



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Texas Vaccines for Children and Adult Safety Net Program

Vaccine Management Plan Templates 2019



Texas Department of State Health Services

Tel: (800) 252-9152 1100 West 49th Street www.ImmunizeTexas.com
Fax: (512) 776-7288 Austin, TX 78756 Immunization.Info@dshs.texas.gov

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Table of Contents

Contact List	3
Texas Vaccines for Children (TVFC) and Adult Safety Net (ASN) Program	
Routine Vaccine Storage and Handling Plan	5
Procedures for Proper Storage and Handling of Vaccine	7
Temperature Monitoring	7
Vaccine Storage.....	7
Vaccine Shipping and Receiving Procedures	8
Vaccine Ordering Procedures.....	10
Inventory Control (e.g., stock rotation)	10
Vaccine Loss (expired, spoiled, and wasted vaccine)	11
Emergency Vaccine Storage and Handling Plan.....	13
Procedures for Proper Emergency Storage and Handling of Vaccine	15
Emergency Vaccine Storage and Handling Plan Checklist: Refrigerated Vaccine	17
Emergency Vaccine Storage and Handling Plan Checklist: Frozen Vaccine ..	19

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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 (backup):			

Resources Contact List

Resources	Phone Number	Email Address	
Primary Responsible Entity (RE): Local Health Department (LHD)			
Backup RE: Local Health Department (LHD)			
DSSH Public Health Region (PHR)			
DSSH Vaccine Call Center	(888) 777-5320	VacCallCenter@dshs.state.tx.us	
Additional Resources	Company / Entity Name	Phone Number	Email Address
Electric/Power Company/Utility Company			
Refrigerator repair			
Freezer repair			
Data logger repair/recalibration			

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TVFC/ASN Program Routine Vaccine Storage and Handling Plan

Instructions: All TVFC and ASN enrolled clinics are responsible for routine management of vaccine inventory. Once completed, this template will serve as the required Routine Vaccine Storage and Handling Plan.

You must review and update this plan **annually** or more frequently if there are changes to the signing clinician, changes to coordinators responsible for vaccine management, or changes in equipment used to store TVFC/ASN vaccine. The most current Routine Vaccine Storage and Handling Plan will be reviewed during TVFC Compliance Site Visits and Unannounced Storage and Handling Visits.

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 TVFC/ASN vaccine.

Clinic Name:	Clinic Address:
PIN:	Email Address:
Telephone number: () -	Fax Number: () -
Signing Clinician or Equivalent:	Primary Vaccine Coordinator:
Backup Vaccine Coordinator:	Alternate Backup:
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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Procedures for Routine Storage and Handling of Vaccine

For guidance, refer to Chapter 3 of the TVFC Provider Manual.

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* (EC-105) must be posted on or near all units storing TVFC/ASN vaccine.
- Current refrigerator/freezer temperatures must be recorded twice daily on the *Temperature Recording Form* (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* (EC-105). The time (hour and minute) and the initials of the staff member monitoring/recording the information must be documented on the form.
- 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* (EC-105).

Vaccine Storage

- Clinics enrolled in the TVFC/ASN 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 the clinic's largest inventory (during back-to-school or flu season) without crowding, including TVFC, ASN, and private stock vaccine.

In order of preference, DSHS recommends the use of a:
1) pharmaceutical, purpose-built units, 2) a stand-alone refrigerator and stand-alone freezer, or 3) a 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 is recommended to be used with a household unit.



Procedures for Routine Storage and Handling of Vaccine

Vaccine Storage (Continued)

- Small combination refrigerator-freezer units outfitted with a single external door (dorm-style) are **never** allowed for the storage of TVFC/ASN 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.
- Place frozen water bottles along both sides of the walls, at the back, on the floor, and in the door of the freezer.
- 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 TVFC/ASN vaccine. Store specimens below or TVFC/ASN 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 always accept vaccine shipments. Never refuse or return vaccine shipments without specific instructions from DSHS or your RE.
- Staff must ensure that an accurate shipping address and delivery hours are entered into the Electronic Vaccine Inventory (EVI) system.



