

Vaccine Storage & Handling FAQs

Refrigerator and Freezer Requirements

1. Are combination household units acceptable for storing vaccines?

CDC strongly recommends standalone refrigerators and freezers. The rationale for this recommendation is:

- Most common household refrigerator/freezers have combined temperature control units that can create cold spots and temperatures fluctuations in the refrigerator portion of the unit
- The risk of freeze-damage to refrigerated vaccines is increased in combination units because air from the freezer is circulated into the refrigerator to cool it. This can freeze temperature-sensitive vaccines.
- The freezer portion of many combination units is not capable of maintaining the correct storage temperature for frozen vaccines.

The purchase of new vaccine storage equipment may requires planning. Existing equipment may be used until new equipment can be purchased. In this situation, CDC recommends using a combination refrigerator/freezer unit for refrigerated vaccines only and using a separate standalone freezer to store frozen vaccines.

Note: Most combination refrigerator/freezers share a single condenser, and freezing air from the freezer compartment is vented into the refrigerator compartment to cool the refrigerator. You should not turn off the freezer portion of the combination unit because it will not maintain the proper temperature for refrigerated vaccines. It is important to add water bottles to the refrigerator to absorb cold air blown in from the freezer to reduce the risk of vaccines becoming too cold.

2. What are the exact dimensions required for a refrigerator used to store vaccines?

CDC does not make a recommendation specific to the size of refrigeration units. For a refrigerator to store vaccine it must:

- Be able to maintain required temperature at all times (2°C - 8°C)

Vaccine Storage & Handling FAQs

- Be large enough to hold the year's largest inventory with no vaccine pushed against the back, walls, on floor, in door or in crisper.
- Have sufficient room to store water bottles as a thermal buffer
- Have a certified calibrated data logger with probe in glycol, reset button, low battery indicator, non-overwriting memory storage, (0.5 degrees C) (VDH supplies these).
- Vaccine must be 2-3 inches from the walls and back, with space for air flow

Refrigeration units for vaccine storage are available in various sizes and shapes. Some stand free and others fit under counters. The small size of under-counter units limits the amount of vaccine that can be stored appropriately. Be sure that the capacity is sufficient to store the vaccine supply and allow for air circulation within the unit. Overstocking units impedes airflow and leads to temperature fluctuations that may result in loss of vaccine. For storage of large quantities of vaccine, additional under-counter units or a full-size unit may be needed. If you are in the process of purchasing a new vaccine storage unit, the Refrigerator and Freezer Guide will provide you with additional information

<http://www.healthvermont.gov/hc/imm/documents/RefrigeratorandFreezerguide.pdf>

3. When is a “dormitory-style” refrigerator adequate for storing vaccine?

Never. A dormitory-style or bar-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. **This type of storage unit is not acceptable for storage of vaccine, not even for temporary storage of vaccine.** Note: There are compact, medical grade storage units made for biologics that are not considered to be dormitory-style or bar style.

4. Can I use the freezer compartment of a combination unit to store frozen vaccine?

National Institute of Standards and Technology (NIST) has found that household freezers cannot reliably hold proper storage temperatures for frozen vaccine. Frozen vaccine should not be stored in a freezer of a combination unit. This applies to both

Vaccine Storage & Handling FAQs

temporary and long-term storage of frozen vaccines. A separate standalone freezer should be used to store frozen vaccines. A storage unit that is frost-free or has an automatic defrost cycle is preferred in order to avoid potential vaccine loss during necessary defrosting, as frozen vaccine should not be moved.

Vaccine Placement

5. Is it true that vaccine stored in a refrigerator cannot be kept on the top or bottom shelf, only in the middle shelves?

Temperature varies within the refrigerator. The temperature in the vegetable bins, on the floor, next to the walls, in the door, and near the cold air venting from the freezer may differ significantly from the temperature in the main body of the refrigerator. Ideal vaccine placement is on the middle shelves, away from walls and the cold air vent.

This is a requirement for state supplied vaccines. Many combined refrigerator/freezer units use a cooling system that directs cold air from the freezer compartment into the main refrigerator compartment through a vent, usually located above the top shelf. Refrigerated vaccines should always be stored far enough away from the air venting from the freezer compartment to avoid freezing the vaccines.

If vaccines can be placed away from the cold air vent and the temperature in this area is within the recommended range of 2° to 8°C, the vaccines may be stored on the upper shelf.

6. We have a large quantity of vaccines, and space is always an issue. Since we cannot put vaccines in the vegetable bins, can we remove the bins and then put vaccines in that space?

No, vaccines cannot be stored in the vegetable bins or in the space occupied by the vegetable bins because the temperature near the floor of the refrigerator is not stable and differs from that in the middle of the unit.

Vaccine Storage & Handling FAQs

7. Is it safe to store vaccines and other biologics in the same refrigerator with lab specimens?

If possible, other medications and other biologic products should not be stored inside the vaccine storage unit. Having other items in the refrigerator increases the amount of time the door is opened and temperature is affected. If there is no other choice, these products should be stored below the vaccines on a different shelf. This prevents contamination of the vaccines should the other products spill.

