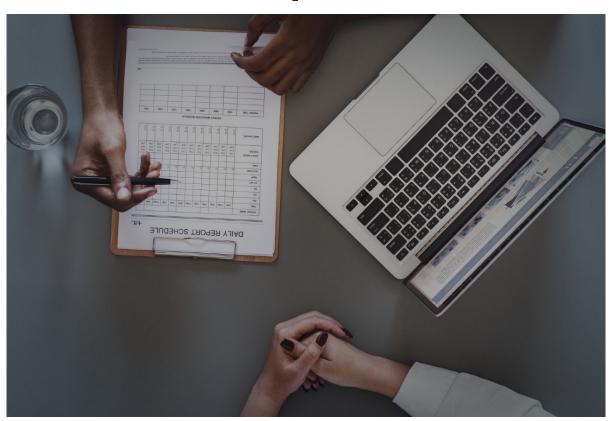


# Texas Vaccines for Children and Adult Safety Net Program

### Vaccine Management Plan Templates



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

#### Table of contents

Contact List	3
TVFC/ASN Program Routine Vaccine Storage and Handling Plan	5
Procedures for Routine Vaccine Storage and Handling of Vaccine	7
Emergency Vaccine Storage and Handling Plan	13
Procedures for Emergency Vaccine Storage and Handling of Vaccine	15
Emergency Vaccine Storage and Handling Plan Checklist:  Refrigerated Vaccine	17
Emergency Vaccine Storage and Handling Plan Checklist:	10

#### **Contact List**

	Vaccine Coordinators				
Vaccine Coordinators (Name/Title)	Phone Number (home, cell)	Alternate Phone Number (home, cell)	Email Address		
Primary:					
Secondary:					
Alternate (back-up):					
	Resoul	rces Contact I	_ist		
Resources	Phone Number		Email Address		
Local Health Department (LHD)					
DSHS Public Health Region (PHR)					
DSHS 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					

## TVFC/ASN Program Routine Vaccine Storage and Handling Plan

**Instructions:** All TVFC and ASN 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*.

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 <u>Emergency</u> 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:
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:

#### **TVFC/ASN Program**

#### Procedures for Routine Storage and Handling of Vaccine

For guidance, refer to Chapter 3 of the TVFC/ASN 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* (stock no. 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* (stock no. EC-105).
- Staff are required to record minimum/maximum 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.
- Record the numbers on both sides of the decimal point, and do not round (Ex: For 46.1°F or 8.1°C, note that the numbers to the right of the decimal meet the criteria for a temperature excursion).
- 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 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 TVFC, ASN, 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 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.
- Small combination refrigerator-freezer units outfitted with a single external door (dorm-style) are <u>never</u> 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 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 Shippii	ng and	Receiving	<b>Procedures</b>
-----------------	--------	-----------	-------------------

•	is responsible for receiving and s	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 Syntropi.
- TVFC/ASN Programs require all sites 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:
  - o Check the vaccine received against the packing list to verify all vaccines have been received.
  - o Verify the packing list against the order placed in VAOS once the vaccine has been properly stored. Receive the order in VAOS and print a new Tally & Physical count sheet.
  - o Ensure adequate diluent is included for vaccines requiring reconstitution.
  - o IMMEDIATELY contact the RE if vaccine or diluent was ordered and not received.
  - o Place vaccine in the appropriate storage unit immediately.
  - o Ensure vaccines with longer expiration dates are stored behind shorter-dated vaccines. This ensures short-dated vaccine is used first.
  - o If the temperature monitoring strip in the package indicates, or if staff suspects that the cold chain has been compromised, damaged, or ruined, staff should immediately:
    - Contact RE to inform. RE may advise to contact the vaccine distributor to aid in the determination of vaccine viability.
    - Place the back-up data logger probe in the shipment that was received warm or questionable, to gain the current temperature. Place the probe in the shipment, near the vaccine and put the lid back on it. Check it frequently to see when the temperature stabilizes.
    - Store questionable shipments appropriately, until official word is received from vaccine distributor or RE.

#### **Vaccine Ordering Procedures**

•	ic	responsible for	ordering	vaccine
	15	responsible for	ordering	i vaccine.

- All vaccine orders are submitted in VAOS (unless internet access is unavailable).
- Staff are required to enter into VAOS 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 Syntropi, 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 TVFC/ASN vaccine
	inventory.	
•		is responsible for reporting vaccine received,
	vaccine transferred, month.	vaccine loss, and physical count in VAOS each

- Vaccine with the shortest expiration date must be used first.
- Staff are required to notify RE 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:		
	0	is responsible for completing and submitting the <i>Vaccine Loss Report</i> (VLR).	
	0	Remove expired/spoiled vaccine from the vaccine storage unit immediately.	

- Report every dose of vaccine that is wasted, spoiled, or expired to the TVFC/ASN Program electronically within four days of the incident.
- o 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:
  - o \_\_\_\_\_\_ is responsible for returning expired or spoiled vaccine.
  - o Complete the VLR as indicated above and submit to the RE.
  - o Once the VLR is processed your primary vaccine coordinator will receive a shipping label via email.
  - o Staff must ensure that all and only vaccines listed on that VLR are included in the box for return.
  - o A copy of the VLR must be included in each box when returning expired or spoiled vaccine.
  - o Shipping/Return labels expire after 30 days. If UPS has not picked up the package within 30 days, another shipping label must be requested.
  - o 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.
  - o Do not return broken vials or syringes and do not return syringes with exposed needles.
  - o 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.