Procedures for Routine Storage and Handling of Vaccine

Vaccine Shipping and Receiving Procedures (Continued)

- TVFC/ASN Programs require all clinics to 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 accuracy of the shipment. Confirm all vaccine received against the packing slip and verify the correct vaccine type, ship date, lot number, expiration date, and amounts received, including diluent if applicable.
 - Verify the packing list against the order placed in EVI once the vaccine has been properly stored. Receive the order in EVI and print a new Tally & Physical count sheet.
 - Ensure adequate diluent is included for vaccines requiring reconstitution.
 - IMMEDIATELY contact the RE 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 temperature monitoring strip in the package indicates, or if staff suspects that the cold chain has been compromised, staff should immediately:
 - Segregate questionable vaccine (in a bag labeled "Do Not Use") and place it in the proper storage unit until viability can be determined. Do not write on the vaccine boxes.
 - Contact RE immediately to inform. RE may advise to contact the vaccine manufacturer to aid in the determination of vaccine viability.
 - Check packing slip ship date and FedEx/UPS tracking log to review cold-chain time frame.
 - Email or fax the manufacturer stability reports to RE informing them of the determination of the viability of the vaccine.



Procedures for Routine Storage and Handling of Vaccine

Vaccine Shipment received in error

- RE must be contacted immediately upon receipt of vaccine(s) received in error.
- Clinics may choose to keep vaccine received in error if there is ample space to store them without crowding. If the vaccine cannot be absorbed into their stock, then their RE may assist in redistributing the vaccine to other TVFC/ASN providers to prevent vaccine wastage.

Vaccine Ordering Procedures

- _____ is responsible for ordering vaccine.
- All vaccine orders are submitted in EVI (unless internet access is unavailable).
- Staff are required to enter into EVI all vaccines received, doses transferred, expired/wasted vaccine, doses administered, and a physical count of all TVFC/ASN vaccines in their inventory each month regardless of whether an order is placed.
- Temperature Recording Forms must be completed and submitted monthly.
- Staff should abide by the suggested quantity when ordering vaccine. Additional quantities exceeding the maximum stock level (MSL) is allowed; however, a justification is required.
- Staff are responsible for updating provider information in EVI, including shipping address, days, and hours available to receive vaccine shipments, and signing clinician, primary and backup contact information.

Inventory Control including stock rotation

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



Procedures for Routine Storage and Handling of Vaccine

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 EVI.
 - Remove expired/spoiled vaccine from the vaccine storage unit immediately.
 - Report every dose of vaccine that is lost (wasted, spoiled, or expired) to the TVFC/ASN Program electronically in EVI within four days of the incident.
 - The completed VLR must be printed and signed by the signing clinician who signed the TVFC/ASN Program Agreement or a prescribing authority that is listed on the TVFC/ASN Program Agreement.
- Staff are required 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 RE.
 - Once the VLR is processed by DSHS Immunization Unit, 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 the expired or spoiled vaccine.
 - 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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TVFC/ASN Program Emergency Vaccine Storage and Handling Plan

Instructions: All TVFC and ASN enrolled clinics are responsible for accurate management of their vaccine inventory in the event of an emergency. Once completed, this template will serve as the required *Emergency Vaccine Storage and Handling Plan*.

You must 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 TVFC/ASN Compliance Site Visits and Unannounced Storage and Handling Visits.

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

Clinic Name:	Clinic Address:
PIN:	Email Address:
Telephone Number: () -	Fax Number: () -
Signing Clinician or Equivalent:	Primary Vaccine Coordinator:
Backup Vaccine Coordinator:	Alternate Backup:
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:



**TVFC/ASN Program
Emergency Vaccine Storage
and Handling Plan (Continued)**

Location vaccines will be transferred to in case of emergency:

Location Name:	Contact Person at Receiving Location:
Address:	Telephone Number:
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:



Procedures for Emergency Storage and Handling of Vaccine

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

The person responsible for enacting the *Emergency Vaccine Storage and Handling Plan* is: _____ . The backup person responsible for enacting the *Emergency Storage and Handling Plan* is:

_____ .

- Identify an emergency contact and storage location to take the TVFC/ASN vaccine for storage. The emergency storage location must have appropriate vaccine storage equipment capable of maintaining temperatures within the acceptable ranges, as well as adequate space to accommodate the largest vaccine inventory 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 alternative location is unavailable or unable to store your vaccine inventory for any reason.
- Using the emergency vaccine storage and handling plan checklist for refrigerated and frozen vaccine:
 - Document the time the emergency situation/power outage occurs.
 - Document the temperature of the refrigerator and freezer before removing any vaccine for transportation.
 - Have containers available that will be used. Review how refrigerated vaccine should be packed for transport.
 - Using the *Vaccine Transfer Authorization Form (EC-67)*, conduct an inventory of the vaccine as you move it to the transport container, indicating the lot number, the number of doses of each vaccine, and the expiration dates.



