

New York State Vaccines for Children Program (NYS VFC) Vaccine Storage Unit Purchasing Guidance*

Selecting an appropriate vaccine storage unit is critical to ensuring the viability of refrigerated and frozen vaccine. Failure to adhere to recommended specifications for storage and handling can reduce vaccine potency, resulting in inadequate immune responses in the recipients and inadequate protection against disease. To reduce waste and spoilage, vaccine storage units must be selected carefully. **Stand-alone refrigerators and freezers are best at maintaining the temperatures necessary to keep vaccines viable.** These guidelines are designed to assist you in selecting the appropriate choice of vaccine storage unit for your practice.

NYS VFC Providers must purchase new, stand-alone units when any of the following apply:

- New enrollment in VFC Program
- Current unit does not meet acceptable VFC specifications
- Current unit has had temperature excursions resulting in spoiled vaccine.

Acceptable Vaccine Storage Unit Types	Unacceptable Vaccine Storage Unit Types
<ul style="list-style-type: none"> • Stand-alone refrigerator units – Strongly recommended. Required for any new/replacement unit purchases. • Stand-alone freezer units – Strongly recommended. Required for any new/replacement unit purchases. • Combination self-defrosting refrigerator/freezer unit with two separate compressors, a thermostat control for each compartment, and no circulating air between the freezer and refrigerator compartments (<u>allowable, but uncommon</u>) • Combination, household-style refrigerator/freezer unit with a single compressor, two doors and two thermostat controls- Not allowed for new/replacement unit purchases. <i>Providers enrolled in the VFC Program and using these types of units prior to 1/1/2015 may continue to use these units as long as they function within acceptable temperature ranges*. See pages 4-5 for more information.</i> • Combination, household-style refrigerator/freezer unit with a single compressor, two doors and one thermostat control (not recommended – Not allowed for new/replacement unit purchases. <i>Providers enrolled in the VFC Program and using these types of units prior to 1/1/2015 may continue to use these units as long as they function within acceptable temperature ranges*. See pages 4-5 for more information.</i> 	<ul style="list-style-type: none"> • Dormitory-style units (small, single-door combination refrigerator/freezer units) – Not allowed
Vaccine Storage Unit Required Features	
<ul style="list-style-type: none"> • Large enough to hold the practice’s year’s largest inventory without overcrowding (e.g. back to school and flu season) • Ability to maintain temperatures between acceptable ranges** 	

*This document replaces all previous guidance.

**The refrigerator must be able to maintain temperatures consistently between 36° and 46° Fahrenheit (or between 2° and 8° Celsius). The freezer must be able to maintain temperatures at or below 5° Fahrenheit (-15° Celsius).

SELECTING A NEW UNIT

Determining Size

To determine what size vaccine storage unit your practice needs, first determine the maximum number of doses of publicly purchased (including Vaccine for Children [VFC], Child Health Plus [CHP], state-funded) and privately purchased vaccine that will be stored in your refrigerator and freezer, using the formulas¹ below:

Note: If you currently have zero doses on hand and have never placed an order, this information can be determined from page 6 of your NYS VFC Program provider profile application.

Refrigerator		Freezer	
Add the number of doses on hand (current inventory from your last order form)		Add the number of doses on hand (current inventory from your last order form)	
VFC/CHP/State vaccine		VFC/CHP/State vaccine	
VFC/CHP/State flu vaccine		VFC/CHP/State flu vaccine*	
Private vaccine		Private vaccine	
Private flu vaccine		Private flu vaccine*	
Total doses =		Total doses =	
Multiply (max inventory)		Multiply (max inventory)	
Maximum doses =		Maximum doses =	

*There are currently no flu vaccines stored in the freezer

Determining Style/Type

Based on the number of maximum doses calculated above:

Volume	Max Doses (Refrigerator)	Minimum Cubic Feet	Types that Meet Criteria
Very High	10,000+	Multiple refrigerators needed	Full-size, stand-alone refrigerator units
High	2,000 – 10,000	May need multiple refrigerators	
Medium – High	1,000 – 2,000	40 cu. ft.	
Medium	901 – 1,000	36 cu. ft.	
	801 – 900	21 – 23 cu. ft.	
	701 – 800	17 - 19.5 cu. ft.	
Low	400 – 700	16.7 cu. ft.	Under-counter, stand-alone refrigerator units
	100 – 399	4.9 – 6.7 cu. ft.	

