

Vaccine Storage and Handling

FAQs

Vaccine Potency

What happens to vaccine contents when vaccines are not properly stored (i.e., not refrigerated?)

Excessive heat or cold exposure damages vaccine, resulting in loss of potency. Excessive cold exposure is as bad, if not worse than excessive heat exposure for most vaccines. Once potency is lost, it can never be restored. Furthermore, each time vaccine is exposed to excessive heat or cold, the loss of potency increases and eventually, if the cold chain is not correctly maintained, all potency will be lost, and the vaccine becomes useless. HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines are sensitive to light, which also causes loss of potency of these particular vaccines. If you have concerns about your vaccine supply, contact the vaccine manufacturer and the state health department immunization program.

How can you determine if vaccine has been out of the safe temperature range long enough to affect its efficacy? Is there a set amount of time that is a guideline for vaccine thresholds?

It depends on the vaccine, the length of time it was outside of recommended storage conditions, and the environment it was in (temperature and light). The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention recommends that whenever there is any doubt about the integrity of a vaccine it should be clearly marked "Do Not Use" and stored under appropriate conditions in a properly functioning vaccine storage unit until the integrity of the vaccine is determined. . If you have concerns about vaccine that may not have been stored or handled properly, follow your state health department immunization program policy and contact either the manufacturer's quality control office or the immunization program for guidance. Do not assume that vaccine inappropriately exposed to light or to excessive temperatures cannot be salvaged.

Refrigerator and Freezer Requirements

What are the exact measurements required by the National Center for Immunization and Respiratory Diseases (NCIRD) for a refrigerator to hold vaccines?

NCIRD has never made a recommendation based on size. NCIRD recommends that any refrigerator, freezer, or combined refrigerator/freezer unit used to store vaccine must:

- Be able to maintain required vaccine storage temperatures year-round;
- Be large enough to hold the year's largest inventory;
- Have a certified calibrated thermometer inside each storage compartment; and
- Be dedicated to the storage of vaccines.

Refrigeration units for vaccine storage are available in various sizes and models, including stand-alone and others models that fit under counters. If an under-counter unit has separate exterior doors for the refrigerator and freezer compartments and can maintain appropriate temperatures in these compartments, both the refrigerator and freezer compartments may be

used for vaccine storage. However, the size of an under-counter unit limits the amount of vaccine that can be stored. Be sure that the capacity is sufficient to store the vaccine supply while still allowing for air circulation within the unit. Avoid overstocking the unit because this impedes air flow and leads to temperature fluctuations that may expose the vaccines to inappropriate temperatures. If you need to store large quantities of vaccine, then additional under-counter units or a full-size unit would be needed.

Small single-door (dormitory-style or bar-style) combined refrigerator/freezer units should not be used for vaccine storage. The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store MMRV, varicella, and zoster vaccines. If attempts are made to cool the freezer compartment to the appropriate temperature, the temperature in the refrigerator compartment will fall below the recommended range, potentially freezing the refrigerated vaccines. However, this type of unit may be adequate for temporarily storing **small quantities** of inactivated and MMR vaccines in the refrigerator compartment (not the freezer compartment) **if** the refrigerator compartment can maintain temperatures at 35° to 46°F (2° to 8°C). Make sure not to overstock the unit and impede cold air circulation.

Do not place vaccines directly beside or directly below the freezer compartment in a dormitory-style unit, as this may expose vaccines to temperatures below the recommended range. Place cold packs (not frozen packs) or water bottles in this space to provide a temperature buffer. To reduce the risk of exposing vaccine to freezing temperatures, consider using a compact refrigerator without a freezer compartment.

When is a “dormitory-style” refrigerator not adequate for storing vaccines?

NCIRD recommends that dormitory-style refrigerators only be used to store a clinic's single-day supply of **refrigerated** vaccines and these vaccines should be returned to the main refrigerator storage unit at the end of each clinic day. Dormitory-style refrigerators are not adequate for long-term or permanent storage of biological products because they do not maintain appropriate temperatures.

Storage of VFC vaccine in refrigerators that are designed for use in small household spaces such as dorm rooms **are never acceptable for permanent storage of VFC vaccines**. Permanent storage is defined as the vaccine supply is maintained in the unit 24 hours a day/7 days a week.

“Dorm Style” refrigerators are acceptable for short-term storage of select VFC vaccines under **very limited conditions** which are listed below:

1. The purpose of using these units is for temporary storage when it is not reasonable for the staff administering the vaccine to go to the main storage unit to obtain vaccine for each and every patient.
2. **The unit is never used for storing varicella-containing vaccines.**
3. Only small amounts of inactivated vaccines can be maintained in these units. The amount of inactivated vaccines stored in the unit must never exceed the amount used in the clinic in one day.
4. The vaccine is returned to the main storage unit at the end of each clinic business day and vaccine is never stored in these units overnight or during periods of time when the practice is not open for business.
5. Each unit has a dedicated certified thermometer in place.

