Vaccine Storage & Handling Toolkit

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U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Table of Contents

Table of Contents

Table of Contents

Table of Contents

Throughout the toolkit, icons will be used to alert the reader to requirements, recommendations, best practices, scenarios that require immediate action, and hyperlink information.

Icon	Description
	Contact your **immunization program** if you are a Vaccines for Children (VFC) provider or have other vaccines purchased with public funds to ensure your storage and handling practices meet state and federal requirements.
	CDC Recommendation that applies to anyone who stores vaccines
	Best Practice
	Take immediate action!
	Link to more information about key messages
	Link to content outside the Toolkit

Print warning! Printing this toolkit may not enable provider to have the most current information. Refer to online version for the most current information.

Where to go for updated CDC information including webinars and other educational offerings

- Additional information is available on CDC's Vaccine Storage and Handling webpage, **http://www.cdc.gov/vaccines/recs/storage/default.htm**. There is a place on this page where you can sign up for notifications about updates to this page.
- Educational programs related to Vaccine Storage and Handling, e.g., webinars or netconferences, can be accessed at **http://www.cdc.gov/vaccines/ed/default.htm**.

Where to get questions answered

- If you have questions, contact your state/local immunization program, **http://www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**
- You can also send questions to CDC at **NIPInfo@cdc.gov**

Key Messages:

- This toolkit provides vaccine storage and handling best practices.
- CDC encourages providers to move toward implementing these recommendations as soon as possible.
- Refer to the manufacturer's product information/**package inserts** for storage and handling guidance for individual vaccines.
- VFC providers or providers who have other vaccines purchased with public funds should consult their **immunization program** for specific recommendations and requirements.

Vaccine Storage and Handling

Background

The Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit provides best practices based on recommendations of the Advisory Committee on Immunization Practices (ACIP), vaccine manufacturers' product information, and studies conducted by the National Institute of Standards and Technology (NIST). CDC encourages immunization providers to move toward implementing these best practices and recommendations as soon as possible.

If you are a Vaccines for Children (VFC) provider or if you have other vaccines purchased with public funds, you should consult your **immunization program** for recommendations and requirements specific to your area.

Value of Vaccine Storage and Handling Best Practices

Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients lose confidence in vaccines and their providers when revaccination is necessary because the vaccine(s) they received may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly). Storage and handling errors can also result in significant financial loss if the vaccine(s) cannot be used.

Vaccine Storage and Handling Protocols

State/local health department immunization programs (herein referred to as "immunization program[s]") throughout the United States have been successful in preventing and eradicating vaccine-preventable diseases in part because of proper storage and handling practices. Immunization programs and practices should have written protocols for routine vaccine storage and handling, as well as for emergency procedures. This toolkit provides guidance for developing and updating those protocols. **Storage and Handling Plans** that include step-by-step protocols should be easily accessible in every facility that provides immunizations.

Manufacturer Protocols

Refer to the manufacturer's product information and **package inserts** for specific, detailed storage and handling protocols for individual vaccines.

Avoiding Mistakes

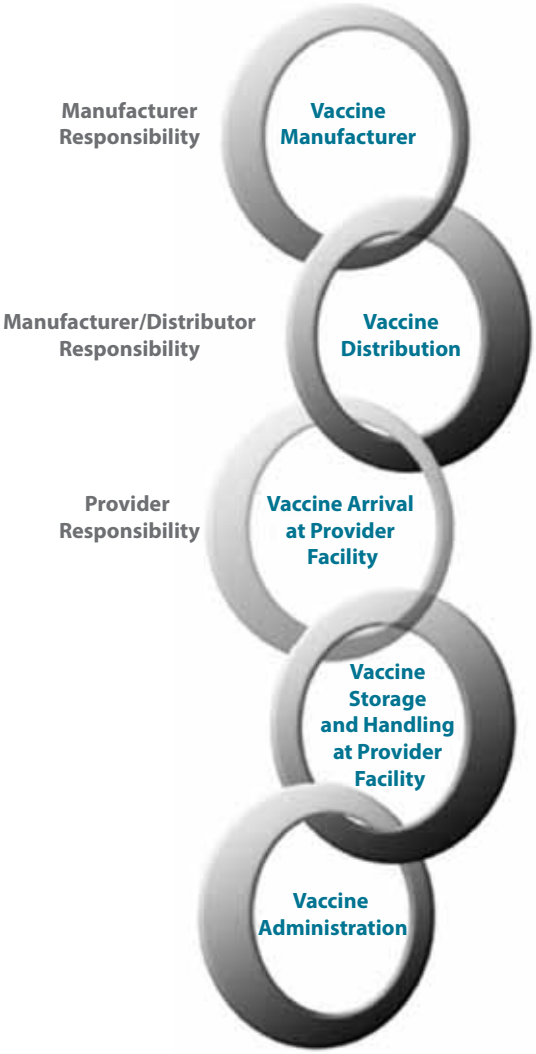
Adherence to best practices and guidance in this toolkit can assist providers in avoiding storage and handling mistakes that can be very costly.

Notes:

Key Messages:

- The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition.
- Monitor the temperature of your storage unit(s) regularly to assure that appropriate conditions are maintained.
- Take immediate corrective action when a storage unit temperature is outside the recommended range (**Troubleshooting**).
- Call the **vaccine manufacturer** for guidance.
- If you are a VFC provider or have other vaccines purchased with public funds, contact your immunization program.
- Vaccine appearance is NOT a reliable indicator that vaccines have been stored under appropriate conditions.
- Vaccine exposed to inappropriate temperatures that is inadvertently administered generally should be repeated. Contact your **immunization program**, **vaccine manufacturer**(s), or both for guidance.

Cold Chain Flow Chart



What is the Vaccine Cold Chain?

The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition. The cold chain relies on three main elements:

- Well-trained personnel
- Reliable transportation and storage equipment
- Efficient management procedures

The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccine(s) to the distributor, then delivery and storage at the provider facility, and ends with administration of vaccine to the patient. Appropriate storage conditions must be maintained at every link in the cold chain.

Importance of Maintaining the Vaccine Cold Chain

Vaccine Potency

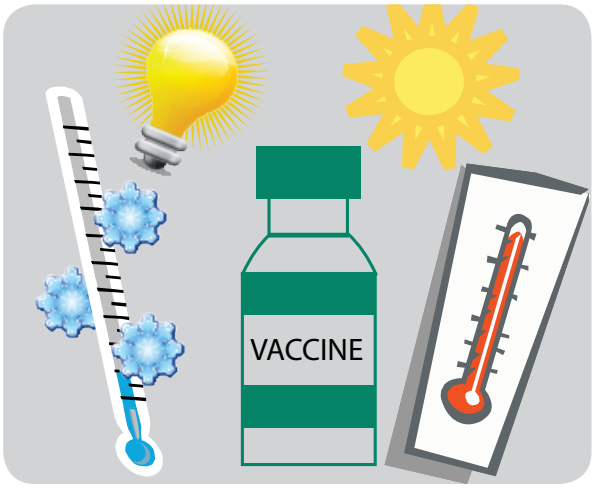
Excessive heat, cold, or light exposure can damage vaccines, resulting in reduced potency. Once potency is lost, it cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. Eventually, if the cold chain is not properly maintained, potency will be lost, and the vaccines become useless.

While exposure to any inappropriate conditions can affect potency of refrigerated vaccines, a single exposure to freezing temperatures will destroy some. Liquid vaccines that contain an aluminum adjuvant* can permanently lose potency when exposed to freezing temperatures. Monitor the temperature of your storage unit(s) regularly.

Take immediate corrective action when a storage unit temperature reading is outside the recommended range (temperature excursion). Call your **immunization program** and/or the **vaccine manufacturer** for guidance (**Troubleshooting**).

If you are a VFC provider or have other vaccines purchased with public funds, contact your **immunization program**.

Vaccine Appearance after Exposure to Inappropriate Storage Conditions



Some vaccines may show physical evidence that potency has been reduced when exposed to inappropriate storage conditions. This may appear as clumping in the solution that does not go away when the vial is shaken. Other vaccines may look normal when exposed to inappropriate storage conditions (see photos below). For example, inactivated vaccines exposed to freezing temperatures (i.e., 32°F [0°C] or colder) may not appear frozen and give no indication of reduced or lost potency. Vaccine appearance is NOT a reliable indicator that vaccines have been stored under appropriate conditions.

Properly stored vaccine
Full Potency

Can you spot the difference?

Improperly stored vaccine
Diminished Potency

Vaccine appearance is NOT a reliable indicator that vaccines have been stored under appropriate conditions.

*Adacel, Boostrix, Cervarix, Comvax, Daptacel, Decavac, Engerix-B, Gardasil, Havrix, Infanrix, Kinrix, Pediarix, PedvaxHIB, Pentacel, Prevnar 13, Recombivax HB, Tenivac, Twinrix, and Vaqta contain an aluminum adjuvant, which boosts the immune response to the vaccine.

Store in Freezer

Between -58°F and +5°F (-50°C and -15°C)

VAR†

HZV†

MMRV†

MMR†§

Store in Refrigerator

Between 35°F and 46°F (2°C and 8°C)

MMR†§

HepA HepB HepA-HepB

Hib† Hib-HepB

Human papillomavirus (HPV2 and HPV4†)

Influenza (LAIV, IIV,† RIV†)

IPV†

Meningococcal-containing

(Hib-MenCY,† MCV4,† MPSV4)

Pneumococcal (PCV13 and PPSV23)

Rotavirus† (RV1 and RV5)

Diphtheria toxoid-, Tetanus toxoid-,

and Pertussis-containing

(DT, DTaP, DTaP-HepB-IPV, DTaP-IPV,

DTaP-IPV/Hib, Tdap, Td, TT)

†Protect the following vaccines from light: Varivax, Zostavax, ProQuad, M-M-R II, Hiberix, Gardasil, Afluria, Agriflu, Fluarix, Flublok, Flucelvax, FluLaval, Fluvirin, IPOL, MenHibrix, Menveo, Rotarix, and RotaTeq.
§Unreconstituted lyophilized (freeze-dried) MMR may be frozen or refrigerated.

Consequences of Vaccine Cold Chain Failure

Reduced vaccine potency due to inappropriate storage conditions can be costly.[1,2,3] Patients who receive vaccine with reduced potency caused by inappropriate storage conditions may not be fully protected against vaccine-preventable diseases.

In General Recommendations on Immunization, ACIP recommends "vaccine exposed to inappropriate temperatures that is inadvertently administered generally should be repeated."[4] Contact your **immunization program**, **vaccine manufacturer**(s), or both for guidance about recalling patients for revaccination. Vaccine recalls due to inappropriate storage can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines. They also can be a liability for a provider's practice. Patients who refuse revaccination can remain unprotected from serious, vaccine-preventable diseases.

Vaccine inventories are very expensive. The costs associated with loss and replacement vaccines, and resources necessary to conduct a recall of patients, can be significant.[5]

References

1. Department of Health and Human Services, Office of Inspector General. Vaccines for Children Program: Vulnerabilities in Vaccine Management, June 2012, **http://oig.hhs.gov/oei/reports/oei-04-10-00430.asp**.
2. Gazmararian JA, Oster NV, Green DC, Schuessler L, Howell K, et al. Vaccine storage practices in primary care physician offices: assessment and intervention. Am J Prev Med 2002;23(4):246–53.
3. Bell KN, Hogue CJR, Manning C, Kendal AP. Risk factors for improper vaccine storage and handling in private provider offices. Pediatrics 2001;107(6):1–5.
4. Centers for Disease Control and Prevention. General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices and the American Academy of Family Physicians. *MMWR* 2011;60 (No. RR-2):17–19. Available from URL: **http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm**
5. Centers for Disease Control and Prevention. CDC vaccine price list. Atlanta, GA: CDC. Available from URL: **http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/**

Notes:

Storage and Handling Plans

Key Messages:

- Develop and stick to a Routine Vaccine Storage and Handling Plan and update annually.
- Develop an Emergency Vaccine Retrieval and Storage Plan and update annually.
- If you are a VFC provider or have other vaccines purchased with public funds, contact your **immunization program** for guidance regarding routine and emergency plans.
- Keep plans near storage unit(s) and make sure staff members know where to find them and are familiar with their contents.
- Ensure that custodial and security staff are aware of the emergency plan and know how to notify appropriate staff if there is a problem.
- If power is lost short-term (usually 2 hours or less), depending on room temperature, and if there are water bottles in the refrigerator and frozen coolant packs in the freezer, storage temperatures can probably be maintained if doors are kept closed.
- Do NOT allow vaccines to remain in a nonfunctioning unit for an extended period of time. Activate the emergency plan.
- Check vaccine temperatures upon arrival at the alternate storage facility and ensure immediate storage at manufacturer-recommended temperatures.
- Consult your agency or **immunization program** for any special emergency instructions.

General Recommendations

Develop and stick to a detailed written Routine Vaccine Storage and Handling Plan that is updated annually. In this plan, include all aspects of routine vaccine management, from ordering and managing inventory to monitoring storage conditions. A well-written plan will help providers stay organized, serve as a reference and training tool, and provide quality assurance of proper vaccine management (**Routine Vaccine Storage and Handling Plan Worksheet**).

In addition, develop a detailed written Emergency Vaccine Retrieval and Storage Plan in the event of refrigerator and/or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate storage conditions. Review and update the emergency plan annually (**Emergency Vaccine Retrieval and Storage Plan Worksheet**).

Include signature, name, and title of the person(s) who prepared the plans.

Ensure that all staff members who administer or handle vaccines in any way are familiar with these plans. Keep plans near storage unit(s) and make sure staff members know where to find them.

Many components of routine and emergency plans will be the same for every facility, but some details may vary depending on local policies.

If you are a VFC provider or have other vaccines purchased with public funds, contact your **immunization program** for guidance regarding routine and emergency plans.

Each facility should have routine and emergency plans.

Routine Vaccine Storage and Handling Plan

The information below is provided as a guideline for developing your routine plan. You may also use the **Routine Vaccine Storage and Handling Plan Worksheet**.