Volume	Max Doses (Freezer)	Minimum Cubic Feet	Types that Meet Criteria
Medium – High	501 – 6,000	7 – 14.8 cu. ft.	Full-size, stand-alone freezer units
Low	201 – 500	5 – 5.6 cu. ft.	Under-counter, stand-alone freezer units and chest-style freezers
	0 – 200	3.5 – 4.9 cu. ft.	Under-counter, stand-alone freezer units

¹ Information obtained from the [American Academy of Pediatrics' Vaccine Storage Document](#)

Full-size



*Reprinted from the Nevada State Immunization Program
Vaccine Storage Unit Protocol*

Under-counter



Chest-style freezer



*Reprinted from the Michigan Department of
Community Health Vaccine for Children Storage
Capacity Form*

Stand-alone units are self-contained units dedicated to a single temperature range, as either a refrigerator OR freezer. **Stand-alone refrigerator and freezer units are considered best practice for vaccine storage as they provide the best temperature stability.**

Full-size stand-alone refrigerators and freezers are an appropriate option for medium-to-very-high-volume providers and can cost between \$800 and \$9000 per unit. Under-counter stand-alone refrigerators are an acceptable option for low-volume providers and can cost between \$200 and \$5000 per unit. Under-counter stand-alone freezers can accommodate low to high-volume providers and can cost between \$200 and \$5,000 per unit. Chest-style freezers can accommodate low to high-volume providers and range in price between \$200 and \$5000 per unit.

When purchasing a stand-alone unit, look for these **recommended features**:

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, RTD, or thermistor)
- Digital temperature display and settings
- Fan-forced air circulation – fans or multiple cool air vents to promote temperature uniformity and fast temperature recovery
- Temperature alarms
- Security features (e.g., temperature set point security)
- Solid (vs. glass) doors (better temperature maintenance during power outages)
- Automatic defrost or frost-free

If purchasing a freezer, look for a unit with automatic defrost or a frost-free feature. A unit that is not frost-free will likely need a manual defrost. While manual defrost units are allowed, they are not recommended because of the complexity of moving vaccines. During a manual defrost procedure, vaccines must be moved to a back-up unit that is deemed acceptable for storage of frozen vaccines. If the defrost is not done properly or frequently enough, the unit may not maintain appropriate temperatures.

The benefits of using stand-alone units include:

- Less risk of vaccine loss
 - Because stand-alone units are dedicated to maintaining a single temperature range, the risk of freezing refrigerated vaccine and/or unintentionally warming frozen vaccine is reduced considerably.
- Increased temperature stability
 - When compared to combination units, stand-alone units maintain much more consistent temperatures; reducing fluctuations that can occur due to busy days or automatic defrost cycles.

Combination Household-Style Refrigerator/Freezer Units

Combination Household-Style Refrigerator/Freezer Units are not allowed for the purchase of new or replacement units. Providers enrolled in the VFC Program and using these types of units prior to January 1, 2015 may continue to use these units as long as they function within acceptable temperature ranges.

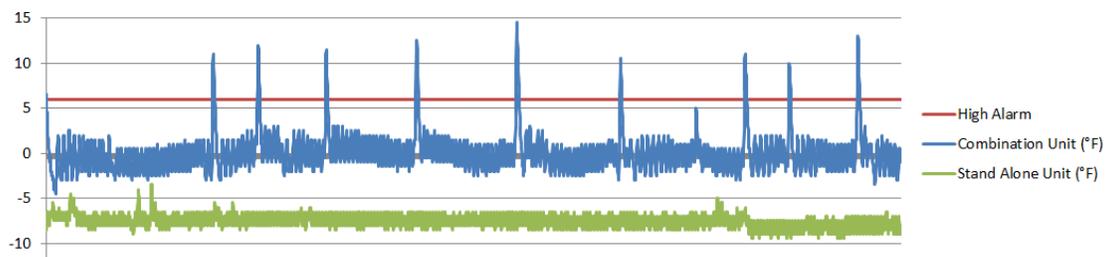
Many combination household-style refrigerator/freezer units share a single compressor. This means that air from the freezer is circulated for cooling into the refrigerator. This can cause cold spots and temperature fluctuations in the refrigerator portion of the unit therefore increasing the risk of freeze-damage to refrigerated vaccines.



