to discard the vaccine, please follow all state and jurisdictional policies for waste management.

- Report every dose of vaccine that is wasted, spoiled, or expired to the Texas DSHS Immunization Program electronically in VAOS/EVI within four days of the incident.
- The completed VLR must be printed and signed by the signing clinician who signed the Texas DSHS Immunization Agreement or a prescribing authority that is listed on the Texas DSHS Immunization Agreement.
- Staff are should to follow these procedures for returning expired or spoiled vaccine:
 - _____ is responsible for returning expired or spoiled vaccine.
 - Complete the VLR as indicated above and submit to the DSHS.
 - Once the VLR is processed, your primary vaccine coordinator will receive a shipping label via email.
 - Staff must ensure that all and only vaccines listed on that VLR are included in the box for return.
 - A copy of the VLR must be included in each box when returning expired or spoiled vaccine.
 - Shipping/Return labels expire after 30 days. If UPS has not picked up the package within 30 days, another shipping label must be requested.
 - All opened multi-dose vials, broken vials, or syringes must be marked through with a single line on the VLR and not included in the box for return.
 - Do not return broken vials or syringes and do not return syringes with exposed needles.
 - You must wait until UPS returns to your office with the next delivery to return the box with the expired or spoiled vaccines; otherwise, charges may be incurred.

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Texas DSHS Immunization Emergency Vaccine Storage and Handling Plan

Instructions: All Texas DSHS Immunization enrolled sites are responsible for accurate management of their vaccine inventory in the event of an emergency. Once completed, this template will serve as the recommended *Emergency Vaccine Storage and Handling Plan*.

You should review and update this plan **annually** or more frequently if there are any changes to the plan, or changes in staff responsible for vaccine management, storage and handling. The most current *Emergency Vaccine Storage and Handling Plan* will be reviewed during DSHS Immunization Compliance Site Visits.

A copy of this plan, along with the *Routine Vaccine Storage and Handling Plan*, must be posted on or near all refrigerators and freezers that store DSHS vaccine.

Clinic Name:	Clinic Address:
COVID/TVFC/ASN PIN PIN (if applicable):	Email Address:
Telephone Number:	Fax Number:
Signing Clinician or Equivalent:	Primary Vaccine Coordinator:
Back-up Vaccine Coordinator:	Alternate Back-up:
Person(s) Responsible for Monthly Vaccine Count:	Person Responsible for Vaccine Monthly Reporting and Ordering:
Person Responsible for Rotating Vaccine Inventory:	Person Responsible for Receiving and storing Vaccine Shipments:

Emergency Vaccine Storage and Handling Plan reviewed and updated by:

Name:	Title:
Signature:	Date of Last Review:

Location vaccines will be transferred to in case of emergency:

Location Name:	Contact Person at Receiving Location:
Address:	Telephone Number:
COVID/TVFC/ASN PIN (if applicable):	Second Person at Receiving Location:
Is there a Temperature Monitoring device for the Refrigerator and Freezer? <input type="checkbox"/> Yes <input type="checkbox"/> No	Is there adequate space to store the vaccine during an emergency? <input type="checkbox"/> Yes <input type="checkbox"/> No
Is there a generator? <input type="checkbox"/> Yes <input type="checkbox"/> No	Date of Agreement:

Emergency Vaccine Storage and Handling Plan reviewed and updated by:

Name:	Title:
Signature:	Date of Last Review:

Texas DSHS Immunization Procedures for Emergency Storage and Handling of Vaccine

- Identify a responsible person and a responsible back-up person who will enact the *Emergency Vaccine Storage and Handling Plan*. Include contact information, such as home, office, and cell phone numbers for each person.

The person responsible for enacting the *Emergency Vaccine Storage and Handling Plan* is _____. The back-up person responsible for enacting the *Emergency Storage and Handling Plan* is _____.

- Identify an emergency contact and storage location to take the DSHS vaccine for storage. The emergency storage location must have appropriate vaccine storage equipment capable of maintaining temperatures within acceptable ranges, as well as adequate space to accommodate the vaccine inventory at the busiest time of the year (e.g. flu or back-to-school season) without crowding. Temperatures for storage units are required to be monitored and recorded, per DSHS guidelines. A location with a power generator or other alternate source of power, such as a hospital or pharmacy is preferable.
- Contact the emergency storage location for their approval before including them on your plan. List the contact person(s) and phone number(s) on your plan. Consider locating a back-up location in case the primary emergency storage location is unavailable or unable to store vaccines.
- Using the emergency vaccine storage and handling plan checklist for refrigerated and frozen vaccine:
 - Document the time the emergency/power outage occurs.
 - Document the temperature of the vaccine storage units before removing any vaccine for transportation.
 - Review how refrigerated vaccine should be packed for transport, and pack them using only approved storage units.