Each routine plan should include:

- Up-to-date contact information for the following:
  - Persons who are responsible for routine vaccine storage and handling, e.g., primary and alternate (back-up) vaccine coordinators (**Staff**)
  - **Immunization Program**
  - **Vaccine Manufacturers**
  - Refrigerator and freezer maintenance and repair company(ies)
  - Utility/power company
  - Vaccine storage unit alarm company (if applicable)
  - Sources of qualified containers, packing materials, and calibrated temperature monitoring devices
- Descriptions of roles and responsibilities of primary and alternate (back-up) vaccine coordinators (**Staff**).
- Policy on education and **training** for facility staff.
- Protocols for:
  - Ordering and accepting vaccine deliveries (**Vaccine Stock Calculations and Ordering** and **Receiving and Unpacking Deliveries**)
  - Storage unit **temperature monitoring**
  - **Storage equipment** maintenance
  - Correct placement of vaccines within storage units (**Vaccine and Diluent Placement within Storage Unit**)
  - Responding to storage and handling problems (**Troubleshooting**)
  - Inventory management (contact your **immunization program** for details and see **Vaccine Inventory Management** for general guidelines)
  - Receiving and unpacking deliveries (contact your **immunization program** for details and see **Vaccine Deliveries**)
  - Transporting vaccines in an emergency or to off-site/satellite facilities (contact your **immunization program** for details and see **Vaccine Transport** for general guidelines)
  - Handling vaccines prior to administration (**Vaccine Preparation**)
  - Proper disposal of vaccines and supplies (contact your **immunization program**

for details and see **Vaccine Disposal** for general guidelines)

- Storage requirements for each vaccine and diluent in your inventory (**package inserts**).
- Samples of forms used in your facility (e.g., ordering forms, temperature logs, stock records, etc.).
- Additional resources are available in **Resources** and from the **Immunization Action Coalition (IAC): Clinic Resources – Storage and Handling**.
- Also establish a checklist of procedures and post it on all vaccine storage unit(s) (IAC's **Checklist for Safe Vaccine Storage and Handling**).

Emergency Vaccine Retrieval and Storage Plan

Advance Preparations

Various situations may compromise vaccine storage conditions, such as equipment failures, power outages, or natural disasters. Ensure that the emergency plan includes up-to-date information regarding procedures to follow to protect and/or retrieve vaccines as quickly as possible when a potentially compromising situation occurs. In addition to facility staff, ensure that custodial and security staff are aware of the emergency plan and know procedures to follow to notify designated staff about any problems with vaccine storage equipment or power outages.

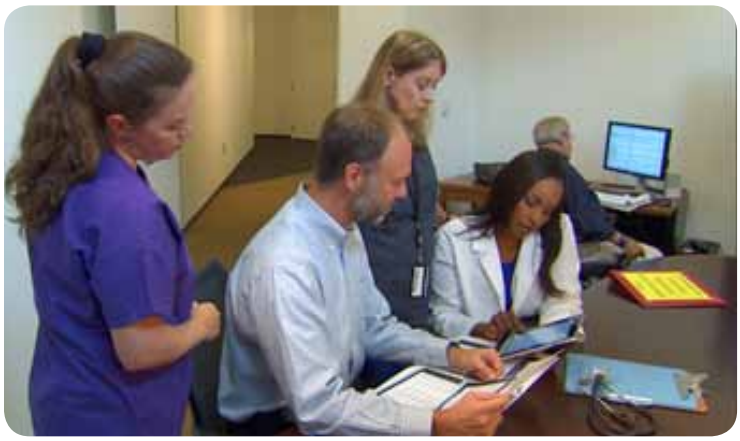
What's in an Emergency Plan?

The information below is provided as a guideline for developing an emergency plan. You may also use the **Emergency Vaccine Retrieval and Storage Plan Worksheet** and IAC's **Emergency Response Worksheet** to help organize your response. Consult your agency or **immunization program** for any special instructions or forms.

Each emergency plan should include:

- Role of vaccine coordinator and alternate (back-up)
- Emergency contact list
- Storage unit specifications
- Alternate storage facilities
- Written instructions for after hours
- Adequate supplies for packing and transport
- Protocol for packing
- Protocol for transport

- Designated primary and alternate (back-up) vaccine coordinators with emergency contact information.
  In addition to routine vaccine storage and handling duties (**Staff**), primary and alternate (back-up) vaccine coordinators should:
  - Monitor operation of storage equipment and systems
  - Track inclement weather conditions
  - Set up and maintain monitoring/



Staff members should be familiar with the Routine and Emergency Vaccine Storage and Handling Plan.

notification system during times of inclement weather or other conditions that might cause a power outage (a continuous-monitoring temperature alarm/notification system should be considered, especially for facilities with large inventories)
  - Post emergency contact information on circuit breaker(s) or electrical panel
  - Ensure appropriate handling of vaccine during a disaster or power outage
  - Ensure 24-hour access to building and vaccine storage unit(s)
  - Ensure that sufficient fuel is on hand to continuously run generator for at least 72 hours if facility has a back-up generator
- Emergency staff contact list in order of contact preference.
  Determine whether all or certain persons on the list should be contacted in the event of a vaccine storage emergency or if the first person reached is sufficient. Include primary and alternate (back-up) vaccine coordinators on the list. Record names (in order) and contact information. Assure that contact information is updated at least quarterly.
- Vaccine storage unit specifications.
  For each vaccine storage unit in your facility, identify type of unit (e.g., stand-alone refrigerator), brand name, model number, and serial number. These specifications may be useful for the repair company.
- Alternate vaccine storage facility or facilities.
  Establish working agreements with at least one alternate storage facility with a back-up generator where vaccines can be appropriately stored and monitored for the interim (e.g., hospital, long-term care facility, state depot, Red Cross, fire station, packing plant, commercial pharmacy). Make advance arrangements with facility(ies) to store your vaccines when weather predictions call for inclement conditions (e.g., tornadoes, hurricanes, ice, severe snowstorms), when your storage equipment cannot be repaired, or when power cannot be restored before the storage unit temperature rises above the recommended range. Record name of alternate facility(ies), name of contact

Establish at least one alternate storage facility where vaccine can be appropriately stored and monitored. This facility should have a back-up generator.

person(s), and telephone number(s). Include instructions for 24-hour access.

- Written instructions for entering your facility and vaccine storage spaces in an emergency if building is closed. In these instructions, include the building security/after-hours access procedure, floor diagram, and locations of the following:
  - Alarms (including instructions for use)
  - Doors
  - Flashlights
  - Spare batteries
  - Light switches
  - Keys
  - Locks
  - Circuit breakers
  - Packing materials
- Adequate supply of qualified containers and packing materials for facility's largest annual inventory. Appropriate materials may include portable actively or passively cooled refrigerator/freezer units, hard-sided insulated containers, "conditioned" coolant packs that are cold or frozen (depending on type of vaccine), and a calibrated temperature monitoring device for each container (**Vaccine Transport**). In situations where an alternate vaccine storage facility with a back-up generator cannot be identified within a reasonable distance, qualified containers and packing materials can be used to store vaccines temporarily and safely at your facility. This temporary storage should only be for as long as the container and pack out are qualified to maintain storage temperatures and the container remains closed. A temperature monitoring device should always be placed with the vaccines. Record names and contact information for sources of materials.
- Written protocol for vaccine packing. Develop standard operating procedures (SOPs) for packing vaccines. Make instructions readily available for staff. Key steps that should be reflected in all SOPs are:
  - Open refrigerator and freezer doors only when absolutely necessary and only after you have made all preparations for packing and moving vaccines to an alternate storage facility.
  - Use qualified containers and packing materials and procedures for refrigerated and frozen vaccines (**Vaccine Transport** for general guidelines).
- Written protocols, vehicles, and drivers for transporting vaccines to and from alternate vaccine storage facility.
  - Vaccines may be transported within non-commercial vehicles inside the passenger compartment (not in trunk because temperatures cannot be controlled inside trunk). Make advance arrangements for primary and back-up vehicles and drivers and record the contact information.
  - If location is far away or if you have a large quantity of vaccines, consider renting a refrigerated truck. In this case, joining with other facilities to reduce costs may be advantageous. Make advance arrangements with a local refrigeration company and an alternate and record contact information.
  - Check with your **immunization program** for guidance and resources on emergency transport of vaccines.
  - Develop written protocols for transporting vaccines to and from alternate storage facility:
- Establish how to load vehicle.

- Have pre-selected routes to take (and alternate routes if necessary).
- Determine estimated time en route.

Improper packing of vaccines for transport is as risky as storage unit failure. Vaccine manufacturers do not support reuse of their containers and packing materials for vaccine transport. Improper repackaging using these materials and improper transportation could negatively impact vaccines.

Emergency Procedures

Equipment failure

No piece of vaccine storage equipment is infallible, and there is always potential for vaccine storage equipment failure. At some point, equipment failure will occur related to a power failure, breakdown, or normal wear and tear. Part of a provider's responsibility for proper vaccine storage is preparing for equipment failure by having back-up equipment and back-up plans available.

Impending emergency

When state officials, local officials, or providers have reasonable cause to believe that weather conditions, natural disasters, or other emergencies might disrupt power in or flood any facility where vaccines are stored, implement emergency procedures in advance of event.

Power outages

If power is lost short-term (usually 2 hours or less) and depending on room temperature, storage temperatures can probably be maintained with water bottles in the refrigerator, frozen coolant packs in the freezer, and by taking the following steps:

- Do not open storage unit door until power is restored.
- Continue to monitor temperature inside each storage unit.
  - Some temperature monitoring devices allow temperature monitoring without opening storage unit door. In this case, record room temperature and temperature(s) inside unit(s) at time problem is discovered, as well as minimum and maximum temperature(s) reached inside unit(s) during power outage.
  - If this type of temperature monitoring device is not being used, do not open a storage unit door to check temperature during power outage. Document room temperature and temperature inside each storage unit as soon as possible after power has been restored. If you have a digital data logger, document length of time power has been off and minimum and maximum temperatures observed within storage unit(s).
- When power is restored, if temperature inside refrigerator is not between 35°F and 46°F (2°C and 8°C) or if temperature inside freezer is not between -58°F and +5°F (-50°C and -15°C), document duration of inappropriate temperature exposure and follow procedures for **Handling Inappropriate Vaccine Storage Conditions (Light and Temperature)**.

Do NOT allow vaccines to remain in a nonfunctioning unit for an extended period of time. If at any time you are unsure how long the power interruption will last, or you determine that power will not be restored in time to maintain internal temperatures within recommended ranges, activate your emergency

plan.

- Suspend vaccination activities before onset of emergency conditions, if possible.
  This will allow sufficient time for packing and transporting vaccines.
- Notify staff at alternate vaccine storage facility.
  Before moving your vaccines, contact alternate storage facility to make them aware of the situation and to ensure that their back-up generator is working.
- Conduct an inventory of vaccines and record actions taken.
  Use the **Emergency Vaccine Retrieval and Storage Plan Worksheet**. Also note if frozen coolant packs were in freezer and water bottles were in refrigerator at time of event.
- Pack the affected vaccines (**Vaccine Transport**).
- Follow established vaccine transport procedures (**Written Protocols, Vehicles, and Drivers for Transporting Vaccines to and from Alternate Vaccine Storage Facility**).
- Check vaccine temperature upon arrival at alternate storage facility and ensure immediate storage at manufacturer-recommended temperatures.

If you have no warning and an emergency event is already occurring or has already occurred, you should still follow these procedures if they can be done safely. Consult your agency or **immunization program** for special instructions.

The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers general guidance concerning storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions (**Impact of Severe Weather Conditions on Biological Products**).

Notes:

Key Messages:

- Designate one staff member to be the primary coordinator.
- Designate at least one alternate (back-up) coordinator.
- Primary and alternate (back-up) coordinators should be fully trained in routine and emergency policies and procedures.
- It is also important that a physician partner or member of management is directly involved with responsible clinical staff—someone with a clear understanding of vaccine replacement costs and clinical implications of mismanaged storage units and vaccines.
- All staff who receive deliveries and handle or administer vaccines should be familiar with storage and handling policies and procedures.
- Storage and handling training should:
  - Be part of new employee orientation
  - Be annual training for all staff involved in these activities
  - Occur whenever recommendations are updated and when new vaccines are added
- Click here for CDC's online training module, **You Call the Shots: Vaccine Storage and Handling**.

Primary Vaccine Coordinator and Alternate (Back-up) Vaccine Coordinator

Designate one staff member to be the primary coordinator. This person will be responsible for ensuring that all vaccines are stored and handled correctly. Coordinator responsibilities include but are not limited to:

- Ordering vaccines
- Overseeing proper receipt and storage of deliveries
- Organizing vaccines within storage unit(s)
- Reading and recording storage unit temperatures a minimum of 2 times each workday
- Reading and recording minimum/maximum temperatures once per workday, preferably 1 time each morning
- Downloading and reviewing temperature data at least 1 time each week
- Making sure the door is firmly closed when not in use
- Rotating stock at least 1 time each week so that vaccine closest to the expiration date will be used first
- Removing expired vaccine from storage unit(s) so that it is not used
- Responding to possible temperature excursions (**Handling Inappropriate Vaccine Storage Conditions [Light and Temperature]**)
- Overseeing proper **Vaccine Transport**
- Maintaining all documentation, including temperature excursion responses and VFC program records
- Ensuring adequately trained staff

Also designate at least one alternate (back-up) coordinator who will assume these responsibilities in the absence of the primary coordinator. Coordinators should be fully trained in routine and emergency policies and procedures. It is also important that a physician partner or member of management is directly involved with responsible clinical staff—someone with a clear understanding of vaccine replacement costs and clinical implications of mismanaged storage units and vaccines.

Designate a Primary Vaccine Coordinator and at least one Alternate (back-up) Vaccine Coordinator.

Training

If you are a VFC provider or have other vaccines purchased with public funds, contact your **immunization program** regarding required training and resources.

All staff who receive deliveries and handle or administer vaccines should be familiar with storage and handling policies and procedures at their facility. This includes anyone who accepts vaccine deliveries or who may have access to unit(s) where vaccines are stored. Include storage and handling training as part of new employee orientation and provide annual training for all staff involved in storage and handling activities. To maintain staff competency, provide training whenever recommendations are updated and when new vaccines are added to inventory. Record dates of trainings and names of participants. Skill checks are also recommended to validate competence (IAC's **Checklist for Safe Vaccine Storage and Handling**).

Click here for CDC's online training module, **You Call the Shots: Vaccine Storage and Handling**. This toolkit can also serve as a reference guide in conjunction with other resources on the **CDC Storage and Handling web page**. Many **immunization programs** and professional organizations also offer vaccine storage and handling training programs.

