

Indiana State Department of Health Vaccines for Children Program

Vaccine Storage Unit Purchasing Guidance

The purchase of a refrigerator or freezer for the storage of vaccine could be a large investment. However, considering the financial loss and public health consequences of vaccine wastage and loss of viability due to storage unit failures, it is an invaluable investment. Vaccines are lifesaving biological agents that must be carefully stored at specific temperatures to ensure viability and protect patients from disease. It is essential that vaccines are not exposed to temperatures outside manufacturer recommendations. Therefore, it is important that your storage unit is suitable for the proper storage of vaccine.

When purchasing a refrigerator or freezer unit, the following must be taken into consideration:

- **Size:** Does the storage unit have adequate space for storage of vaccine during time of largest inventory (i.e. flu season or back to school)?
- **Temperature Requirements:** Will the unit be able to maintain temperatures appropriate for the storage of vaccine (2°C – 8°C for refrigerator and -15°C – (- 50) °C for freezer)?
- **Type of unit:** Is the unit a pharmaceutical grade or household grade? Is it standalone or a combination unit? (*Note: Only the refrigerator section of combination units may be used to store VFC vaccine. Newly enrolled VFC providers are **required** to purchase standalone storage units*)
- **Technical specifications:** Does the unit have an automatic defrost cycle/frost free cycle or does it require manual defrosting? Are there security safeguards?

Size of Storage Unit

To determine the size of storage unit most appropriate for your clinic:

- Consider the inventory of vaccine you expect to have at your clinic's busiest vaccination period
 - Make sure there will also be room for sufficient room for the storage of water bottles or coolant packs
- The space and dimensions of the room where storage unit will be placed
 - CDC requires that storage units be placed in a well ventilated room with standard indoor temperatures
 - There must be sufficient room to have 4 inches between the storage unit and the wall of the room
- The budgetary constraints of your clinic

To determine your office's maximum inventory:

- Add the number of doses on hand of: VFC/317 vaccine, VFC/317 flu vaccine, private vaccine, and private flu vaccine

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- Estimate how much more vaccine is in your inventory during your office’s busiest vaccination season, and add to the number of doses on hand

Keep in mind that vaccine boxes may come in different shapes and sizes that may impact the amount of space needed in the storage unit.

Equipment Size Recommendations

Office Size	Recommended Equipment Size
Very High Volume 10,000 doses/year	Pharmacy-grade or biologic-grade refrigerator-only units and stand-alone freezer units
High Volume 2,000-10,000 doses/year	Refrigerator-only (16.7 cubic feet minimum) and stand-alone freezer units
Medium Volume 500-2,000 doses/year	Refrigerator-only (11 cubic feet minimum) and stand-alone freezer units
Low Volume Less than 500 doses/year	OR Pharmacy-grade or biologic-grade under the counter units

Temperature Requirements

Storage units must be able to maintain temperatures suitable for vaccine storage. Refrigerators and freezers need to reliably hold temperatures between 2°C – 8°C, and -15°C – (-50)°C year round.

Technical Specifications

Recommended features:

- Microprocessor-based temperature control with a digital temperature sensor
- Fan-forced air circulation, fans or air vents that promote temperature uniformity and fast temperature recovery
- Temperature alarm system that will alert staff to after-hour temperature excursions
- Storage unit should be frost-free or have an automatic defrost cycle (**self-defrost refrigerators are prohibited**)

Per ISDH policy, all storage units must have separate exterior doors, with separate gaskets, that seal tightly and properly for both the refrigerator and freezer areas

Acceptable Storage Units

The following table lists the acceptable types of storage units as of January 1, 2017.