8. What are the guidelines for storing vaccine during off-site clinics?

Vaccines must always be stored at the temperatures recommended by the manufacturer even during off-site clinics. You can use a hard plastic cooler properly packed with cold packs, insulating material and a thermometer. Upon return to your office, transfer vaccine directly back to the vaccine refrigerator. If during the off-site clinic the temperature inside the cooler goes out of range, store the vaccine in the refrigerator and call the Immunization Program immediately.

Temperature Monitoring

9. How often should temperatures be recorded for the refrigerator and freezer compartment where vaccine is stored?

Twice a day, measure and record the current temperature inside the refrigerator and freezer compartments. Do this at the start of the clinic day and a second time before the clinic closes for the day (one hour before closing if possible). Immediate action – including a call to discuss the occurrence with immunization program staff--must be taken if the temperature is outside the recommended range for either compartment or if the data logger shows an “Alarm”.

Vaccine Storage & Handling FAQs

10. Why is it required to continue to document temperatures twice daily, if I have a continuous data logger and/or alarm system?

CDC requires documenting temperatures twice daily even with a continuous data logger and/or alarm system because twice daily checks will give you an earlier indication of any problems with your storage unit's function. This additional safety check ensures that any temperature excursions recorded by the data logger and alarm system are acted on and addressed promptly.

11. When should I record the min/max temperature? Is this a new requirement?

CDC recommends recording the min/max temperature in the morning at the beginning of the workday. This is a new recommendation for all providers. Use VDH supplied colored temperature logs to record this information (updated May 2014). If you record out of range temperature when checking Min/Max, immediately call the Immunization Program.

12. If the Immunization Program advised me to adjust the dial inside my vaccine storage unit, how long should the temperature be monitored after a refrigerator or freezer thermostat is adjusted to assure that the temperature is within the recommended range and safe for vaccine storage?

After slightly adjusting the thermostat in a working refrigerator or freezer, check the temperature **in both the refrigerator and freezer** (if using a combined unit) every half hour until the temperature stabilizes. If the temperature rises or falls rapidly or is

Vaccine Storage & Handling FAQs

outside the recommended range, again slightly adjust the thermostat inside the unit and repeat the process.

CDC also recommends monitoring the temperature inside the refrigerator for five business days in any new (or newly repaired) unit before it is used for vaccine storage. This is a requirement for state supplied vaccine storage. This practice allows you to monitor the unit performance and allows time to make any necessary adjustments before expensive vaccine is stored in the unit.

13. What is the appropriate action to take if I check the temperature and it is out of range?

Immediately call the Immunization Program for guidance on appropriate steps to take to avoid vaccine wastage. Document on the VDH temperature log or the practice log what action was taken and include the date and time of the call.

14. Why is it required that we keep temperature logs and other records for 3 years?

This CDC requires VFC records be maintained for a minimum of three years and the state VFA program also has this requirement. VFC records include: VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records and temperature logs. Archived temperature logs also show how well the vaccine storage unit is working and can be used to determine when a unit may need adjustment, maintenance, or replacement.

Vaccine Storage & Handling FAQs

Vaccine Expiration

15. When the expiration date of a vaccine indicates a month and year, does the vaccine expire on the first or last day of the month?

When the expiration date is marked by only a month and a year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial.

16. When a multidose vial is opened and a dose is withdrawn, how long can that vial be retained for use?

Certain vaccines are distributed in multidose vials. These products contain antibiotics or preservatives that allow their continued use until **the expiration date** printed on the vial or vaccine packaging, if the vial has been stored correctly and the vaccine is not contaminated.

17. How long is a vaccine dose viable if it has been pre-drawn and stored in the refrigerator in a syringe?

There is inadequate data to answer this question. Disposable syringes are meant for administration and not for storage. CDC strongly discourages prefilling syringes and has identified the following problems associated with this practice:

- Once a vaccine is inside the syringe, it is difficult to tell which vaccine is which; this may lead to administration errors.
- Prefilling syringes leads to vaccine wastage and increases the risk of vaccine storage under inappropriate conditions.
- Most syringes are designed for immediate administration and not for vaccine storage. Bacterial contamination and growth can occur in syringes that are pre-filled with vaccines that do not contain bacteriostatic agents, such as the vaccine supplied in single-dose vials.
- No stability data are available for vaccine stored in plastic syringes. Vaccine components may interact with the plastic syringe components with time and thereby reduce vaccine potency.

Vaccine Storage & Handling FAQs

- Finally, prefilling syringes is a violation of medication administration guidelines, which state that an individual should only administer medications s/he has prepared and drawn up. This is a quality control and patient safety problem, because the person administering a dose is responsible for the composition and sterility of the dose being administered.

Because of the lack of data concerning the stability and sterility of vaccine stored in syringes prefilled by providers, and reasons listed above, CDC recommends that vaccines drawn into syringes be discarded at the end of the clinic day.

Vaccine Packing and Transport

18. How can I safely pack and transport vaccine?

Approval is required before moving the state supplied vaccine. Guidelines for transporting vaccine can be found in the VDH Vaccine Management Plan that can be downloaded from the Health Department website

<http://www.healthvermont.gov/hc/imm/documents/VaccineManagementPlan.pdf>

Before transporting vaccine, contact the VDH Immunization Program 24/7 at 1-800-640-4374 for approval and for detailed instructions on packing vaccine for transport, if approved.