Notes:

Vaccine Storage Equipment

Key Messages:

- Keep a logbook for each piece of storage equipment.
- CDC recommends stand-alone units or pharmacy grade/purpose-built units.
- CDC does not recommend and VFC does not allow storage of any vaccine in a dormitory-style (or bar-style) refrigerator under any circumstances.
- When setting up a storage unit, allow at least 4 inches (10 cm) of space between unit and wall.
- Nothing should block the cover of unit motor compartment.
- Make sure that unit stands firm and level and is 1 to 2 inches (2.5 to 5 cm) above the floor.
- Set refrigerator temperature mid-range to achieve an average of about 40°F (5°C).
- The freezer should maintain temperatures between -58°F and +5°F (-50°C and -15°C).
- Only primary or alternate (back-up) coordinator should adjust temperature of a vaccine storage unit.
- Before using a new storage unit, allow for 1 week of temperature readings a minimum of 2 times each workday, including minimum/maximum temperatures 1 time each morning.
- Water bottles can help maintain stable temperatures and serve as a physical barrier to placing vaccines in an area where there is greater risk for temperature excursions (for example, top shelf, floor, and in door racks of refrigerator).
- Frozen coolant packs can help maintain stable temperatures and serve as a physical barrier when placed along walls, back, and bottom of freezer, and inside racks of freezer door.
- Routinely check unit door throughout the day and at end of workday to ensure it is tightly closed. An open door alarm and self-closing door may prevent a problem. Check door seals for sign of wear and tear.
- Back-up generators should:
  - Be tested quarterly
  - Receive maintenance at least annually
  - Have sufficient capacity to run continuously for 72 hours
  - Have adequate fuel supply on hand

Vaccine Storage Equipment

Disclaimer: This chapter provides guidance on vaccine storage equipment, equipment maintenance, and methods and devices used to protect vaccines against equipment failure. Use of trade names and commercial sources in this toolkit is for identification only, and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or the Centers for Disease Control and Prevention (CDC). Photographs from non-federal organizations are provided solely as a service to our users. These photographs do not constitute an endorsement of these organizations by CDC or the federal government and none should be inferred.

If you provide VFC vaccines or other vaccines purchased with public funds, contact your immunization program regarding requirements for vaccine storage equipment.

General Recommendations

Think of your storage equipment as an insurance policy to protect patients' health and your facility against costly vaccine replacement, inadvertent administration of compromised vaccine, and other consequences (e.g., costs of revaccination and loss of patient confidence in your practice).

Equipment Logbook

Keep a logbook for each piece of storage equipment that includes the following:

- Serial number(s)
- Manuals, instructions, or links to equipment websites
- Dates of installation
- Dates of routine maintenance
- Dates of repairs or servicing
- Name of company(ies) and contact information

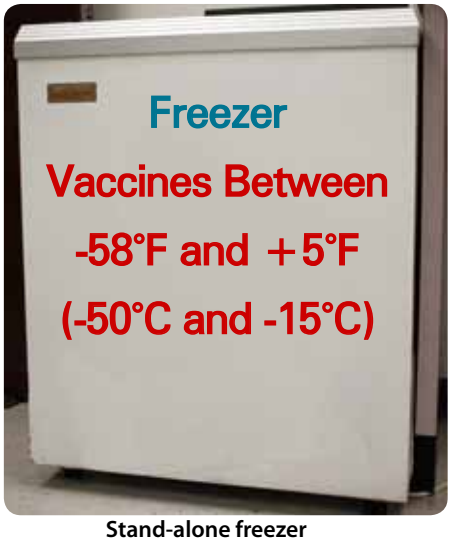
Vaccine Storage Equipment Recommendations

While CDC does not recommend specific brands of storage units, CDC does provide guidance on types of storage units that offer greater assurance of proper temperatures based on equipment testing by NIST.

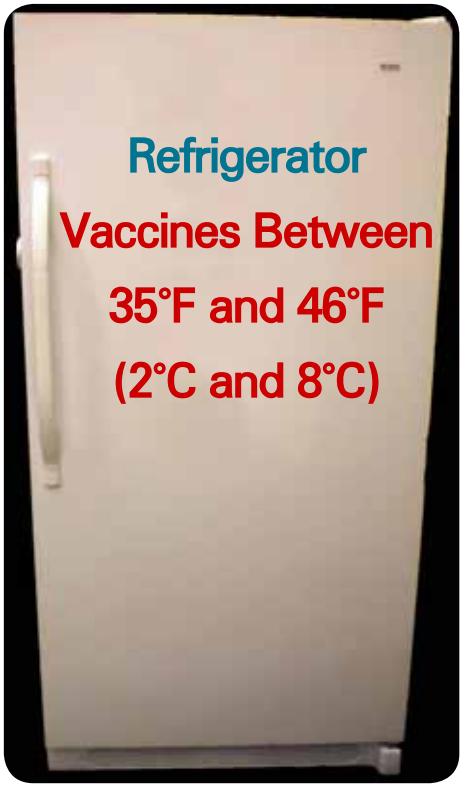
Refrigerators and freezers are available in different grades (household, commercial, and pharmaceutical) and types (stand-alone, combination).

Stand-alone Units

CDC recommends stand-alone units that either refrigerate or freeze or pharmaceutical/purpose-built units. These units can vary in size, from compact, under-the-counter style to large, stand-alone units.



Stand-alone freezer



Stand-alone refrigerator

Vaccine Storage Equipment

A **NIST** study, conducted in 2009, demonstrated that stand-alone or pharmaceutical units maintain required temperatures better than household/commercial combination units, particularly the freezer section of household, combination units.[1]

Minimum characteristics of refrigerators and freezers used for vaccine storage include:

- Enough room to store the year's largest inventory a provider might have at busiest point in the year without crowding (e.g., flu season)
- Enough room to store water bottles in refrigerator and frozen coolant packs in freezer to stabilize temperatures (**Stabilizing Temperatures with Water Bottles and Frozen Coolant Packs**)
- Reliably maintains appropriate vaccine storage temperatures year-round

It is normal for ice and frost to accumulate inside the freezer (and even in some types of refrigerators). A thin layer of frost does not affect cooling performance, but a thick layer will affect a unit's ability to efficiently maintain temperatures and will eventually cause failure. If your stand-alone freezer is manual defrost, defrost it regularly to maintain temperature stability. You will need another storage unit that maintains appropriate freezer temperatures for temporary vaccine storage while defrosting. The following is a suggested defrosting procedure:

1. Check inside walls of freezer weekly
   a. When frost has accumulated to a thickness of approximately 1 cm, unit should be defrosted
   b. The more the unit is opened/closed, the quicker frost will accumulate
   c. Follow manufacturer's recommendations for defrosting
2. Remove all vaccines
3. Place vaccines in alternate unit that maintains appropriate temperatures
4. Turn off power and unplug unit being defrosted
5. Remove frozen coolant packs and keep frozen
6. Keep freezer door open and allow ice to melt
7. Remove loose ice by hand, do NOT use a sharp tool
8. Place container of warm (NOT boiling) water in freezer to speed melting
9. Clean and dry unit when all ice is melted
10. Clean refrigerator compartment, if combination unit
11. Connect to power and set thermostat to correct setting
12. Monitor temperature with calibrated thermometer every hour for several hours until stable and within appropriate range. May take days for some units
13. Restock with vaccines once temperature is stable
14. Continue to monitor temperature closely

If defrosting is necessary every month or more frequently, check door seals or call a technician for necessary maintenance.

A frost-free unit with an automatic defrost cycle may be preferred if regular manual defrosting cannot be assured.

Combination Units

Typical household single-condenser combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in refrigerator and freezer compartments. Most of these types of units have cold spots and temperature fluctuations in the refrigerator portion of the unit. Risk of freeze-damage to refrigerated vaccines is increased because air from the freezer is circulated for cooling into the refrigerator. Freezer compartments in these units have demonstrated that they are not capable of maintaining correct temperatures for frozen vaccines.

Purchasing new vaccine storage equipment may require planning. If existing equipment is a household, combination refrigerator/freezer, CDC recommends using only the refrigerator compartment for refrigerated vaccines. Keep the freezer compartment on to maintain proper temperatures in the refrigerator. However, water bottles should be added to the refrigerator to reduce risk of freezing vaccines (**Stabilizing Temperatures with Water Bottles and Frozen Coolant Packs**). Use a stand-alone freezer for frozen vaccines.

Because freezing refrigerated vaccines can affect vaccine potency, it is especially important that refrigerators be selected and set up in a way that eliminates this risk (**Refrigerators**).

Combination refrigerator/freezer

Water bottles in refrigerator to absorb cold air blown in from freezer to reduce risk of vaccines becoming too cold

Dormitory-style Units

CDC does not recommend storage of any vaccine in a dormitory-style (or bar-style), combined refrigerator/freezer unit under any circumstances. A dormitory-style refrigerator is defined as a combination refrigerator/freezer 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. In performance testing, this type of unit demonstrated consistently unacceptable performance, regardless of where vaccines were placed. It also exhibited the inability to maintain temperatures and there were wide variations throughout the unit. There is no "good" vaccine storage area in this style unit.[1] These units pose a significant risk of freezing vaccine even when used for temporary storage.

Use of dormitory-style units for storage of VFC vaccines or other vaccines purchased with public funds is prohibited. Note, size is not always an indicator of this type unit. There are compact, purpose-built storage units for biologics that are not considered to be dormitory-style or bar-style and can be used for vaccine storage.

Dormitory-style (or bar-style) combined refrigerator/freezer units should NOT be used for any storage of any vaccine.

Storage Unit Placement

Good air circulation around the storage unit is essential. Place the unit(s) in a well-ventilated room with space around the sides and top. Allow at least 4 inches (10 cm) of space between unit and wall. Nothing should block the cover of the motor compartment, which is normally located at the back or side of the unit. Make sure the unit stands firm and level and wheels or leveling legs are adjusted so the bottom of the unit is 1 to 2 inches (2.5 to 5 cm) above the floor. Refer to the manufacturer-supplied owner's manual for additional guidance on placement.

Required Temperature Ranges for Storage Units

Refrigerators

The refrigerator should maintain temperatures between 35°F and 46°F (2°C and 8°C). Set the temperature mid-range to achieve an average of 40°F (5°C). This temperature setting will provide the best safety margin.

Freezers

The freezer should maintain temperatures between -58°F and +5°F (-50°C and -15°C).

Setting and Stabilizing Temperatures in Storage Units

Thermostats

Consult the owner's manual for instructions on how to operate the thermostat. Refrigerator and freezer thermostats are marked in various ways, depending on brand, to indicate the temperature setting. For example, some have a series of numbers or letters on the control knob. Others have "MIN," "MED," and "MAX" marked on the knob or a dial ranging from "cold" to "coldest." In general, thermostats do not show temperatures, but rather levels of coldness. The only way to know what the temperature is where vaccines are stored is to measure and monitor it with a calibrated thermometer.

Adjusting Storage Unit Temperatures

Only primary or alternate (back-up) coordinators should adjust the temperature of a vaccine

storage unit. Post a **warning sign** on storage unit(s) that says, "Do NOT adjust refrigerator (or freezer) temperature controls. Notify (insert name) if adjustments are necessary." In some situations, the thermostat may need to be reset in summer and winter, depending on room temperature.

Refrigerator unit thermostat

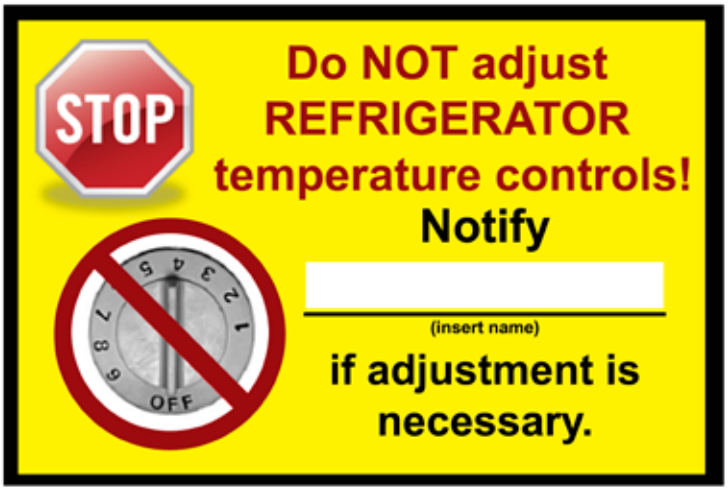
Freezer unit thermostat

Use caution in adjusting a thermostat. It should not be done during a busy clinic day when there is frequent door opening and closing.

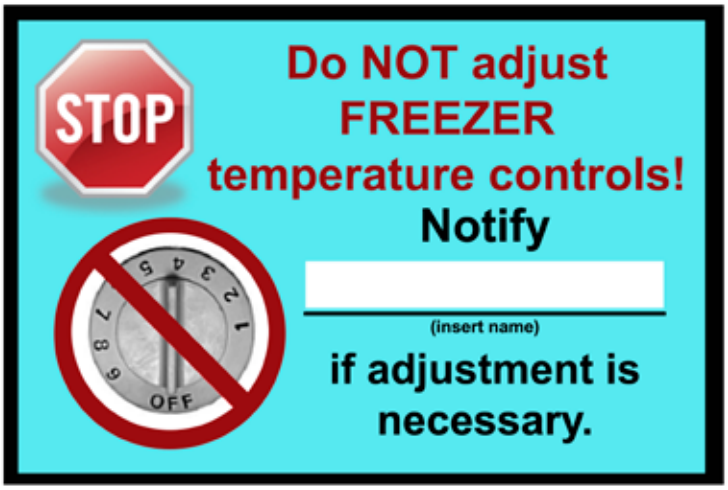
- First, be sure unit is plugged into power source.
- Then check temperature inside storage unit.
- Next, check thermometer data from continuous data loggers (if applicable) to verify that temperature control reset is appropriate.

To adjust the control and avoid exceeding the required temperature range:

- Turn thermostat knob slowly, making small adjustments toward a warmer or colder setting as necessary.
- Allow temperature inside unit to stabilize for 30 minutes.
- Then recheck temperature.
- Adjust thermostat again as necessary. Aim to stabilize refrigerator temperature around 40°F (5°C). Aim to stabilize freezer temperature between -58°F and +5°F (-50°C and -15°C).
- Recheck temperature every 30 minutes until stable.
  - Consider placing additional water bottles to increase temperature stability



Only primary or alternate (back-up) vaccine coordinators should adjust the temperature of a vaccine storage unit.



Only the primary or alternate (back-up) vaccine coordinator should adjust the temperature of a vaccine storage unit.

If you are using the refrigerator compartment of a household, combination unit, use care when adjusting the freezer temperature because this will affect the temperature of air venting into the refrigerator compartment. Without careful and frequent temperature monitoring inside the refrigerator compartment, there is risk of freezing refrigerated vaccines.