- 6. Temperatures are monitored and documented twice a day on temperature log specifically for that unit.** Appropriate action is immediately taken when the temperatures are outside the appropriate range.
- 7. These units must be included and examined during the VFC compliance visit and corrective actions taken and documented by the grantee if any of the above conditions are not met.**

We work in a mobile van that has a dorm-like refrigerator for vaccine storage. I have been unable to find a refrigerator and a separate freezer that would meet the vaccine storage temperature requirements. What do you advise?

A dormitory-style refrigerator may be used for temporarily storing small quantities of vaccines (one day's supply) that require only refrigeration if the unit can maintain temperatures at 35° to 46°F (2° to 8°C) **and** if the volume of vaccine stored in the unit is small enough to allow adequate cold air circulation. Zoster vaccine should NOT be stored in the refrigerator. If you store single-antigen varicella vaccine or MMRV in a refrigerator, they **must** be used within 72 hours or discarded and they cannot be refrozen.

Vaccine Storage Locations

I was told that vaccine stored in a refrigerator could not be stored on the top or bottom shelf and the vaccine could only be in the very middle of the shelves. Is this true?

The temperature inside the refrigerator compartment is not consistent throughout. 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. Ideally, vaccines should be situated on the middle shelves, away from these areas.

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, which is 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 the vaccines can be situated away from the cold air vent and the temperature in this area is within the recommended range of 35° to 46°F (2° to 8°C), the vaccines may also be stored on the upper shelf. If the upper shelf must be used for vaccine storage, it would be best to place MMR on this shelf because MMR is not sensitive to freezing temperatures like the other refrigerated vaccines. In addition, top shelves are less affected than lower shelves by the temperature of room air drawn into the refrigerator when the door is opened.

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?

Vaccines should not 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 compartment. It is recommended that you remove the vegetable bins and put bottles of water in that space to help maintain a constant temperature in your refrigerator.

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. If there is no other choice, these products must be stored below the vaccines on a different shelf. This prevents contamination of the vaccines should the other products spill, and reduces the likelihood of medication errors.

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

It does not matter whether the vaccine is being stored at a traditional office or off-site. Vaccines **must** be stored at the temperatures recommended by the manufacturers regardless of where they are. Ideally, vaccines should be stored at the recommended temperatures inside a properly functioning storage unit (e.g., refrigerator, freezer, refrigerator/freezer combination) at the off-site clinic. If such a unit is not available and the vaccine must be maintained in an insulated cooler during the off-site clinic, keep the cooler closed as much as possible. A thermometer must be kept in the cooler with the vaccines, and temperatures should be checked and recorded periodically to ensure that the cold chain is not broken. It is recommended that, at a minimum, vaccine temperatures be checked and recorded **hourly**.

Temperature Monitoring

How often should temperatures be recorded for refrigerator and freezer compartments where vaccines are stored?

Temperatures inside refrigerator and freezer compartments should be measured and recorded at least twice a day; once at the start of the clinic day and a second time before the clinic is closed for the day. Immediate action must be taken if the temperature is outside the recommended range for either compartment.

How long do you need to monitor temperatures after a refrigerator or freezer thermostat is adjusted before you know the temperatures are within the recommended range and you can safely store vaccines in them?

After the thermostat in a working refrigerator or freezer has been adjusted, 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 outside the recommended range, adjust the thermostat inside the unit and repeat the process. As a general guideline, the National Center for Immunization and Respiratory Diseases (NCIRD) also suggests that you monitor temperatures inside the refrigerator and freezer for a week in any new (or newly repaired) unit before it is used for vaccine storage. This practice allows you to check that the unit is performing well and allows time to make any necessary adjustments before expensive vaccines are put at risk. Of course, twice daily temperature monitoring should be an ongoing practice as well.

Our clinics use a digital thermometer in the refrigerators where vaccines are stored (battery powered and National Institute of Standards and Technology certified). These thermometers also have alarm capability and can show the temperature range since the thermometer was last checked and cleared. Is it still necessary to record temperatures twice a day or will once a day be adequate?

The National Center for Immunization and Respiratory Diseases (NCIRD) still recommends twice daily temperature monitoring and recording. Alarms and continuous recording thermometers add another layer of protection and are a great addition but they are not a substitute for manually checking and recording the temperatures twice daily. Relying solely on alarms can lead to complacency and inappropriate temperatures may not be discovered in a timely manner (e.g., alarm battery failure). Temperatures may be recorded continuously by some thermometers but, unless someone physically checks the recordings twice a day, inappropriate storage temperatures may not be detected and corrected in a timely manner.