Reprinted from the Nevada Immunization Program's Vaccine Storage Unit Protocol

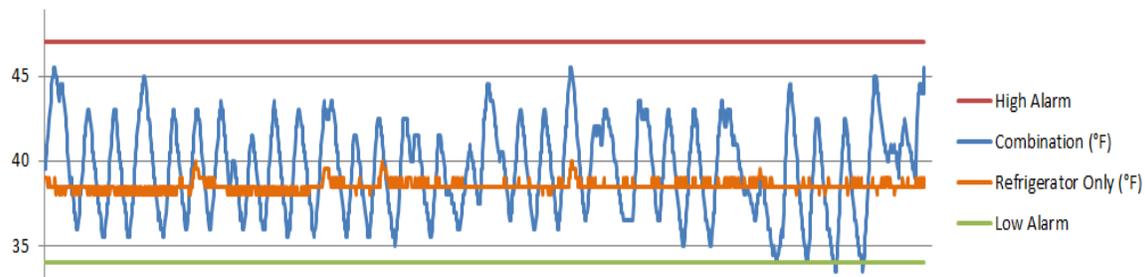
A study² conducted by the National Institute of Standards and Technology (NIST) found that the freezer compartments in these types of units may be incapable of maintaining correct temperatures for frozen vaccines. The graph below illustrates significant temperature variations in the freezer compartment of the household-style combination unit when compared with a stand-alone freezer. If existing equipment is a household-style, combination refrigerator/freezer unit, the CDC strongly recommends using only the refrigerator compartment for refrigerated vaccines and a separate stand-alone freezer for frozen vaccine.

Stand-alone Freezer vs. Household-Style Combination Unit Freezer³



Due to air circulation between the two compartments in the combination unit, air temperature of the refrigerator is highly dependent on the temperature of the freezer. As shown below, refrigerator temperatures fluctuate more frequently during freezer defrost cycles and can put refrigerated vaccine at risk of being frozen.

Stand-alone Refrigerator vs. Household-Style Combination Unit Refrigerator⁴



² National Institute of Standards and Technology (NIST); Thermal Analysis of Refrigeration Systems Used for Vaccine Storage: Report on Pharmaceutical Grade Refrigerator and Household Refrigerator/Freezer, <http://www.nist.gov/pml/div685/grp01/upload/NISTIR7753-Thermal-Analysis-of-a-Dual-zone-Refrigerator-and-Pharmaceutical-Refrigerator-for-Vaccine-Storage.pdf>

³ New York State Department of Health (2013) [Continuous temperature monitoring data]. Unpublished raw data.

⁴ New York State Department of Health (2013) [Continuous temperature monitoring data]. Unpublished raw data.

Dormitory-Style units (NOT ALLOWED)

Dormitory-Style units are defined as small single-door combination refrigerator/freezer units without separate temperature controls. The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store frozen vaccine. Additionally, the refrigerated compartment in this type of unit can subject vaccine to freezing temperatures. These types of units **are incapable of storing any vaccine at an appropriate temperature in any part of the unit and are therefore not allowed by the NYS VFC program.**



Reprinted from the CDC's Vaccine Storage and Handling Toolkit

Preparing Units for Use

Always consult the unit's product manual for additional information on proper setup.

Before placing vaccines into a new unit, follow these steps:

