



September 1, 2018

Dear TVFC and ASN Providers,

Summary

Refrigerators and freezers that are typically used for vaccine storage are available in different grades and types. The Texas Department of State Health Services Immunization Unit approves the use of auto-dispensing and other purpose-built vaccine storage units for storage of TVFC/ASN vaccines if they meet the specific storage and handling requirements outlined below.

Details

Regular review and access to temperature data are crucial for determining whether vaccine has been stored within the appropriate temperature range.

TVFC/ASN policy states that the following storage and handling requirements must be met by all vaccine storage units:

- Use of data loggers to monitor the temperature of the units that contain vaccines that will be administered to TVFC/ASN patients.
- Data loggers, including backup units, must include the following features:
 - Current and valid Certificate of Calibration Testing.
 - Logging interval (or reading rate) no less frequently than every 30 minutes;

- Current, minimum, and maximum temperature display visible on or near the unit that can be accessed without a password;
- Alarm for out-of-range temperatures;
- Low-battery indicator;
- Recommended uncertainty of $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$);
- For units that are not pharmaceutical-grade, lab-grade or purpose built for vaccine storage, the following additional data logger requirements must be met:
 - Detachable probe (applies to all data loggers that are manufactured outside of the unit)
 - Buffered probe in glycol, glass beads, sand, or Teflon[®];
- The combination of all refrigerator and freezer units must be large enough to store the year's largest inventory (such as during flu season or back-to-school) without crowding.

Refrigerators and freezers typically used for vaccine storage are available in different grades (pharmaceutical, purpose-built and household) and types (stand-alone and combination refrigerator/freezer). In addition to traditional refrigeration units, there are also purpose-built, auto-dispensing units that do not have doors.

Several sites that participate in TVFC/ASN have made heavy investments in building a state-of-the-art storage and handling infrastructure and are requesting approval to use

auto-dispensing units for the storage of TVFC and ASN vaccines.

The DSHS Immunization Unit has determined that as long as the vaccine storage units meet the above requirements, the units are approved for use to store TVFC/ASN vaccines.

The process of documenting and submitting temperatures must continue using temperature recording form (EC-105). An electronic version of the EC-105 temperature recording form is only acceptable if the report is generated from a purpose-built unit and includes the following information twice daily.

- Date
- Current, minimum and maximum temperatures
- Time (hh/mm)
- Name of the individual that verified the temperature

Thank you for your continued support of the TVFC/ASN Programs. If you have any questions, please contact your responsible entity listed below.

PINS Beginning With	Responsible Entity	Phone Number
00	City of San Antonio	210-207-3965
01	HSR 1	806-783-6412
02	HSR 2	325-795-5660
03	HSR 3	817-264-4790

PINS Beginning With	Responsible Entity	Phone Number
04 or 05 not in Hardin, Jefferson or Orange Counties	HSR 4/5N	903-533-5310
05 in Hardin, Jefferson or Orange Counties, 06	HSR 6/5S	713-767-3410
07	HSR 7	254-778-6744
08	HSR 8	210-949-2067
09	HSR 9	432-571-4137
10	HSR 10	915-834-7924
11	HSR 11	956-421-5552
25	City of Houston	832-393-5188

Sincerely,



Nancy Ejuma

Immunization Unit Director