## 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 <u>Emergency</u> 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 <u>Routine</u> 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:
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:
<u>Emergency</u> Vaccine Storage and Hand	ling 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:
	( ) -
TVFC/ASN PIN (if applicable):	Second Person at Receiving Location:
Is there a Temperature Monitoring device for the Refrigerator and Freezer?	Is there adequate space to store the vaccine during an emergency?
Yes No	Yes No
Is there a generator?	Date of Agreement:
Yes No	
Emergency Vaccine Storage and Handl	ing Plan reviewed and updated by:
Name:	Title:
Signature:	Date of Last Review:

#### **TVFC/ASN Program**

## Procedures for <u>Emergency</u> 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.
	numbers for each.

The person responsible for enact	ing the Emergency Vaccine Storage
and Handling Plan is:	The back-up person
responsible for enacting the <i>Eme</i>	ergency 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.
- Due to strict temperature storage and monitoring requirements of vaccine, the Texas DSHS does not permit the TVFC/ASN vaccine to be stored at a private residence.
  - o Private residences include, but are not limited to, the part of structure used as a dwelling, including, without limitation: a private home, townhome, condominium, apartment, mobile home, vacation home, cabin, or cottage. DSHS reserves the right to decline to send vaccine to providers as it deems appropriate.
- Using the emergency vaccine storage and handling plan checklist for refrigerated and frozen vaccine:
  - o Document the time the emergency/power outage occurs.

- o Document the temperature of the refrigerator and freezer before removing any vaccine for transportation.
- o Have containers available that will be used. Review how refrigerated vaccine should be packed for transport.
- o Using the *Vaccine Transfer Authorization Form* (stock no. 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.
- o 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.

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 <u>emergency</u> 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: AM PM			
Perso	Person Transporting Vaccine:			
	Transport of <b>REFRIGERATED</b> Vaccine			
	Assemble packing supplies.  Container used to transport refrigerated vaccines:  Portable fridge Cooler			
	Other supplies needed if using a cooler:  Conditioned frozen water bottles*  Certified, calibrated data logger  Packing material (2" of bubble wrap or crumpled paper and 2 pieces of cardboard that is cut to cooler size)			
	* 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.			
	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.			
	Stack vaccine boxes on the bubble wrap or crumpled paper. Vaccines must not touch the conditioned water bottles in the cooler.			
	Place the data logger probe with vaccines.			
	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.			
	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.			
	Using a <i>Vaccine Transfer Authorization Form</i> (stock no. EC-67), include a list of the vaccines that are in the container.			

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

Contact with responsible entity made prior to transport by:				
Date:				
Perso	Person Transporting Vaccine:			
	Transport of <b>REFRIGERATED</b> Vaccine (Continued)			
	Record temperatures on a <i>Temperature Recording Form</i> (stock no. EC-105) prior to transport.  Temperature of <b>storage unit</b> when the vaccines are removed:  C F  Time vaccines were removed from <b>storage unit</b> : AM PM  Temperature of <b>transport container</b> when the vaccines were placed inside: C F			
	Record temperatures on a <i>Temperature Recording Form</i> (stock no. EC-105) upon arrival at the emergency storage location.  Temperature of <b>transport container</b> when the vaccines are removed:  C F  Time vaccines were removed from <b>transport container</b> : AM PM  Temperature of <b>storage unit</b> when the vaccines were placed inside: C F			

## **Emergency** Vaccine Storage and Handling Plan Checklist: FROZEN Vaccine

Contact with responsible entity made prior to transport by:				
Date: / /		ïme:	AM PM	
Perso	Person Transporting Vaccine:			
	Transport of <b>FRO</b>	DZEN Vaccine		
	Assemble packing supplies.			
	Container used to transport frozen vaccines:  Portable freezer  VaxiPac  Cooler			
	Other supplies needed if using a cooler:  ☐ Frozen water bottles ☐ Certified, calibrated data logger (to be used with VaxiPac too) ☐ Packing material (2" of bubble wrap or crumpled paper and 2 pieces of cardboard that is cut to the size of the cooler size)			
	Do not freeze diluent 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 with vaccines.			
	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 the cooler.	e bubble wrap, crur	npled paper, or outside	

## **Emergency** Vaccine Storage and Handling Plan Checklist: FROZEN Vaccine (Continued)

Contact with responsible entity made prior to transport by:					
Date:					
Perso	Person Transporting Vaccine:				
	Transport of <b>FROZEN</b>	Vaccine (Continu	ed)		
	If a VaxiPa	ac is used:			
	Pack vaccine in accordance with manufacturer instructions (place one freezer brick on the bottom, followed by vaccine and probe, followed by 4 more freezer bricks).				
	Include data logger probe with vaccines. Place the data logger display outside the VaxiPac.				
For all transport of frozen vaccine:					
	Using a <i>Vaccine Transfer Authorization Form</i> (stock no. EC-67), include a list of the vaccines that are in the container.				
	Record temperatures on a <i>Temperature Recording Form</i> (stock no. EC-105) prior to transport.				
	Temperature of <b>storage unit</b> when the vaccines are removed:   C  F				
	Time vaccines were removed from <b>storage unit</b> :   AM  PM				
	Temperature of <b>transport container</b> when the vaccines were placed inside:				
	Record temperatures on a <i>Temperature Recording Form</i> (stock no. EC-105) upon arrival at the emergency storage location.				
	Temperature of <b>transport container</b> when the vaccines are removed:    C   F				
	Time vaccines were removed from <b>transport container</b> : AM PM				
	Temperature of <b>storage unit</b> when the vaccines were placed inside:   C F				



Texas Department of State Health Services