Grade/Type	Description	Rating
Pharmaceutical grade/purpose-built units (stand-alone)	Specifically engineered to maintain consistent temperatures throughout the unit. Purpose-built or pharmacy-grade refrigerators can be compact, making them ideal for small offices	Best
Pharmaceutical grade/purpose-built units (combination) *This does NOT include household combination units	Pharmaceutical grade and purpose-built units are specifically engineered to maintain consistent temperatures throughout the unit. These units have more than one compressor allowing for better and separate temperatures control of the refrigerator and freezer compartments.	Best
Commercial units* (stand-alone)	Usually intended to store food and beverages and are often larger and more powerful than household units. These units are not specifically designed to store biological materials	Best
Household* (stand-alone)	Usually smaller than commercial units and are intended for use in small offices and in homes, typically for food storage. Like commercial units, they are not designed to store biological materials	Good
Household* (stand-alone)	Usually smaller than commercial units and are intended for use in small offices and homes, typically for food storage. Like commercial units, they are not designed to store biological materials.	OK

*These units may require additional water bottles (refrigerator) or frozen cold packs (freezer) to maintain stable temperatures. Consult your District Field Representative for guidance.

The following storage units are unacceptable for use in the VFC programs and are not to be used store vaccine at any time.

Grade/Type	Description	Rating
Dormitory-style and bar-style combined refrigerator/freezers	These units pose a significant risk of freezing even when used for temporary storage.	Unacceptable
Manual defrost (cyclic defrost) refrigerators	These models have an exposed vertical cooling plate at the back of the refrigerator. They have significant temperature variation and risk freezing vaccines. Manual defrost refrigerators are most likely going to be household combination units, small dorm size combination units, or older single door units (essentially a dorm style – one outside door with the freezer compartment located within the refrigerator – but larger like the size of a household unit). These types of units are not allowable.	Unacceptable
Convertible refrigerator-only units	These units have an internal switch that converts an “all-refrigerator unit” to an “all freezer” unit.	Unacceptable
Cryogenic Freezers	These freezers reach temperatures well below -50.0 C (-58.0 F), too cold for frozen vaccines. The recommended temperature range for frozen vaccines is between -50.0 C and -15.0 C (-58.0 F and 5.0 F).	Unacceptable

Pharmaceutical and Medical Grade Vaccine Storage Unit Manufacturers*

Amercan Biotech Supply

<http://www.americanbiotechsupply.com/>

Lab Research Products

<http://www.labresprod.com/>

Compact Appliance

<http://www.compactappliance.com/>

Sanyo Biomedical

<http://www.biomedical.panasonic.eu/>

Fisher Scientific

<https://www.fishersci.com/>

Sun Frost

<http://www.sunfrost.com/>

Follett

<https://www.follettice.com/>

Thermo Scientific

<https://www.thermofisher.com/>

Helmer

<http://www.helmerinc.com/>

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**This list is not exhaustive, and is for reference purposes only. The Indiana State Department of Health cannot endorse a specific brand or product. It is your responsibility to ensure your storage unit meets CDC guidelines before purchasing.*

Preparing the refrigerator/freezer for vaccine storage

1. The unit must be placed in a well-ventilated room with sufficient space (at least 4 inches) around the sides and top for air circulation. Ensure the refrigerator/freezer is plugged into an outlet in a protected area where it cannot be accidentally disconnected. **DO NOT USE EXTENTION CORDS OR SURGE PROTECTORS!**
 - The use of a “safety-lock plug” or an outlet cover is strongly recommended to reduce the change of the unit becoming inadvertently unplugged
 - Label the refrigerator, electrical outlets, and circuit breakers on the power circuit with information that clearly identifies the perishable nature of vaccines and immediate steps to be taken in case there is an interruption of power.
 - Place “DO NOT UNPLUG” signs by the electrical outlet for the refrigerator and freezer and circuit breaker panel to ensure that the power is not turned off.
 - Instruct maintenance and/or cleaning personnel not to unplug the refrigerator and freezer or switch off the circuit breaker.
2. Store water bottles against the inside walls, crisper bin(s) (if so equipped), and door of the refrigerator.
3. Store extra frozen water bottles, ice packs and/or gel packs along the walls, back and door of the freezer compartment
4. Place a calibrated data logger in the middle of the unit and **record temperatures for 5 days** before storing VFC vaccine in the unit. Proper documentation that the storage unit is able to maintain temperatures optimal for vaccine storage must be submitted before vaccine ordering privileges will be granted.