It may take 2 to 7 days to stabilize the temperature between 35°F and 46°F (2°C and 8°C) in a newly installed or repaired refrigerator. Likewise, it may take 2 to 3 days to stabilize the temperature between -58°F and +5°F (-50°C and -15°C) in a newly installed or repaired freezer. Allow a week of refrigerator and freezer temperature readings/recordings a minimum of 2 times each workday, including minimum/maximum temperatures 1 time each morning (**Storage Unit Temperature Monitoring**) to make sure temperatures are within appropriate ranges before using units to store vaccines.

NEVER store vaccine in a unit that cannot maintain the required temperature range. Identify an alternate unit that is able to maintain the appropriate temperature range and has sufficient storage space until the primary unit is ready.

Stabilizing Temperatures with Water Bottles and Frozen Coolant Packs

Water bottles and frozen coolant packs will help maintain stable temperatures with frequent opening and closing of unit doors, in the event of a power failure, and serve as a physical barrier to placing vaccines in an area where there is greater risk for temperature excursions. Place water bottles on top shelf, floor, and in door racks of refrigerator. The Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) does not recommend storage of food or beverages in a medication storage unit, so label water bottles "Do NOT Drink."

Place frozen coolant packs along walls, back, and bottom of freezer, and inside door racks. Place items in unit doors carefully so they cannot dislodge, and prevent doors from closing or weighing them down so much that seals are not tight.

Stabilize temperature in a refrigerator with water bottles labeled "Do NOT Drink." Stabilize temperature in a freezer with frozen coolant packs.

Doors

Avoid letting the door stand open unnecessarily. Not only does this affect temperature in the unit, it also exposes vaccines to light, which can reduce potency of some vaccines (see **package inserts**). Leaving the door open can cause the temperature control to respond to warmer air temperatures from the room. The unit will then continue to work harder to maintain the correct temperature inside the unit. The unit will continue to adjust output of cool air and increase the possibility that temperatures will become very cold in some part of the unit. Routinely check refrigerator and freezer doors throughout the day and at the end of each workday to ensure they are tightly closed. Use of an open door alarm and self-closing doors may be helpful in preventing a problem.

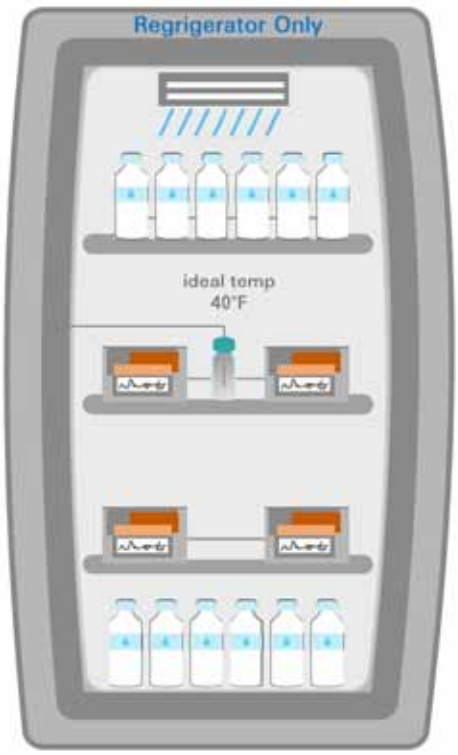
Also ensure door seals are tight each time the door is closed and at the end of the workday.

Check regularly for signs of wear and tear. Seals should not be torn or brittle and there should be no gaps between seals and body of the unit when the door is closed. The door should open and close properly and fit squarely against body of the unit. For this to happen, hinges must be correctly adjusted. If there are any problems with a door seal, see **Assessing Storage Unit Door Seals**. Call a repair technician if seals need to be replaced.

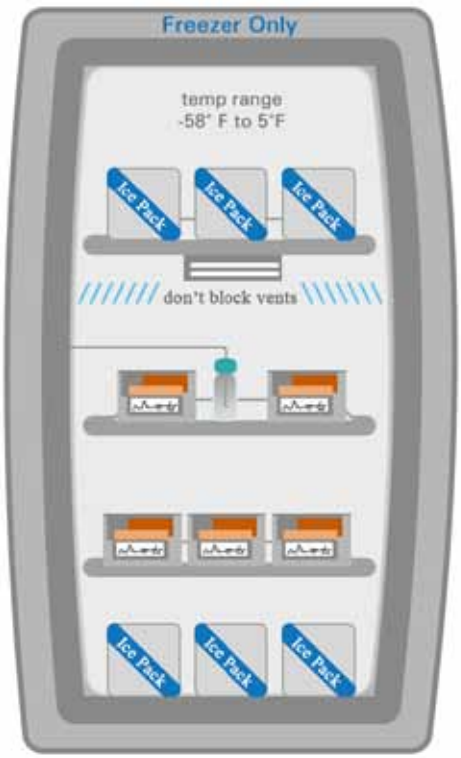
Deli, fruit, and vegetable drawers

Remove any deli, fruit, and vegetable drawers from the refrigerator. Removing drawers not only provides extra space for storing containers of water, but it also removes the temptation to use drawers for storage of food, beverages, or vaccines.

Some pharmaceutical grade units have built-in drawers. Testing demonstrated that these units maintain good temperatures for vaccine storage. However, maintaining appropriate vaccine temperature relies on good air circulation.



Place water bottles on the top shelf, floor, and in door racks of refrigerator.



Place frozen coolant packs along walls, back, and bottom of freezer, and inside door racks.

Storage Unit Maintenance

Regular maintenance is required to ensure proper operation, to maintain required temperatures, and to extend useful life of the equipment. Check manufacturer specifications for cleaning instructions and recommended maintenance schedules. Document routine maintenance tasks and repairs (**Equipment Logbook**).

Routine Maintenance Tasks

Clean coils and motor.

Keep storage unit coils and motor free of dust and dirt build-up. Dust and dirt build-up affect transfer of heat from coils and, therefore, efficiency of the unit. For safety reasons, you may need to unplug your unit to do this, so check manufacturer instructions.

Refrigerator Coils

Clean inside refrigerator and freezer units.

This discourages bacterial and fungal growth. Cleaning should be done quickly to minimize risk of the temperature going out of range.

Clean drain pan.

Clean the drain pan periodically. Frost-free freezers have a drain pan at the bottom of the unit. It holds water that collects after frost melts during the defrost cycle. You do not need to empty the pan regularly as the water should evaporate. However, over time, it may begin to smell and become moldy so check and clean as needed.

Back-up Generators

Facilities storing large vaccine inventories should consider installing back-up generators that automatically provide power to storage units in the event of power outages. Back-up generators should be tested quarterly and should receive maintenance at least annually (check manufacturer specifications for test procedures and maintenance schedules).

Back-up Generators

References

1. Chojnacky MJ, Miller WW, Ripple DC, Strouse GF. Thermal Analysis of Refrigeration Systems Used for Vaccine Storage. November 2, 2009. http://www.nist.gov/manuscript-publication-search.cfm?pub_id=904574

Notes:

Temperature Monitoring Equipment

Key Messages:

- CDC recommends and VFC requires using only calibrated temperature monitoring devices with a Certificate of Traceability and Calibration Testing (also known as Report of Calibration).
- Calibration testing should be performed every 1 to 2 years or according to manufacturer's suggested timeline. VFC providers should consult their **immunization program** for specific requirements.
- If calibration testing indicates that your thermometer is no longer accurate within +/-1°F (+/-.5°C), then your thermometer should be replaced.
- CDC recommends and **immunization program** may require having a back-up thermometer.
- CDC recommends using digital data loggers for continuous temperature monitoring.
- Staff should be trained and understand how to set up, read, and analyze temperature data provided by the data logger. Consult your **immunization program** for data logger selection and training resources.
- The temperature monitoring device should be near where vaccines are stored.

Disclaimer: This chapter provides guidance on temperature monitoring equipment. Use of trade names and commercial sources in this toolkit is for identification only, and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or the Centers for Disease Control and Prevention (CDC). Photographs from non-federal organizations are provided solely as a service to our users. These photographs do not constitute an endorsement of these organizations by CDC or the federal government and none should be inferred.

If you provide VFC vaccines or other vaccines purchased with public funds, contact your immunization program regarding requirements for temperature monitoring equipment.

Temperature Monitoring Devices

General Recommendations

Accurate temperature history that reflects actual vaccine temperatures is imperative to effective vaccine management. Investing in reliable temperature monitoring devices is less expensive than replacing vaccines wasted due to inaccurate temperature readings.

Calibrated Temperature Monitoring Devices

For measuring vaccine storage unit temperatures, CDC recommends using only calibrated temperature monitoring devices with a Certificate of Traceability and Calibration Testing (also known as Report of Calibration). Calibration testing and traceability that is performed by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body assures the user that testing performed meets the appropriate standard. An alternative is a

laboratory or manufacturer that provides documentation that demonstrates calibration testing performed meets International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 international standards for calibration testing and traceability. If a temperature monitoring device claims to be "certified," this does not mean that it has been tested to meet ISO/IEC 17025 standards.

CDC's recommendation is that testing be performed by ILAC accredited laboratories because it is the easiest way to identify that the instrument has been tested correctly according to international standards. Providers are responsible for maintaining up-to-date certificates of calibration.

If calibration testing was performed by ILAC/MRA accredited laboratories, certificates should include the following elements:

1. Clearly identifiable accreditation
2. Name of device (optional)
3. Model number
4. Serial number
5. Date of calibration (report or issue date)
6. Measurement results that indicate passed testing and documented uncertainty within suitable limits (recommended uncertainty is +/-1 F [+/-.5 C])

Non-ILAC accredited laboratories and manufacturers must provide a Certificate of Traceability (Report of Calibration) that includes the following elements:

1. Name of device (optional)
2. Model number
3. Serial number
4. Date of calibration (report or issue date)
5. Measurement results that indicate passed testing and documented uncertainty within suitable limits (recommended uncertainty is +/-1 F [+/-.5 C])
6. Measurement results for the device
7. Statement that calibration testing conforms to ISO 17025

Follow links for listings of accredited laboratories:

The American Association for Laboratory Accreditation (A2LA)
http://www.a2la.org/dirsearchnew/newsearch.cfm

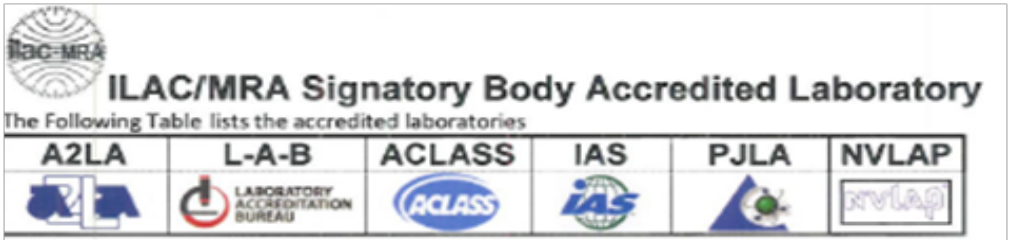
Laboratory Accreditation Bureau (L-A-B)
http://www.l-a-b.com/content/directory-accredited-labs

ANSI-ASQ National Accreditation Board (ACLASS)
http://www.aclasscorp.com/search-accredited-companies.aspx

International Accreditation Service (IAS)
http://www.iasonline.org/Calibration_Laboratories/CL.html

Perry Johnson Laboratory Accreditation, Inc.(PJLA)
http://www.pjlabs.com/search-accredited-labs

A listing of signatory bodies outside of the U.S. can be found on the ILAC website:
https://www.ilac.org/members_contact_details.html



Temperature Monitoring Equipment

All temperature monitoring devices experience "drift" over time that affects their accuracy.

When traceability and calibration testing needs to be done, CDC recommends one of the following:

- Have accuracy of your temperature monitoring device tested. Calibration testing should be performed every 1 to 2 years from the last testing date or according to the manufacturer's suggested timeline. Providers who receive VFC vaccines or other vaccines purchased with public funds should consult their **immunization program** regarding the required timeframe for calibration testing.
- Purchase a new temperature monitoring device with a Certificate of Traceability and Calibration Testing (also known as a Report of Calibration).
- Contact your **immunization program** for resources on checking the accuracy of your temperature monitoring device.

If calibration testing indicates that your temperature monitoring device is no longer accurate within +/-1°F (+/-.5°C), then it should be replaced. Adjustments to correct accuracy of the device are not recommended.

If a temperature monitoring device is dropped or hit against the side of the storage unit, CDC recommends that at minimum, the device be checked for accuracy against a known calibrated temperature monitoring device. Mishandling a temperature monitoring device can affect its accuracy. If there is any question about accuracy, your device should be sent for calibration testing or a new device should be obtained.

Some temperature monitoring devices require batteries. If you use one of these, have a supply of extra batteries on hand. If you change a battery (this does not include an alarm battery) in your device, it should undergo calibration testing as described above.

Purchasing a replacement device may be less expensive than calibration testing.

Types of Temperature Monitoring Devices

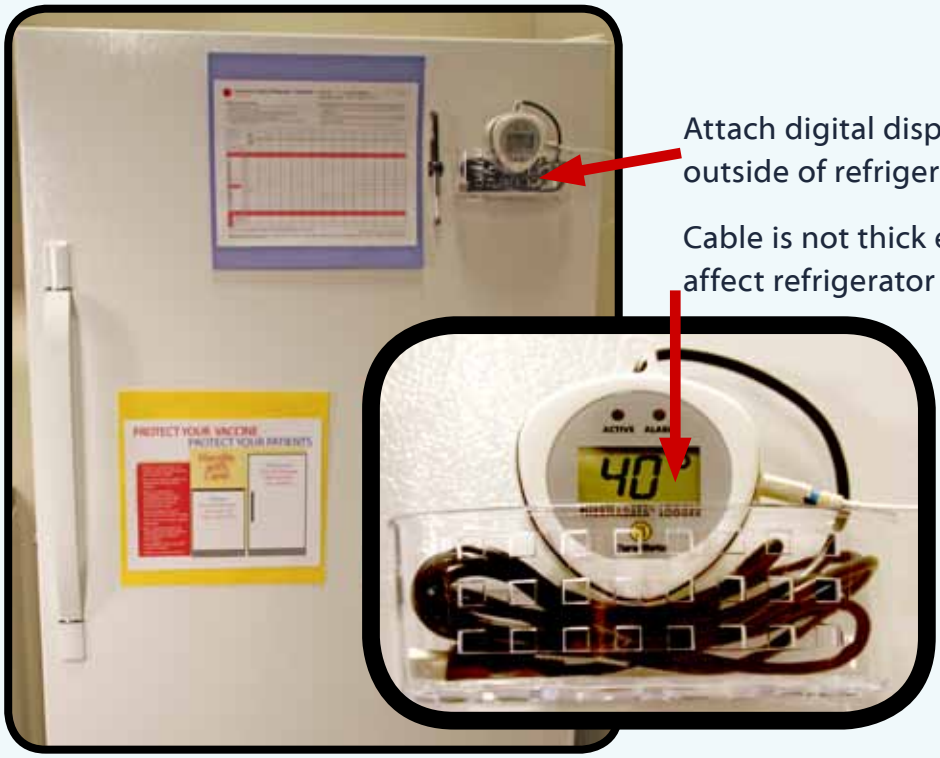
Continuous monitoring devices

CDC recommends using a continuous temperature monitoring device for each storage unit. These devices can provide an indication of length of time a unit has been operating outside the recommended vaccine storage temperature (excursion) and when an excursion occurred. Unlike a simple min/max thermometer, which provides only information about warmest and coldest temperatures that were reached, the continuous monitoring device provides detailed information on all temperatures recorded at preset intervals. There are a variety of devices available.