- Place the unit in a well-ventilated room away from direct sunlight and heat sources. Allow for space around the top and sides of the unit, and at least 4 inches (10 cm) of space between the unit and wall.
- Plug the vaccine storage unit *directly* into a wall or floor outlet. **Do not use extension cords. Do not use multi-outlet power strips, such as surge protectors.**
- Place a [warning sign](#) near the outlet and/or circuit breaker informing staff and others not to unplug the storage unit or turn off the circuit breaker.
- Place a paper copy of the temperature log form on the front of the unit(s) for temperature recording:
 - Printable Temperature Log for Refrigerator [Fahrenheit Celsius](#)
 - Printable Temperature Log for Freezer [Fahrenheit Celsius](#)
- Place a [warning sign](#) on the unit informing staff not to adjust the thermostat.
- Place filled water bottles in the doors and along the bottom shelf of the refrigerator unit⁵.
- Place filled water bottles along the walls and in the door of the freezer unit (recommendation effective March 2016⁵).
- Label the areas where vaccine will be stored. Specify between public (includes VFC, CHP, state) and private stock. Store vaccine on the middle shelves of the unit, away from cold air vents.
- Set the refrigerator temperature to 40° Fahrenheit or 5°Celsius. Set the freezer temperature to 0° Fahrenheit or -18° Celsius.
 - **Consult the product manual for instructions on how to operate the thermostat**
- Place a calibrated thermometer, inserted into a thermal buffer, such as glycol, in the center of the unit. If the unit is purpose built for storing vaccines or medical supplies, placement of the buffered probe can be adjusted, effective March 2016⁶. For more information on thermometer requirements, see the [NYSDOH Temperature Monitoring Device Guidance](#).
- Monitor the temperatures in any new or repaired unit(s) for at least five business days before moving vaccine into them.

⁵ Filled water bottles should be placed throughout each storage unit in order to stabilize temperatures during a power outage and to serve as physical blocks to help prevent placement of vaccines in areas of the unit that are at higher risk for temperature excursions (i.e., doors, vegetable bins, floor, near/under cooling vents).

⁶ Previous NYS VFC program requirements indicated that a buffered probe must be centrally located. However, an allowance for purpose-built units can be made if either 1) the thermometer is built in to the unit and cannot be adjusted or 2) the location of the probe port dictates that the probe be placed non-centrally.

- Refer to the [manufacturer product inserts](#) that come with each vaccine and diluent to learn the most up-to-date storage and handling practice for that product.

Transferring Vaccine into the Unit(s)

The temperatures must have remained in range in the unit for at least five business days before vaccines can be moved into it.

- Keep vaccines and diluents in their original packages with lids closed until ready for administration.
- Vaccine should be placed in breathable plastic or mesh baskets, grouped by pediatric, adolescent and adult types and labeled accordingly.
- These baskets should be placed at least 2-3 inches from walls and other baskets. This will allow air to circulate around the vaccine.
- Label pediatric and adult versions of the same vaccine to avoid confusion and store on separate shelves.
- Keep vaccines with similar packaging and names on different shelves. (e.g. DTaP and Tdap, Hib and Hep B)
- Vaccines with shorter expiration dates should be kept toward the front of the shelf.
- Vaccines should always be stored on the middle shelves of the refrigerator.
- Refrigerated vaccines should never be placed directly under cold air vents, which are commonly found near the top shelf.
- **Never store food or beverages in a storage unit that is used to store vaccines.**



Reprinted from the CDC's Vaccine Storage and Handling Toolkit

Glossary

- **Standalone, stand-alone**—a storage unit dedicated to a single temperature range, refrigerate only or freeze only; physically separate
- **Combination (dual-zone)** - a single storage unit with both refrigerator and freezer compartments
- **Compressor (evaporator, condenser)** - Cooling coil in the unit
- **Single compressor combination unit** – A combination unit with an evaporator in the freezer and fan that blows cold air into refrigerator. Single compressor units either have a single thermostat or two, separate thermostats.
- **Dual compressor combination unit** – A combination unit with independent cooling systems for refrigerator and freezer sections (and separate temperature controls)
- **Household/consumer** - Term used to identify the style of storage unit; typically seen in home residences. Household combination units typically have a single compressor.

Resources

New York State Department of Health, Vaccines for Children (VFC) Program
(1)800–543-7468 nyvfc@health.ny.gov <http://www.health.ny.gov/vfc>

Centers for Disease Control (CDC), Vaccine Storage and Handling Toolkit
<http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Immunization Action Coalition (IAC), Clinic Resources, Storage and Handling
<http://www.immunize.org/clinic/storage-handling.asp>

American Academy of Pediatrics (AAP), Vaccine Storage Document
https://www.aap.org/en-us/Documents/immunization_vaccinestorageerf.pdf