Procedures for Emergency Storage and Handling of Vaccine

- Insert a certified and calibrated data logger probe in the transport container in the center of the vaccines and note the time and document the temperature when the vaccine is placed in the transport storage container. This information will show if the cold-chain was intact during the emergency transport. Before storing the vaccine inside of the receiving emergency storage unit, document the temperature of that storage unit.

The *Emergency Vaccine Storage and Handling Plan Checklist* is available for documenting this process in the event of an emergency.

You must use a *Vaccine Transfer Authorization Form (EC-67)* when transferring vaccines in the event of an emergency. For detailed guidance regarding transfer of vaccines and cold chain management, refer to Chapter 3 of the TVFC/ASN Provider Manual.

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. Do not use dry ice, even 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	() -

In the event of a citywide evacuation, contact your responsible entity for assistance.



Emergency Vaccine Storage and Handling Plan Checklist Refrigerated Vaccine

Contact with responsible entity 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> <ul style="list-style-type: none"> <input type="checkbox"/> Portable fridge <input type="checkbox"/> Cooler <p>Other supplies:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Conditioned frozen water bottles* <input type="checkbox"/> Certified, calibrated data logger <input type="checkbox"/> Packing material (2" of bubble wrap or crumpled paper and 2 pieces of cardboard that is cut to cooler size) <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"/>	<p>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 size of the cooler. Cover with a 2" layer of bubble wrap or crumpled paper.</p>
<input type="checkbox"/>	<p>Stack vaccine boxes on the bubble wrap or crumpled paper. Vaccines must not touch the conditioned water bottles in the cooler.</p>
<input type="checkbox"/>	<p>Place the data logger probe next to vaccines.</p>
<input type="checkbox"/>	<p>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.</p>
<input type="checkbox"/>	<p>Fill the cooler to the top with bubble wrap or crumpled paper.</p>
<input type="checkbox"/>	<p>Place the data logger display on top of the bubble wrap, crumpled paper, or outside the cooler.</p>



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

Contact with responsible entity 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"/>	Using a Vaccine Transfer Authorization Form (EC-67), include a list of the vaccines that are in the container.
<input type="checkbox"/>	Record temperatures on a Temperature Recording Form (EC-105) prior to transport. Temperature of storage unit when the vaccines are removed: _____ ° <input type="checkbox"/> C <input type="checkbox"/> F Time vaccines were removed from storage unit : _____ <input type="checkbox"/> AM <input type="checkbox"/> PM Temperature of transport container when the vaccines were placed inside: _____ ° <input type="checkbox"/> C <input type="checkbox"/> F
<input type="checkbox"/>	Record temperatures on a Temperature Recording Form (EC-105) upon arrival at the emergency storage location. Temperature of transport container when the vaccines are removed: _____ ° <input type="checkbox"/> C <input type="checkbox"/> F Time vaccines were removed from transport container : _____ <input type="checkbox"/> AM <input type="checkbox"/> PM Temperature of storage unit 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 responsible entity made prior to transport by:

Date: / /

Time: AM PM

Person Transporting Vaccine:

Transport of FROZEN Vaccine

Assemble packing supplies.

Container used to transport frozen vaccines:

- Portable freezer
- VaxiPac w/freezer bricks
- Cooler

Other supplies:

- Frozen water bottles (do not condition)
- Certified & calibrated data logger
- Packing material (2" of bubble wrap/paper and 2 pieces of cardboard that is cut to cooler size)

Never freeze diluents, not even during transport.

If a cooler is used:

- 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.
- Stack vaccine boxes on the bubble wrap or crumpled paper. Vaccines must not touch the frozen water bottles.
- Place the data logger probe next to vaccines on top of the bubble wrap or paper.
- 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.
- Fill the cooler to the top with bubble wrap or crumpled paper.
- 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 responsible entity made prior to transport by:

Date: / /

Time: AM PM

Person Transporting Vaccine:

Transport of FROZEN Vaccine (Continued)

If a VaxiPac is used:

- Pack vaccine in accordance with manufacturer instructions... Include data logger probe with vaccines.

For all transport of frozen vaccine:

- Using a Vaccine Transfer Authorization Form (EC-67)... Record temperatures on a Temperature Recording Form (EC-105) prior to transport... Record temperatures on a Temperature Recording Form (EC-105) upon arrival at the emergency storage location.

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