Contact your **immunization program** for resources and information on acceptable temperature monitoring devices.

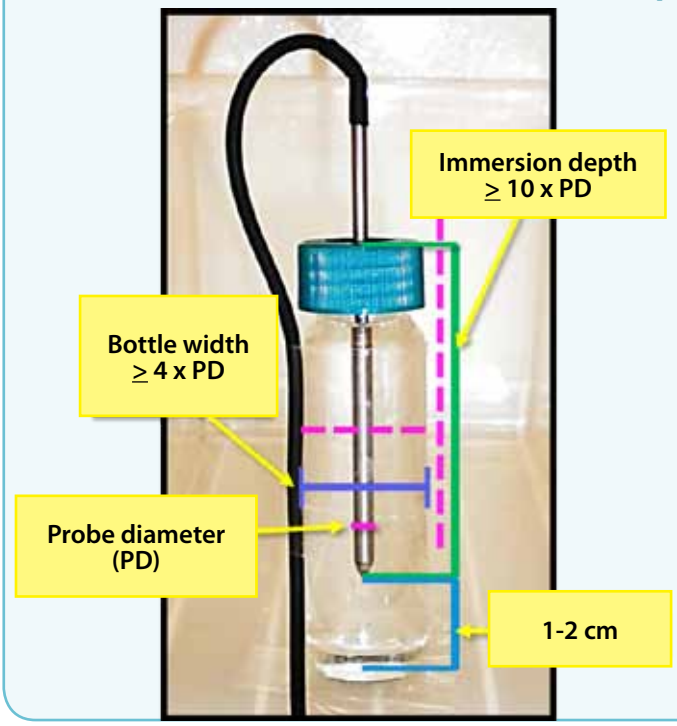
Based on studies of temperature monitoring devices conducted by NIST in 2009,[1] CDC recommends devices with the following characteristics:

1. Digital display on outside of storage unit to allow reading temperatures without opening unit door
2. Detachable probe in a bottle filled with a thermal buffer, like glycol, which more closely reflects vaccine temperatures. Vaccine temperatures have been found to be more thermostable than air temperature, which fluctuates with defrost cycles and



Digital display of temperature monitoring device on outside of storage unit

How to Set up a Probe in Fluid-filled Bottle



Select a glass or plastic bottle

- Minimum diameter = 4 x probe diameter (PD)
- Bottle height chosen so that:
  - Immersion depth ≥ 10 x probe diameter
  - Probe tip to bottom ≥ 1 to 2 cm
- Sealable lid preferred (e.g., pierceable, rubber septum cap)

Note: If manufacturer supplies a fluid-filled bottle/vial with data logger, this may be used instead.

Completely fill bottle with fluid (e.g., glycol)

Insert probe through center of cap

- Position probe tip to achieve depth ≥ 10 x PD
- Make sure tip doesn't touch bottom of bottle
- Make sure entire length of probe is centered within bottle
- To keep probe from shifting, fix cable to outside of bottle with tape or cable tie

Probe in thermal buffer such as glycol, inside unit is attached by cable to main monitor

opening and closing the unit door

3. Alarm to alert out- of- range temperatures
4. Accuracy within +/-1°F (+/-.5°C)
5. Low battery indicator
6. Continuous monitoring and recording capabilities to track and record temperatures over time
7. Display of current, as well as minimum and maximum temperatures, which indicate the coldest and warmest temperatures recorded since device was reset

CDC recommends having a back-up temperature monitoring device in the event that something happens to the primary device or if the primary device needs to be sent to a laboratory for calibration testing. The back-up temperature monitoring device should have the same set-up as the primary set-up (i.e., probe in buffer such as glycol). In addition, CDC recommends that the back-up device have a different calibration testing schedule so that your back-up is available when the primary is sent for testing.

Some immunization programs require VFC providers to have a back-up thermometer. Contact your **immunization program** for specific requirements.

Digital data loggers

CDC recommends using digital data loggers for continuous temperature monitoring and recording. These electronic devices may be programmed to record temperatures at intervals throughout the day, with frequency of reading set by user. Digital data logger temperature monitoring devices are capable of recording and storing thousands of individual temperature readings.

Digital data loggers are typically battery operated. They are often simple to use and have a number of beneficial features. Choose a model that is capable of displaying current, as well as minimum and maximum temperatures. An alarm that rings outside the storage unit is preferable as it is readily noticed and can be responded to quickly.

Digital data loggers

Digital units store continuous temperature data, which can then be downloaded into a computer or retrieved from a website for review and archiving. These devices may be accompanied by special software that is installed on a computer. Either the software or the website may allow the user to set frequency of temperature readings, download data from device, and review minimums and maximums. To review temperature history, the user must download data from the digital data logger on a regular basis. Even if you don't have a computer for downloading data, these devices are still helpful in monitoring temperatures a minimum of 2 times each workday, as well as providing minimum and maximum temperatures since the last reading.

CDC recommends that temperatures displayed on the unit are still reviewed and recorded a minimum of 2 times each workday, as well as minimum and maximum temperatures since the last reading, to determine if temperatures are out of range.

Data logger

Most data loggers contain a probe that is used to detect temperature readings. As stated previously, CDC recommends using probes encased in a thermal buffer such as glycol because they provide a more accurate reading of actual vaccine temperature. Some data loggers have digital displays showing current and min/max temperatures, as well as current room temperature. Some data loggers have an audible alarm to alert the user to out-of-range temperatures. Other data loggers have external lights that alert the user (a green light indicates temperatures have remained in range and a red light indicates an inappropriate temperature occurred).

If the alarm activates, take immediate corrective action. Download and review temperature readings and proceed as noted in **Handling Inappropriate Vaccine Storage Conditions (Light and Temperature)**.

In conclusion, the data logger should have the following:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperatures
- Low battery indicator
- Accuracy of +/-1°F (+/-.5°C)
- Memory storage of at least 4,000 readings
- User programmable logging interval (or reading rate)

Use of calibrated digital data loggers is a best practice.

Staff should be trained and understand how to set up, read, and analyze temperature data provided by the data logger. Consult your **immunization program** for data logger selection and training resources.

Temperature Monitoring Devices that are NOT Recommended

CDC does NOT recommend the following temperature monitoring devices:

- Fluid-filled biosafe liquid temperature monitoring devices
- Bi-metal stem temperature monitoring devices
- Food temperature monitoring devices
- Household mercury temperature monitoring devices
- Chart recorders
- Infrared temperature monitoring devices
- Temperature monitoring devices that are not calibrated

These devices can have significant limitations. They can be difficult to read and most only provide information on the temperature at the precise time they are read. Therefore, temperature fluctuations outside the recommended range may not be detected.

Testing demonstrated that infrared thermometers (IR thermometers) are not reliable or accurate for assessment of vaccine storage temperatures. [1]

Do not use temperature monitoring devices that do not have a certificate of calibration. Generally, devices obtained in hardware and appliance stores are not calibrated instruments and are designed to monitor temperatures for domestic food storage. These devices are not accurate enough and can pose a significant risk of losing expensive vaccines.

Temperature Monitoring Device Placement

Prior to storing vaccines in a unit, determine where the most reliable and consistent temperature readings are and store your vaccines there. The probe should be near where vaccines are being stored.
This should be in the main body of the storage unit, away from walls, ceiling, cooling vents, doors, floor, and back of the unit.

Placement of probe

Vaccine Security

Protecting Power Supply

To prevent problems with the power supply, take the following steps:

- Plug only one storage unit into an outlet to avoid triggering a safety switch and turning off power, and to avoid creating a fire hazard.
- Use a safety-lock plug or an outlet cover to prevent unplugging.
- Post warning signs at plugs and on storage units alerting staff, custodians, electricians, or other workers not to unplug units (**Do NOT unplug**).
- Label fuses and circuit breakers to alert people not to turn off power to storage units. Labels should include immediate steps to take if power is interrupted. If your building is owned by a third party and you do not have access to circuit breakers, work with your building manager.

Avoid using power outlets with:

- Built-in circuit switches (they have little red reset buttons)
- Outlets that can be activated by a wall switch
- Multi-outlet power strips

These can be tripped or switched off, resulting in loss of electricity to the storage unit.

Temperature Alarms

Continuous monitoring temperature alarm/notification systems

Alarms are a useful tool to alert staff to potential problems. However, any alarm is only as good as the people responding to it. Large vaccine losses and the need to revaccinate have occurred despite using alarmed, continuous monitoring systems. Issues around untrained staff who do not know how to read the monitor, unexpected events, poor monitoring and response procedures, equipment failure, and improper maintenance have all been implicated in vaccine mishandling incidents. Refer to **Storage Unit Temperature Monitoring**. VFC providers or providers who receive other vaccines purchased with public funds should contact their **immunization program** for further guidance.

References

1. National Institute of Standards and Technology (NIST); Assessing the Use of Infrared Thermometers for Vaccine Temperature Determination, **http://www.nist.gov/pml/div685/grp01/upload/IR_Test_Results.pdf**

Notes:

Vaccine Storage and Handling Best Practices

Key Messages:

- Always refer to manufacturer's product information/**package inserts** for the most up-to-date storage and handling recommendations for specific vaccines and diluents.
- Store frozen vaccines in freezer between -58°F and +5°F (-50°C and -15°C).
- Store refrigerated vaccines between 35°F and 46°F (2°C and 8°C), with a desired average temperature of 40°F (5°C).
- Place vaccines and diluents with soonest expiration dates in front of those with later expiration dates.
- In refrigerator, do not store vaccines in deli, fruit, and vegetable drawers, or on floor.
- Avoid storing vaccines on refrigerator top shelf. If top shelf must be used, place water bottles close to vent and only store vaccines not sensitive to coldest temperatures (e.g., MMR).
- Place vaccines and diluents 2 to 3 inches from walls and allow space between rows of vaccines and diluents to promote cold air circulation. Do not place near vents or pack unit too tightly.
- Keep vaccines and diluents in original packaging with lids closed until ready for administration.
- Label and store look-alike or sound-alike vaccines (e.g., Hib and HepB), and pediatric and adult formulations (e.g., DTaP and Tdap) of the same vaccine in different locations to lessen risk of administration errors (**Vaccine Labels for Storage Unit**).
- Clearly label diluents (IAC's **Vaccines with Diluents: How to Use Them**).
- Store food and beverages in separate refrigerator and storage units than where vaccines are stored.
- NEVER store vaccines and other medications or biologics in same tray or containers/bins. If possible, store products other than vaccines in different unit.

Vaccine and Diluent Storage Temperatures

Always refer to the manufacturer's product information/**package inserts** for the most up-to-date storage and handling recommendations for specific vaccines and diluents.

Freezer Temperature

Store frozen vaccines (e.g., varicella-containing vaccines [VAR, HZV, and MMRV]) in a freezer between -58°F and +5°F (-50°C and -15°C) until reconstitution and administration. These vaccines can deteriorate rapidly after removal from the freezer. Measles, mumps, and rubella vaccine (MMR) can be stored in a refrigerator or in a freezer.

Refrigerator Temperature

Store all other routinely recommended vaccines in a refrigerator between 35°F and 46°F (2°C and 8°C), with a desired average temperature of 40°F (5°C). This will allow for slight temperature fluctuations while still maintaining the recommended temperature range.

Diluents

Some diluents must be stored in the refrigerator. Other diluents have an option of being stored at room temperature (no warmer than 77°F [25°C]) or in the refrigerator.

Whenever possible, store diluent with the corresponding refrigerated vaccine. Diluents for Pentacel (DTaP-IPV-Hib combination vaccine) and Menveo (meningococcal conjugate vaccine) contain antigen. They are packaged together with the corresponding lyophilized vaccine and must be stored together (**package inserts**). NEVER store diluent in the freezer.

Vaccine and Diluent Placement within Storage Unit

Place vaccines and diluents with soonest expiration dates in front of those with later expiration dates.

Freezers

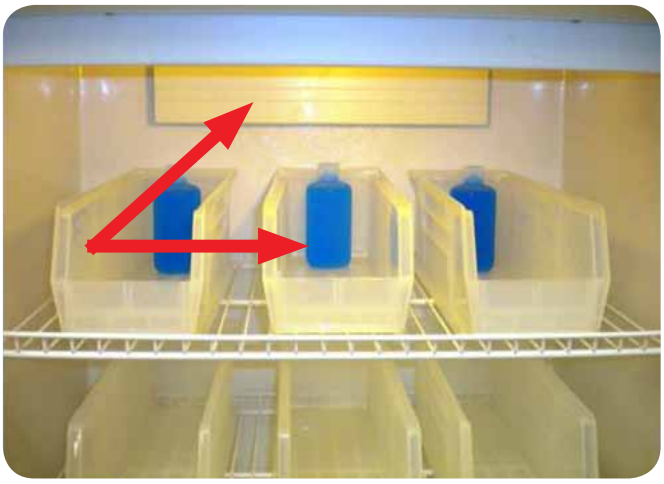
- Store vaccines away from walls, ceiling, and vents.
- Do not store vaccines in the door. The temperature in the door is not stable and differs from that inside the unit.