- Insert a certified and calibrated data logger probe in the in the center of the vaccine storage unit, and note the time temperature when the vaccine is placed in the storage unit. Before storing the vaccine inside of the receiving emergency storage unit, document the temperature of that storage unit.
- Conduct an inventory of the vaccine as you move it to the transport container and record the information:
 - Lot number,
 - Number of doses of each vaccine, and
 - Expiration dates

You must follow all guidance provided by DSHS when transferring vaccines in the event of an emergency.

In the table below, provide the information where you will obtain the necessary items for emergency transport of vaccine and the appropriate contact information.

- **Do not use frozen gel packs or coolant packs from vaccine shipments to pack refrigerated/frozen vaccines.**
- **Dry ice is only to be used to transport Pfizer COVID-19 vaccine when in ultra-cold state.**
- **Do not use dry ice to keep normal freezer temperatures for any other vaccine, even if for temporary storage.**

Where to obtain:	Phone number:
Portable Refrigerator: (Optional)	
Portable Freezer: (Optional)	
Cooler(s):	
Frozen Water Bottles:	
Bubble-wrap / Corrugated cardboard:	

VaxiPac™ w/Bricks:	
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In the event of a citywide evacuation, contact DSHS for assistance.

Emergency Vaccine Storage and Handling Plan Checklist:
Refrigerated Vaccine

Contact with DSHS made prior to transport by:	
Date:	Time: <input type="checkbox"/> AM <input type="checkbox"/> PM
Person Transporting Vaccine:	
Transport of REFRIGERATED Vaccine	
<input type="checkbox"/>	<p>Assemble packing supplies.</p> <p>Container used to transport refrigerated vaccines:</p> <p><input type="checkbox"/> Portable fridge</p> <p><input type="checkbox"/> Cooler</p> <p>Other supplies needed if using a cooler:</p> <p><input type="checkbox"/> Conditioned frozen water bottles*</p> <p><input type="checkbox"/> Certified, calibrated data logger</p> <p><input type="checkbox"/> Packing material (2" of bubble wrap or crumpled paper and two pieces of cardboard that is cut to cooler size)</p> <p>* Frozen water bottles that are not "conditioned" can freeze vaccines. To "condition" frozen water bottles, remove them from the freezer and immerse in a sink of water or under running water until the ice spins freely in the bottle.</p>
<input type="checkbox"/>	Spread a layer of conditioned water bottles at the bottom of the cooler. Cover the conditioned water bottles with a piece of cardboard, cut to the size of the cooler. Cover with a 2" layer of bubble wrap or crumpled paper.
<input type="checkbox"/>	Stack vaccine boxes on the bubble wrap or crumpled paper. Vaccines must not touch the conditioned water bottles in the cooler.
<input type="checkbox"/>	Place the data logger probe with vaccines.
<input type="checkbox"/>	Cover the vaccine with 2" layer of bubble wrap or crumpled paper. Add a piece of cardboard, cut to the size of the cooler. Add conditioned water bottles to cover the cardboard.
<input type="checkbox"/>	Fill the cooler to the top with bubble wrap or crumpled paper.
<input type="checkbox"/>	Place the data logger display on top of the bubble wrap, crumpled paper, or outside the cooler.

Emergency Vaccine Storage and Handling Plan Checklist:
Refrigerated Vaccine (Continued)

Contact with DSHS made prior to transport by:	
Date:	Time: <input type="checkbox"/> AM <input type="checkbox"/> PM
Person Transporting Vaccine:	
Transport of REFRIGERATED Vaccine (Continued)	
<input type="checkbox"/>	Include a list of the vaccines that are in the container.
<input type="checkbox"/>	Record temperatures on a Temperature Recording Form prior to transport. Temperature of <u>storage unit</u> when the vaccines are removed: _____ <input type="checkbox"/> C <input type="checkbox"/> F Time vaccines were removed from <u>storage unit</u> : _____ <input type="checkbox"/> AM <input type="checkbox"/> PM Temperature of <u>transport container</u> when the vaccines were placed inside: _____ <input type="checkbox"/> C <input type="checkbox"/> F
<input type="checkbox"/>	Record temperatures on a <i>Temperature Recording Form</i> upon arrival at the emergency storage location. Temperature of <u>transport container</u> when the vaccines are removed: _____ <input type="checkbox"/> C <input type="checkbox"/> F Time vaccines were removed from <u>transport container</u> : _____ <input type="checkbox"/> AM <input type="checkbox"/> PM Temperature of <u>storage unit</u> when the vaccines were placed inside: _____ <input type="checkbox"/> C <input type="checkbox"/> F