Therefore, NCIRD recommends checking and recording the temperatures first thing in the morning to be sure there has not been a problem overnight. Check and record the temperatures at the end of the clinic day to make sure there has not been a problem during the day (which acts as a backup for the alarm in case it is not working or in case no one heard it). This end-of-the-day temperature reading also gives you a reference point should there be a subsequent temperature problem overnight. Recording twice daily temperatures also gives you a record over time of how well your refrigerator and freezer are working so you can spot trends in temperature during the day or overnight. Vaccines are expensive and if they have been damaged because of storage at inappropriate temperatures you may not be protecting your patients. Manually checking and recording the temperatures twice daily takes very little time and is worth the extra effort.

Why is it recommended that we keep temperature logs for 3 years?

By keeping temperature logs for at least 3 years, you can track recurring temperature problems and determine how long they have been happening. This information allows you to better define the time frame in question and take appropriate action. For example, out-of-range temperature problems are sometimes detected after-the-fact. A record review can determine how long temperatures have been out of range, which vaccines may have been compromised, and which vaccine recipients may need to be recalled. Archived temperature logs also show how well the vaccine storage unit is working over time and can be used to determine when a unit may need adjustment, maintenance, or replacement, such as when temperatures are consistently at the limit or sometimes beyond the limit of the recommended temperature range.

Vaccine Expiration

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 with only a month and year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial. Any unused vaccine or diluent should not be used after this month has passed.

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. When opened, the remaining doses from partially used multidose vials can be administered until the expiration date printed on the vial or vaccine packaging, provided that the vial has been stored correctly and that the vaccine is not visibly contaminated unless otherwise indicated in the manufacturer's package insert.

Some multidose vaccine vials contain lyophilized (freeze-dried) vaccine. Once reconstituted, the life of each vaccine varies from product to product and the new expiration date and time most likely will differ from that printed on the vial of lyophilized vaccine. Consult the package insert for the most up-to-date information about expiration dates and times following reconstitution. Unused reconstituted vaccines kept beyond these limits should not be administered.

Our state supplies us with 2 mL vials of Immune Globulin (Human) USP. Often we only use parts of the vial. I read in the package insert that because the Immune Globulin does not contain a preservative the vial should be entered only once for administration purposes. Do we need to throw away a vial if it is partially used?

Multiple doses may be withdrawn from this vial during that same clinic day because bacterial growth from contamination is unlikely during that short interval. However, this vial must be discarded at the end of the clinic day—it must not be kept overnight for use the next day. This is the same recommendation as that for the use of single-dose vials of vaccine. Single-dose vials with broken seals (either the metal tab or the rubber stopper) should be discarded at the end of the clinic day.

How long is a vaccine dose viable if it has been stored in the refrigerator in a syringe?

There are inadequate data to answer this question. Disposable syringes are meant for administration of immunobiologics not for storage. The National Center for Immunization and Respiratory Diseases (NCIRD) strongly discourages prefilling syringes and has identified the following problems associated with this practice:

- Once 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 you prefill with vaccines that do not contain bacteriostatic agents, such as the vaccines 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**.
- 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 if you do not draw up the vaccine yourself, you cannot be sure of the composition and sterility of the dose you are administering.

Because of the lack of data concerning the stability and sterility of vaccine stored in syringes prefilled by providers and because of the other reasons just listed, NCIRD recommends that

vaccines drawn into syringes be discarded at the end of the clinic day. This does not apply to manufacturer-supplied prefilled glass syringes.

Vaccine Packing and Transport

In our county we have a number of district offices that are located a significant distance away from the main office where the vaccines are stored. Some offices are as far as 2 hours away from the main office. Nurses in these offices place monthly orders; the orders are filled and the vaccines are transported with ice packs to these offices (not always in a Styrofoam™ container or ice chest). Are guidelines available that outline how the vaccines should be packaged and transported?

Contact the vaccine manufacturer and the state health department immunization program for detailed instructions on packing vaccine for transport. In general, vaccines should be packed and transported in properly insulated containers. You may use the shipping containers the vaccines arrived in from the manufacturer. Alternatively, you may use hardsided plastic insulated coolers or Styrofoam™ coolers with at least 2-inch thick walls. Thinwalled Styrofoam™ coolers, such as those purchased at grocery stores to hold beverages, are not acceptable. Pack the vaccines with an adequate supply of refrigerated/frozen packs. Be sure to place insulating material (e.g., bubble wrap, crumpled paper) between the refrigerated/frozen packs and the vaccine to prevent accidental freezing. Use properly placed thermometers in each container. The thermometers should be placed along side the vaccine and should not be in direct contact with the refrigerated/frozen packs. Frozen vaccines (i.e., varicella-containing vaccines) require dry ice and special procedures for transport. The manufacturers' storage guidelines should be maintained throughout packing and transport and vaccines should be transferred to properly functioning refrigerators/freezers upon arrival.