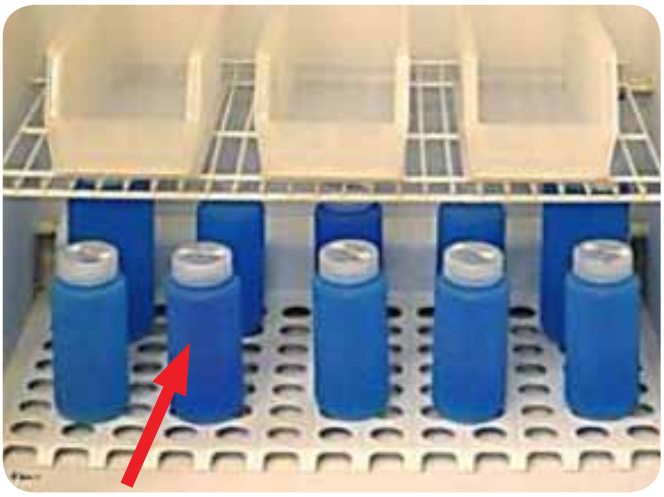
Vaccines in freezer with frozen coolant packs

Refrigerators

- Store vaccines away from walls, floor, ceiling, and vents.
- Do not store vaccines in deli, fruit, and vegetable drawers, or in the door. Temperature and air flow in these areas may not be stable, exposing vaccines to inappropriate storage temperatures.
- Avoid storing vaccines on top shelf. If top shelf of refrigerator must be used, place water bottles close to vent and only store vaccines that are not sensitive to coldest temperatures (e.g., MMR).

Air vents and water bottles





Water bottles on unit floor

Water bottles in unit door

Spacing

Place vaccines and diluents in central area of unit 2 to 3 inches away from storage unit walls. Store vaccines and diluents by type and arrange in rows.

Allow space between rows to promote cold air circulation around vaccines and diluents. Adequate cold air circulation helps each vaccine and diluent maintain a consistent temperature.

Do NOT pack any vaccine storage unit too tightly.

Packaging

Keep vaccines and diluents in their original packaging with lids closed until ready for administration to protect them from light. Removing vaccines and diluents from original packaging is not recommended. This can increase risks for storage, handling, and administration errors.

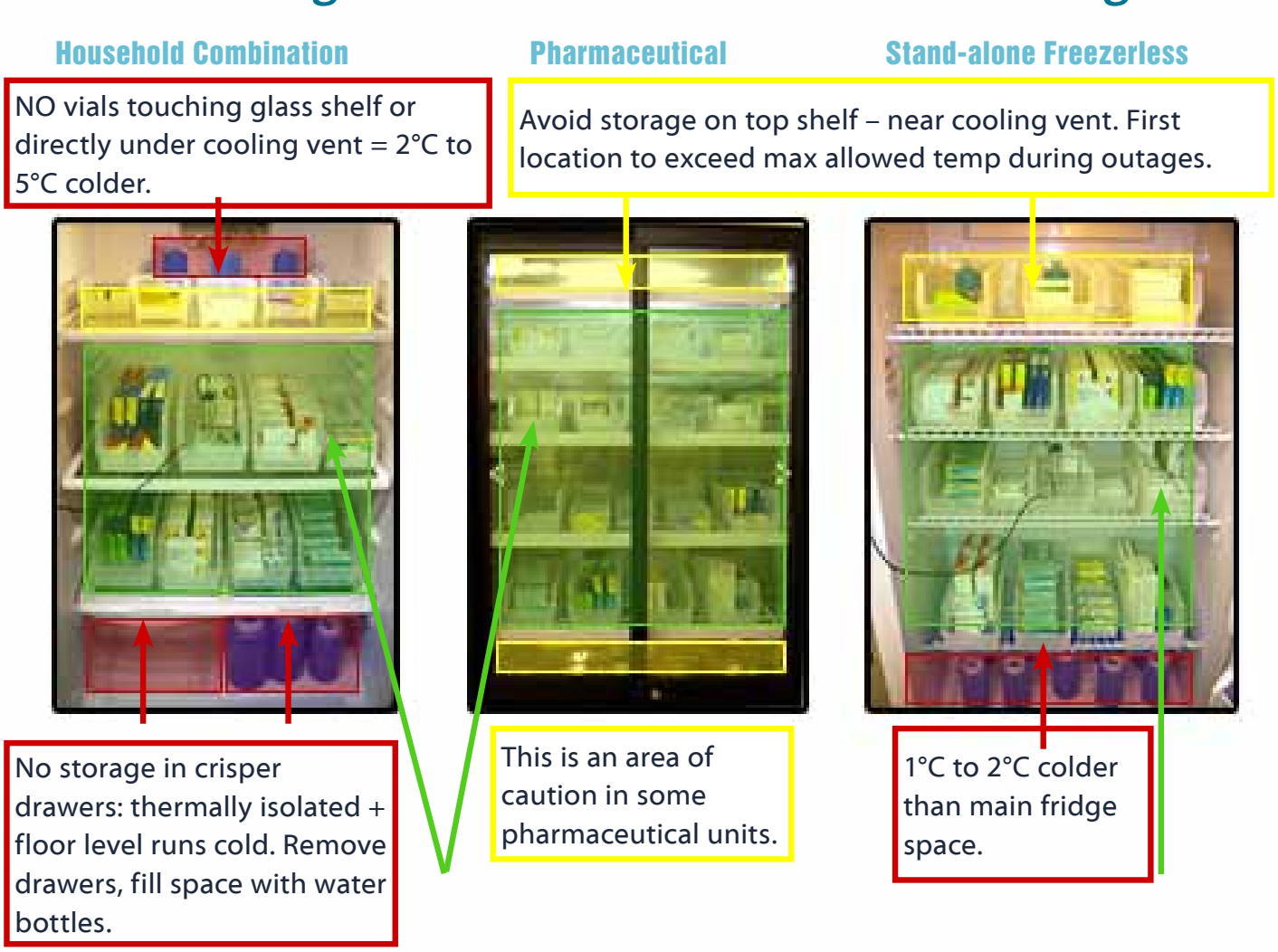
Do NOT store loose vials or manufacturer-filled syringes outside of their packaging. This practice makes managing inventory and tracking expiration dates more difficult, increases risk of administration errors, and exposes vaccines to light.

Store vaccines and diluents with similar packaging or names on different shelves to lessen risk of administration errors. If you have pediatric and adult formulations of the same vaccine, label and store them on different shelves. For example, DTaP and Tdap might be easily confused, as might Hib and HepB.

Trays and Containers/Bins

Trays and uncovered containers/bins may be used for better organization. Each should only contain vaccine or diluent of the same type. Always allow space between trays and containers/bins for air circulation.

Vaccine Storage Methods and Locations in the Refrigerator



Best and worst locations for storage can vary with different types of units. A best practice is to place vaccines in central area of unit and keep vaccines in original packaging in trays or containers/bins 2 to 3 inches away from walls.

Labeling

Clearly identify the location of each specific vaccine type and diluent by attaching labels to shelves, trays, or containers/bins where each is stored. Label pediatric and adult versions of the same vaccine to avoid confusion (**Vaccine Labels for Storage Unit**).

A diluent must only be used with the corresponding vaccine.

If diluent is stored separately from the corresponding vaccine, label the shelf, tray, or container/bin where it is stored (IAC's **Vaccines with Diluents: How to Use Them**).

HepA—Pediatric Formulation

Ages: 12 months through 18 years
Use for: Any dose in the series
Route: Intramuscular (IM) injection

HepA—Adult Formulation

Ages: 19 years and older
Use for: Any dose in the series
Route: Intramuscular (IM) injection

Storage of Non-Vaccine Products

Food and Beverages

Store food and beverages in a separate storage unit, not where vaccines are stored. Storing food and beverages in the same unit with vaccines can result in:

- Frequent opening of the door
- Greater risk of temperature fluctuations
- Excessive light exposure
- Risk of spills and contamination

Do NOT store food or beverages inside a vaccine refrigerator or freezer.

Other Medications and Biologic Products

If possible, these products should be stored in a different unit. If they must be stored in the same unit as vaccines, always store them below vaccines on a different shelf. This prevents contamination of vaccines should other products spill, and reduces the likelihood of medication errors. NEVER store these products in the same tray or container/bin as vaccines.

If other medications/biologics are stored in same unit with vaccines, store on a lower shelf.

Notes:

Storage Unit Temperature Monitoring

Key Messages:

- Routine storage and handling plans should include protocols for reviewing and recording storage unit temperature readings a minimum of 2 times each workday and minimum and maximum temperatures 1 time each morning.
- Use of a continuous monitoring device/digital data logger to record and store temperatures for 24-hour monitoring at regular intervals is recommended.
- The data logger should have a digital display attached to the outside of unit to allow reading temperatures without opening door and disturbing the probe.
- Download and review stored temperature data at least 1 time each week.
- Maintain ongoing file of temperature data, including hard copies and downloaded data, for 3 years.
- If storage temperatures are in question, contact your **immunization program** and/or **vaccine manufacturer**(s) per your protocol for further guidance in determining if vaccine can be used. Be prepared to provide data from temperature logs and/or data logger (**CDC's Temperature Excursion Checklist**).
- Document date and time of any mechanical malfunction or power outage.

Reviewing and Recording Temperatures

If you are a VFC provider or have other vaccines purchased with public funds, contact your **immunization program** regarding specific requirements for reviewing and recording storage unit temperatures.

CDC recommends that routine vaccine storage and handling plans include protocols for reviewing and recording storage unit temperature readings a minimum of 2 times each workday. This can prevent inadvertent loss of vaccine and the potential need for revaccination by assuring that temperature excursions are identified quickly and immediate corrective action is taken. This is also an opportunity to visually inspect the storage unit, reorganize any vaccines that are inadvertently misplaced, and remove any expired vaccines.

This best practice recommendation applies to all vaccine storage units, regardless of whether or not there is a temperature alarm or a digital data logger temperature monitoring device. This assures that any temperature excursions are recognized promptly and provides early identification of problems with your storage unit.

CDC recommends use of a continuous monitoring device/digital data logger to record and store temperature information at frequent programmable intervals for 24-hour temperature monitoring.

Storage Unit Temperature Monitoring

The data logger's active digital display should be attached to the outside of unit to allow reading temperatures without opening the door and disturbing the probe. Set data loggers to measure temperatures at regular intervals.

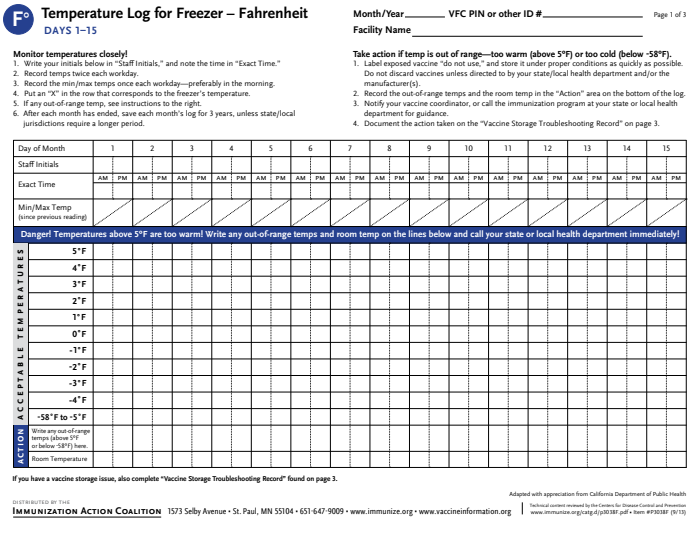
Best practices include:

1. Post a temperature log on each storage unit door or nearby in a readily accessible and visible location.
2. Read temperature monitoring devices in both refrigerator and freezer units a minimum of 2 times each workday, at least in the morning and before leaving at the end of the workday.
3. Record readings in both refrigerator and freezer units on temperature logs.
4. If alarm systems are used, temperatures should still be reviewed and recorded a minimum of 2 times daily.
5. Take immediate action to correct out-of range temperatures.
6. Record incident and action taken (IAC's **Vaccine Storage Troubleshooting Record**).
7. If a temperature reading is missed, log entry should remain blank.
8. Download and review stored temperature data at least 1 time each week.
9. Maintain an ongoing file of temperature data, including hard copies and downloaded data, for 3 years (unless state statutes or rules require longer retention). As a vaccine storage unit ages, you can track recurring problems or identify how long problems have existed by referring to these data.

CDC recommends reviewing and recording minimum and maximum temperature readings at the beginning of the workday. This helps to ensure temperature excursions are identified quickly and corrections are made to prevent vaccine loss.

Record times of readings and initials of person who took readings.

The Immunization Action Coalition has developed **Temperature Logs** to support these activities.



Temperature Log for Freezer – Fahrenheit
DAYS 1–15

Month/Year _____ VFC PIN or other ID # _____ Page 1 of 3
Facility Name _____

Monitor temperatures closely!
1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).
1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACCEPTABLE TEMPERATURES 5°F															
4°F															
3°F															
2°F															
1°F															
0°F															
-1°F															
-2°F															
-3°F															
-4°F															
-58°F to -5°F															
ACTION Write any out-of-range temps (above 5°F or below -58°F) here.															
Room Temperature															

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

DISTRIBUTED BY THE IMMUNIZATION ACTION COALITION 1573 Selby Avenue • St. Paul, MN 55104 • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

Adapted with appreciation from California Department of Public Health

Technical content reviewed by the Centers for Disease Control and Prevention www.immunize.org/catg.d/p3038f.pdf • Item #P3038F (9/13)

Temperature Log

Any temperature reading outside the recommended range is considered a temperature excursion (**Troubleshooting**). If, at any time,

storage temperatures are in question, contact your **immunization program** and/or **vaccine manufacturer**(s) per your protocol for further guidance in determining if vaccine can be used. When contacting the manufacturer or immunization program, be prepared to provide them with data from temperature logs and/or data logger so they can offer you the best guidance (**CDC's Temperature Excursion Checklist**).

Reviewing Temperature Recording Data

The primary vaccine coordinator should review temperature recording data at least 1 time each week to ensure appropriate temperature documentation. If the primary vaccine coordinator is monitoring and recording temperatures, the alternate (back-up) vaccine coordinator should review data at least 1 time each week.

Noting Equipment Failures and Room Temperatures

Document date and time of any mechanical malfunction or power outage (e.g., IAC's **Vaccine Storage Troubleshooting Record**).

Take immediate action to correct these situations (**Handling Malfunctioning Vaccine Storage Units** and **Power Outages**).