Emergency Vaccine Storage and Handling Plan Checklist:
Frozen Vaccine

Contact with DSHS made prior to transport by:	
Date:	Time: <input type="checkbox"/> AM <input type="checkbox"/> PM
Person Transporting Vaccine:	
Transport of FROZEN Vaccine	
<input type="checkbox"/>	<p>Assemble packing supplies.</p> <p>Container used to transport frozen vaccines:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Portable freezer <input type="checkbox"/> VaxiPac™ <input type="checkbox"/> Cooler <p><input type="checkbox"/> Other supplies needed if using a cooler:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Frozen water bottles. <input type="checkbox"/> Certified, calibrated data logger (to be used with VaxiPac™ too). <input type="checkbox"/> Packing material (2" of bubble wrap/paper and two pieces of cardboard that is cut to the the cooler size). <p align="center">Do not freeze diluent during transport</p>
If a <u>cooler</u> is used:	
<input type="checkbox"/>	Spread a layer of frozen water bottles on the bottom of the cooler. Cover the frozen water bottles with a piece of cardboard, cut to the size of the cooler, and a 2" layer of bubble wrap or crumpled paper.
<input type="checkbox"/>	Stack vaccine boxes on the bubble wrap or crumpled paper. Vaccines must not touch the frozen water bottles.
<input type="checkbox"/>	Place the data logger probe with vaccines.
<input type="checkbox"/>	Cover vaccine with 2" layer of bubble wrap or crumpled paper. Add a piece of cardboard, cut to the size of the cooler. Add frozen water bottles to cover the cardboard.
<input type="checkbox"/>	Fill the cooler to the top with bubble wrap or crumpled paper.
<input type="checkbox"/>	Place the data logger display on top of the bubble wrap, crumpled paper, or outside the cooler.

Emergency Vaccine Storage and Handling Plan Checklist:
Frozen Vaccine (Continued)

Contact with DSHS made prior to transport by:	
Date:	Time: <input type="checkbox"/> AM <input type="checkbox"/> PM
Person Transporting Vaccine:	
Transport of FROZEN Vaccine (Continued)	
If a <u>VaxiPac</u>™ is used:	
<input type="checkbox"/>	Pack vaccine in accordance with manufacturer instructions (place one freezer brick on the bottom, followed by vaccine and probe, followed by four more freezer bricks).
<input type="checkbox"/>	Include data logger probe with vaccines. Place the data logger display outside the VaxiPac™.
For <u>all</u> transport of frozen vaccine:	
<input type="checkbox"/>	Using a <i>Vaccine Transfer Authorization Form</i> (stock no. EC-67), include a list of the vaccines that are in the container.
<input type="checkbox"/>	Record temperatures on a <i>Temperature Recording Form</i> (stock no. EC-105) prior to transport. Temperature of <u>storage unit</u> when the vaccines are removed: _____ <input type="checkbox"/> C <input type="checkbox"/> F Time vaccines were removed from <u>storage unit</u> : _____ <input type="checkbox"/> AM <input type="checkbox"/> PM Temperature of <u>transport container</u> when the vaccines were placed inside: _____ <input type="checkbox"/> C <input type="checkbox"/> F
<input type="checkbox"/>	Record temperatures on a <i>Temperature Recording Form</i> (stock no. EC-105) upon arrival at the emergency storage location. Temperature of <u>transport container</u> when the vaccines are removed: _____ <input type="checkbox"/> C <input type="checkbox"/> F Time vaccines were removed from <u>transport container</u> : _____ <input type="checkbox"/> AM <input type="checkbox"/> PM Temperature of emergency <u>storage unit</u> when the vaccines were placed inside: _____ <input type="checkbox"/> C <input type="checkbox"/> F

VaxiPac™ Vaccine Transport

- Do Not Use dry ice. Most manufacturers do not recommend transporting vaccines on dry ice as it may expose the vaccine to temperatures below -58° F.
- A VaxiPac™ is an approved method for transporting frozen vaccine that does not short date the product. The VaxiPac™ can reliably maintain an average temperature between +5°F and -58° F when used with either VaxiSafe™ (-20°C) or VaxiSafe™(-15°C) frozen bricks. Refer to the VaxiPac™ manual for specific instructions.
- If vaccine is not transported in a VaxiPac™, then document EXPLICITLY:
1) time storage began; 2) time storage ended; and 3) storage temperatures under which the vaccine was kept for this period of time.

The manufacturer should be called before discarding frozen vaccine that has been kept under less than ideal storage conditions.

Questions regarding Vaccine shipments or transport should be directed to the manufacturer.