Notes:

Key Messages:

- Any temperature reading outside ranges included in manufacturers' **package inserts** is considered a temperature excursion.
- Responses from vaccine manufacturers to events are dependent on information received. Different information about the same event will inevitably lead to different recommendations on usability of vaccine or need to revaccinate. In addition, each event is unique and manufacturer recommendations based on existing stability data cannot be applied to what may appear to be similar events.
- Do not allow vaccines to remain in a nonfunctioning storage unit for an extended period of time (in general, more than 2 hours). If longer, activate **Emergency Vaccine Retrieval and Storage Plan**.
- If temperature monitoring device indicates temperature is outside recommended range, first check that device is appropriately placed.

Handling Inappropriate Vaccine Storage Conditions (Light and Temperature)

If you are a VFC provider or have other vaccines purchased with public funds, contact your **immunization program** regarding required actions in the event of a temperature excursion.

Take immediate action to correct inappropriate vaccine storage conditions. Any temperature reading outside ranges included in manufacturers' **package inserts** is considered a temperature excursion. However, depending on the vaccine, it may be total amount of time (cumulative) out of range that affects whether the vaccine can be used. If there is any question that a vaccine has been exposed to inappropriate conditions, take the following steps:

1. Notify primary or alternate (back-up) vaccine coordinator immediately. If not available, report problem to your supervisor
2. At minimum, document (IAC's **Vaccine Storage Troubleshooting Record**):
   a. Date and time of event
   b. Room and storage unit temperatures (include minimum/maximum temperatures, if available)
   c. Person completing report
   d. Description of event*
      i. General description (i.e., what happened)
      ii. Estimated length of time vaccine may have been affected (for example, if your temperature monitoring device shows that temperature of refrigerated vaccine rose to 48°F [9°C] for 10 minutes in morning and 5 minutes in afternoon, total time out of range was 15 minutes)
      iii. Inventory of affected vaccines
      iv. At time of event, what else was in storage unit (e.g., water bottles in refrigerator or frozen coolant packs in freezer)

v. Prior to this event, any problems with storage unit and/or with affected vaccines
vi. Other relevant information

e. Action taken
   i. Do NOT discard vaccines
   ii. Label exposed vaccines "Do NOT Use"
   iii. Store exposed vaccines under appropriate conditions (set apart from other vaccines)
   iv. Contact your **immunization program** and/or **vaccine manufacturer**(s) per your protocol for further guidance on whether to use affected vaccines
   v. What you did to prevent a similar problem in the future
f. Results (i.e., what happened to affected vaccines)

You may also use the **Emergency Vaccine Retrieval and Storage Plan Worksheet** to help organize your response. Consult your agency or **immunization program** for any special instructions or forms.

Notify the primary or alternate (back-up) vaccine coordinator immediately of any vaccine storage unit temperature that is outside the recommended range.

Handling Malfunctioning Vaccine Storage Units

General Instructions

Do not allow vaccines to remain in a nonfunctioning unit for an extended period of time (in general, more than 2 hours). If longer than 2 hours, activate **Emergency Vaccine Retrieval and Storage Plan**.

The temperature in a refrigerator or freezer can vary throughout the unit. In addition, several external factors can affect the temperature in the unit, including:

1. Seasonal weather affecting room temperature
2. Frequency of opening and closing unit door
3. Unit's mechanism for cooling

Leaving a refrigerator door open can cause the thermostat to respond to warmer room temperatures by working harder at adjusting cooling output to maintain correct temperature inside the unit. This increases the possibility that the temperature will become very cold inside the unit and possibly freeze refrigerated vaccines. Using an open door alarm and self-closing doors may be helpful.

Refer to the equipment user's guide for instructions on handling malfunctions in the unit. Another helpful problem-solving tool is **CDC's Temperature Excursion Checklist**.

Assessing Storage Unit Door Seals

To check that door is sealing properly:

1. With door open, place thin paper strip

***Responses from vaccine manufacturers to events depend on information received. If different information about the same event is provided to different manufacturers, this will inevitably lead to different recommendations on usability of vaccine or need to revaccinate. In addition, each event is unique and manufacturer recommendations based on existing stability data cannot be applied to what may appear to be similar events.**

against front of unit (see Illustration 1).
2. Close door.
3. Pull paper strip. If it moves easily or falls away by itself, door may need adjustment and/or rubber seals may need to be replaced.
4. Check all the way around door to make sure seals are tight. Pay particular attention to corners.
5. If problem suspected, contact repair technician.

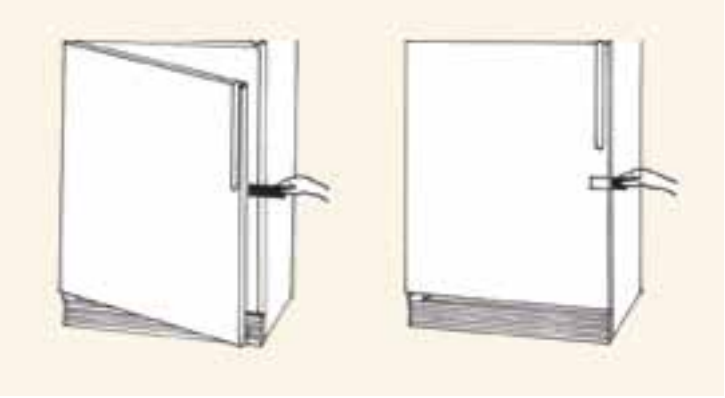


Illustration 1—Checking the door seal (Adapted from the User's Handbook for Compression Refrigerators WHO/EPI/LOG/8415)

Temperature Monitoring Device Problems

Temperature Monitoring Device Set-up

If the temperature monitoring device indicates that the temperature is outside the recommended range, check that the device is appropriately placed. It should be placed in proximity to the vaccines. If the device is placed near walls, floor, vent, or ceiling, or in the door, it may indicate colder or warmer temperatures than if it was properly placed. Proper placement helps the provider accurately assess actual vaccine temperatures and take immediate corrective action if necessary.

In addition, vaccine temperatures measured in air can be misleading with regard to actual vaccine temperatures. A buffered probe is the most accurate way to measure actual vaccine temperatures.

Checking if Device Works

It is common with some devices to see a slight variation in temperature from one reading to another, even when unit thermostat is set at a particular temperature. If no change in temperature reading occurs, the device may be faulty and may need calibration testing or replacement.

Checking Repeated Alarm Alerts

If temperature alarm goes off repeatedly, do NOT disconnect alarm until you are sure it is a false alarm. Start by conducting basic checks of unit door, power supply, and thermostat settings. If alarm continues to sound, transfer vaccines to back-up unit (**Emergency Vaccine Retrieval and Storage Plan**). A repair technician should check your equipment to determine need for repair or replacement. Check the temperature every 30 minutes using a calibrated temperature monitoring device until the unit is in the recommended range and stable before returning vaccines.

Notes:

Vaccine Inventory Management

Key Messages:

- Expiration dates vary by type of vaccine or diluent and lot number. They indicate the date by which a product should be used (**package inserts**).
- Once lyophilized (freeze-dried) vaccine is mixed with diluent (liquid) and reconstituted, there is a limited time frame in which vaccine can be used (**package inserts**).
- If inadvertently administered, an expired or mishandled dose generally should not be counted as valid and should be repeated. Contact your **immunization program** and/or **vaccine manufacturer**(s) for guidance on revaccination.
- At least 1 time each week and each time vaccines are delivered, vaccine coordinator should ensure that someone checks and rearranges placement of vaccines and diluents in storage unit according to expiration dates.
- If you receive multiple doses of same vaccine with same presentation (i.e., single-dose vial, multidose vial, or manufacturer-filled syringe) from same lot with same expiration date, these doses may be documented as one entry on stock record.
- Number of vaccine doses in unit and number of doses reflected on stock records should match.
- Order smaller quantities to help prevent over-ordering and subsequent risk of expired, wasted vaccines.

If you provide VFC vaccines or other vaccines purchased with public funds, contact your **immunization program** regarding requirements pertaining to vaccine inventory management.

Vaccine Access

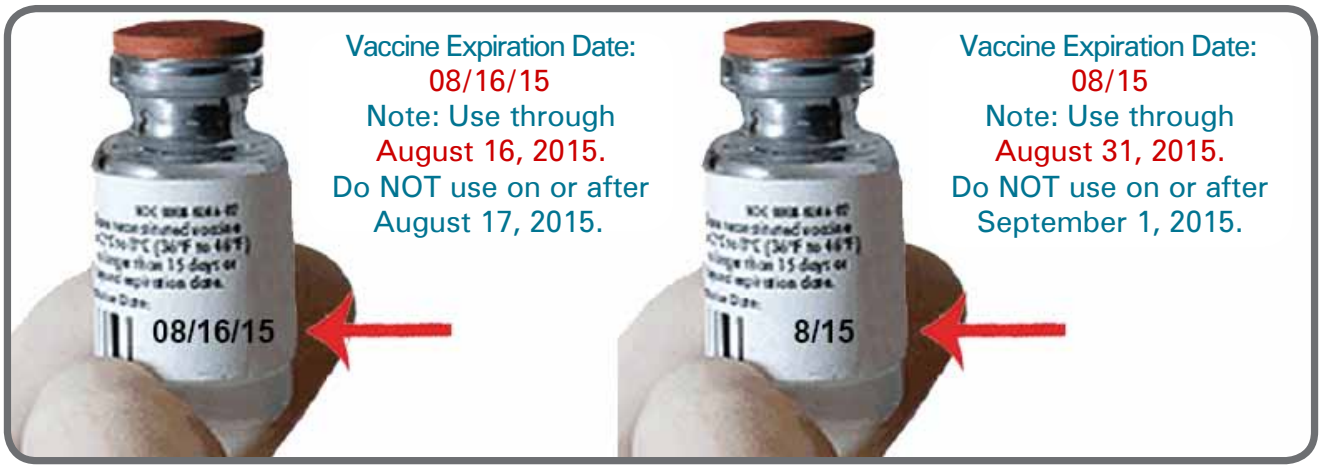
Only authorized staff should have access to vaccine supplies.

Expiration Dates

Interpreting Expiration Dates

All vaccines and diluents have expiration dates. These dates vary by type of vaccine or diluent and lot number and are printed on vials, manufacturer-filled syringes, and packages. They indicate the date by which a product should be used (**package insert**).

When the expiration date is marked with only month and year, vaccine or diluent may be used up to and including the last day of the month indicated. If a day is included with month and year, the vaccine may only be used through that day.



Vaccine may be used up to and including the expiration date.

Exceptions to Expiration Dates on Labels (Beyond Use Date)

There are 3 instances when vaccines must be used prior to the expiration date printed on the label.

1. **Reconstitution**
   Once a lyophilized (freeze-dried) vaccine is mixed with a diluent (liquid) and reconstituted into a liquid form, there is a limited time frame in which the vaccine can be used. This time frame is indicated in the manufacturer's **package insert**. Also see **Reconstitution** and IAC's **Vaccines with Diluents: How to Use Them**.
2. **Multidose vials**
   Most multidose vials may be used until the expiration date printed on the vial unless contaminated or compromised in some way. However, some multidose vials have a specified time frame for use once the vial is entered with a needle (**package insert**). Also see **Multidose Vials**.
3. **Manufacturer shortened expiration date**
   If vaccine has been exposed to inappropriate storage conditions, its potency may be reduced before the expiration date printed on the label. A manufacturer may determine that the vaccine can be used, but with a shortened expiration date. Contact your **immunization program** and/or the **vaccine manufacturer**(s) per your protocol for further guidance in determining if the vaccine can be used with a shortened expiration date or if it should be discarded.

When vaccines must be used prior to the expiration date on the label, this is referred to as the "beyond use date" or "BUD" noted in the **package insert**. For reconstituted vaccines, this may be a date and/or time after which the vaccine cannot be used. The "BUD" (date and/or time) should be noted on the label along with the initials of the person changing the date/time.

Vaccines and Diluents that Cannot Be Used Before Expiration

If vaccine transfer is necessary so vaccine can be used before expiration, contact your **immunization program** and/or **vaccine manufacturer**(s) per your protocol for guidance (**Emergency or Off-site/Satellite Facility Transport**). Appropriate inventory management can be helpful in reducing need for transfer and transport of vaccines.

What to Do with Expired and Mishandled Vaccines and Diluents

Contact your **immunization program** and/or **vaccine manufacturer**(s), as appropriate for your situation, for specific policies regarding disposition of expired or mishandled vaccines. If inadvertently administered, the dose generally should not be counted as valid and should be repeated. If this occurs, contact your **immunization program** and/or **vaccine manufacturer**(s) for guidance on revaccination.

Stock Rotation

Immediately unpack vaccine deliveries.

At least 1 time each week and each time vaccines are delivered, vaccine coordinator should ensure that someone checks and rearranges placement of vaccines and diluents in storage unit according to expiration dates. Vaccines with soonest expiration dates should be placed in front of other vaccines of same type that have later expiration dates.

Immediately remove expired vaccines and diluents from storage units to avoid risk of inadvertent administration.

Vaccine Inventory Accounting

General Recommendations

Proper vaccine and diluent inventory management includes recording quantities:

- Received
- Administered, wasted, spoiled, expired, transferred
- Currently in stock
- To be used first
- Which need to be ordered

Vaccine Stock Records

All vaccine doses removed from unit should be totaled by vaccine type and recorded on a stock record. Stock records should be completed weekly. The balance of doses remaining in stock is indicated on stock record using tally of doses administered, wasted, spoiled, expired, or transferred during that week. For lyophilized (freeze-dried) vaccines that require reconstitution, document information for diluents on a separate vaccine stock record. Quantities of these vaccines and diluents should be equal at all times. Stock records may be kept in either computerized or written formats. One benefit of participation in an **immunization information system (IIS)** is ability to manage vaccine inventory electronically.

Stock records should contain the following:

- Date each vaccine and diluent delivered
- Initials of person who unpacked delivery (this person should document delivery on stock record)
- Condition of each vaccine and diluent upon arrival (i.e., did vaccine arrive in good condition at proper temperature)
- Cold chain monitor (CCM) readings if

included in shipping container and actions taken if monitor was triggered (**Unpacking Deliveries**)
- Name of each vaccine and diluent
- Name of manufacturer(s)
- Vaccine presentation (i.e., single-dose vial, multidose vial, or manufacturer-filled syringe)
- Lot number(s) (each lot should be documented separately)
- Expiration date(s) for each lot (including new expiration dates/times based on beyond use date [BUD] guidance in manufacturers' product information/**package insert**)
- Number of doses received (or balance of doses carried forward)
- Number of doses used (i.e., administered, wasted, compromised, expired, or transferred – if vaccine is transferred, note destination beside number of doses)
- Balance remaining (in DOSES) after subtracting amount used (i.e., administered, wasted, compromised, expired, or transferred)

If you receive multiple doses of same vaccine with same presentations from same lot with same expiration date, these doses may be documented as 1 entry on stock record. Simply indicate total number of doses received of that particular presentation (regardless of number of vials or syringes those doses came in). For example, if you receive 10 single-dose vials of same vaccine meeting above criteria, these 10 vials can be documented as single entry, noting that 10 doses were received.

If you do not have a stock record, see **Sample Stock Record** for information that should be included. A blank **Stock Record** is also available. If you are a VFC provider or have other vaccines purchased with public funds, contact your **immunization program** for information about stock records and inventory protocols and procedures.

accounts of doses used.

Vaccine Type: PPSV23 **Month and Year:** August 2015

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type (SDV, MDV, MFS)	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
08/02/15	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
08/09/15										1	1
08/15/15	LST	G	PPSV23	Merck	MDV	03958	09/15/15	N/A	5	3	3
08/22/15										1	2
08/29/15										0	2

Sample Stock Record

Tally Sheets

These should be placed in easily accessible locations (e.g., outside unit door) and used to document each time doses are removed from unit, including administered, wasted, compromised, expired, or transferred. This can be documented with tick marks.

Tally sheets can be used to keep stock records updated. For example, at the end of the week, the vaccine coordinator or designated person should add up number of doses on tally sheet of each vaccine used and update stock record accordingly. The old tally sheet should then be removed and replaced with a new one for the following week. Store and maintain used tally sheets in a file for future reference.

If you do not have a tally sheet, see **Sample Tally Sheet** for information that should be included. A blank **Tally Sheet** is also available. If you are a VFC provider or have other vaccines purchased with public funds, contact your **immunization program** for information about tally sheets and inventory protocols and procedures.

Documenting Administered, Wasted, Compromised, Expired, and Transferred Doses

Contact your **immunization program** for details about inventory accounting practices.

General Guidelines

Document every dose removed from storage unit whether administered, wasted, compromised, expired, or transferred. Expiration dates should be checked a minimum of 1 time each week and stock should be rotated to ensure that soonest to expire is in front (**Expiration Dates** and **Stock Rotation**). Document each time vaccine or diluent doses expire and immediately remove from unit. These records will help you decide how much vaccine to order to minimize future waste. Note each time vaccine doses cannot be used because they have been exposed to inappropriate storage conditions or because vials have been damaged. Once confirmed unusable by your immunization program or manufacturer(s), immediately remove these vaccines from unit. Subtract these unusable doses from running balance on stock record to calculate new balance of doses. Contact your

Storage Location (R or F) *	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired **	Doses Unusable	Doses Transferred (Viable) ***	Total
F	VAR	///// /// (8)	/				9
R	DTaP	///// ///// // (12)					12
R	Hib-HepB	///// ///// // (12)					12
R	IPV	///// ///// // (12)		//			14
R	HepA (pediatric)	// (2)					2
R	PPSV23	/ (1)					1
		( )					
		( )					
		( )					

Sample Tally Sheet

immunization program for instructions on how to dispose of these doses. They may have to be discarded, but sometimes unused vaccines may be returned for credit.

Contact immunization program and/or vaccine manufacturer(s) for guidance if vaccine transfer is required. Document transfer details on appropriate tally sheet and stock record, including:

- Vaccine(s)/diluent(s) transferred
- Contact name
- Telephone number on delivery note or packing slip that accompanies transfer

This helps recipient know exactly what items are being transferred. Copies of temperature logs that document appropriate storage also can be included.

Counting Stock

At least 1 time each month and before ordering, vaccine and diluent doses should be counted. This will ensure there are enough vaccine doses to meet needs of the facility, and is useful for checking accuracy of running balance of doses in the stock record. Number of vaccine doses in unit and number of doses reflected on stock records should match.

When counting vaccine doses:

- Always review expiration dates.
- Immediately remove expired vaccines and diluents. Contact your immunization program and/or vaccine manufacturer(s) for specific policies regarding disposition of expired vaccines. If expired vaccines are VFC vaccines or other vaccines purchased with public funds, contact your immunization program for instructions on returning them. If expired vaccines cannot be returned, dispose of them appropriately (Vaccine Disposal).
- If there is a difference between count of doses in unit and stock record balance, enter correct balance from your count on a separate line in stock record below old balance. Write a note with your signature beside it to indicate that your count has confirmed new balance. Use new corrected balance for all future stock calculations. If there are inventory discrepancies of VFC vaccines or other vaccines purchased with public funds, contact your immunization program for guidance.
- At end of every month, make a summary of amount of each vaccine and diluent used during that month and amount of stock still available at end of that month.
- At end of every year, total amount of each vaccine and diluent received and amount used. This information is useful for determining annual vaccine needs of facility.

Vaccine Stock Calculations and Ordering

There are three main principles for calculating amount of vaccine needed when placing orders:

1. Order and stock only enough vaccines to ensure there is an adequate supply to meet patient needs. Vaccines and presentations ordered should be appropriate for ages and types of patients facility serves. An adequate supply for most facilities would normally be enough vaccines to last 60 days, with re-ordering threshold of 30 days. While vaccine orders usually arrive within 1-2 weeks, delays can occur. Avoid placing last-minute or rush orders to minimize the risk that you will run out of vaccines.

2. Order smaller quantities to help prevent over-ordering and subsequent risk of expired, wasted vaccines. Over-ordering can lead to unnecessarily large volumes of vaccine being stored, increasing risk of losing a large quantity should vaccines be compromised (e.g., mechanical failure of the storage unit).

Notes:

Vaccine Deliveries

Key Messages:

- Arrange for vaccine and diluent deliveries to be made only when vaccine coordinator or alternate (back-up) coordinator is on duty.
- All staff members who may be involved in deliveries should be trained to immediately notify vaccine coordinator or alternate (back-up) coordinator when deliveries arrive and ensure that vaccines and diluents are properly stored in a timely manner.
- Immediately unpack and examine deliveries upon arrival.
- After contents have been checked according to procedures, immediately store vaccines and diluents at recommended temperatures.
- Staff members who accept deliveries for facility must be aware that vaccine deliveries require immediate attention and know their responsibility in assuring cold chain is maintained.

Standard Operating Procedures

Each facility should develop its own written standard operating procedures (SOPs) for handling deliveries (**Routine Vaccine Storage and Handling Plan**). Without SOPs, there can be no assurance that proper procedures will be followed or that problems will be identified, reported, and corrected.

If you provide VFC vaccines or other vaccines purchased with public funds, contact your **immunization program** for protocols and requirements pertaining to vaccine deliveries.

Receiving and Unpacking Deliveries

Receiving Deliveries

Arrange for vaccine and diluent deliveries to be made only when the vaccine coordinator or alternate (back-up) coordinator is on duty. Consider holidays, vacations, staff schedules, and changes in hours of operation. All staff members (including non-medical staff, e.g., receptionists and other front desk personnel) who may be involved in deliveries must be aware of importance of maintaining cold chain. They should be trained to:

immediately notify coordinator or alternate (back-up) when deliveries arrive and ensure that vaccines and diluents are properly stored in a timely manner.

All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and the need to immediately notify the vaccine coordinator or alternate (back-up) coordinator upon arrival.

If you need to pick up vaccines or diluents from another facility, you must ensure that cold chain

can be maintained.

If you have VFC vaccines or other vaccines purchased with public funds, you must coordinate any transfer with your immunization program. See **Vaccine Transport**.

Unpacking Deliveries

Immediately unpack and examine deliveries upon arrival.

- Examine shipping container and contents for signs of physical damage.
- Cross-check contents with packing slip to be sure they match.
- Check expiration dates to ensure that you have not received any vaccines or diluents that have already expired or will expire soon (**Expiration Dates**).
- Check that lyophilized (freeze-dried) vaccines have been shipped with correct type and quantity of diluents. For varicella-containing vaccines, diluents should be in a separate compartment.
- If you suspect heat or cold damage, check:
  - Vaccine cold chain monitor(s) (CCM), if present, and contact distributor or manufacturer for guidance. CCMs may not be required when vaccines are shipped directly from the manufacturer. Note: CCMs are one-time use and should be discarded.
  - Vaccines were properly packed. There should be an insulating barrier (such as bubble wrap, Styrofoam pellets, or some other barrier) between vaccines and the refrigerated or frozen coolant packs.

Examine the shipping container and its contents for any signs of physical damage.

- If there are any discrepancies with the packing slip or concerns about contents, immediately notify **immunization program** and/or **vaccine manufacturer**(s) for guidance.

Label vaccines "Do NOT Use" and store under appropriate conditions (set apart from other vaccines).

Storing and Documenting Deliveries

After contents have been checked according to procedures, immediately store vaccines and diluents at recommended temperatures and record each vaccine and diluent, noting all details on **Stock Record**. Do NOT leave shipping container unpacked and unattended as vaccines and diluents inside might warm to inappropriate

temperatures and become unusable. Staff members who accept deliveries for the facility must be aware that vaccine deliveries require immediate attention and know their responsibility in assuring cold chain is maintained.

Notes:

Vaccine Transport

Key Messages:

- If at all possible, have vaccines delivered directly to an off-site/satellite facility.
- If vaccines must be transported to off-site/ satellite facility, the amount transported should be limited to only what is needed for that workday. Transport and workday should total no more than a maximum of 8 hours.
- Use a calibrated temperature monitoring device with continuous monitoring and recording capabilities during transport.
- CDC recommends transport of refrigerated or frozen vaccines using a portable refrigerator/ freezer unit.
- If necessary, varicella-containing vaccines that have not been reconstituted may be transported at refrigerated temperatures. However, you must contact the **vaccine manufacturer** for guidance upon arrival at off-site/satellite facility.
- When packing vaccines for transport, use a barrier layer between coolant packs and vaccines and place a calibrated temperature monitoring device next to vaccines.
- Do NOT use dry ice to transport varicella-containing vaccines.
- Diluents should be transported with corresponding vaccines at storage temperatures specified in **package insert**.
- In advance, refrigerate diluents stored at room temperature before transporting in same container with refrigerated vaccines so they will not increase temperature in container.
- NEVER freeze diluents, even in transport.
- Read and record storage unit temperature at off-site/satellite facility a minimum of 2 times during the workday.
- If vaccines are kept in transport container, read and record temperatures hourly.

Emergency or Off-site/Satellite Facility Transport

If you provide VFC vaccines or other vaccines purchased with public funds, contact your **immunization program** regarding vaccine transport, details on how to pack vaccine and diluent, and procedures for maintaining the cold chain.

General Recommendations

Transport involves the movement of vaccine over a short time and distance between providers. Vaccine manufacturers do not generally recommend or provide guidance for transport of vaccines and CDC discourages routine transport.

If at all possible, have vaccines delivered directly to an off-site/satellite facility. Each

transport increases risk of exposing vaccines to inappropriate storage conditions.

If vaccines must be transported to off-site/satellite facility, the amount transported should be limited to only what is needed for that workday. Transport and workday should total no more than a maximum of 8 hours.

CDC recommends using a calibrated temperature monitoring device with continuous monitoring and recording capabilities during transport.

CDC does NOT recommend using cold chain monitors (CCMs in **Unpacking Deliveries**) during transport since they do not provide adequate data on excursions that may occur. Providers should contact **immunization program** and/or **vaccine manufacturer**(s) for guidance.

The facility SOP should specify that vaccines are:

- Monitored with calibrated temperature monitoring device
- Not placed in vehicle trunk
- Delivered directly to facility
- Promptly unpacked and placed into appropriate storage units upon arrival (**Unpacking Deliveries**)

When transporting vaccines in non-commercial vehicles use the passenger compartment—not the trunk.

There are many variables to consider when transporting vaccines:

- Type of vaccines
- Time of year and seasonal temperature
- Amount of vaccines
- Container, packing materials, pack out method
- Number of times container is opened and closed

Contact your **immunization program** for specific guidance regarding vaccine transport, details on how to pack vaccine and diluent, and procedures for maintaining cold chain.

General Guidance

Refrigerated vaccines

- Pack refrigerated vaccines before packing frozen vaccines.
- CDC recommends transport with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls may be used if it can maintain recommended temperature range (between 35°F and 46°F [2°C and 8°C]).
- Place a layer (at least 2 inches) of "conditioned" coolant packs in transport container first. Coolant packs that are frozen must be "conditioned" by leaving them at room temperature for 1 to 2 hours until edges have defrosted and packs look like they've been "sweating." Frozen coolant packs that are not "conditioned" can freeze vaccines.
- Place an insulating barrier layer on top of coolant packs (e.g., bubble wrap or Styrofoam pellets).
- Next, place a calibrated temperature monitoring device (preferably with a probe

in a thermal buffer, e.g., glycol) on top of barrier.
- Next, stack vaccines with temperature monitoring device on top of barrier.
- Place another insulating barrier layer on top of vaccines.
- Place another layer of "conditioned" coolant packs on top of barrier.
- Always ensure there is no direct contact between coolant packs and vaccines.
- Place a final insulating barrier layer (at least 2 inches) on top of coolant packs along with a list of vaccines in container.

Transporting Varicella-containing Vaccines

The vaccine manufacturer does not recommend transporting varicella-containing vaccines (VAR, HZV, MMRV).

If these vaccines must be transported (e.g., during an emergency):

- CDC recommends transport in a portable freezer unit that maintains temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places.
- If not using a portable freezer, use same packing layers as noted above.
- Coolant packs should be frozen.

If necessary, varicella-containing vaccines that have not been reconstituted may be transported at refrigerator temperature between 36°F and 46°F (2°C and 8°C) for up to 72 continuous hours prior to reconstitution (**package inserts**). Follow these steps:

1. Place a calibrated temperature monitoring device (preferably with a probe in a thermal buffer, e.g., glycol) in the container as close as possible to vaccines. If transported in same container with refrigerated vaccines, place insulating material (e.g., bubble wrap) around refrigerated vaccines to protect from freezing temperatures and use rubber bands around frozen vaccines to keep them separate.
2. Record:
   a. Time vaccines are removed from storage unit and placed in container
   b. Temperature during transport
   c. Time at end of transport when vaccine returned to main storage unit
3. Immediately upon arrival at off-site/satellite facility:
   a. Place varicella-containing vaccines in freezer between -58°F and +5°F (-50°C and -15°C) and label "Do NOT Use." Any stand-alone freezer that reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) is acceptable for storage of varicella-containing vaccines.
   b. Document time vaccines are removed from container and placed in alternate storage unit.
   c. Note: This is considered a temperature excursion. Do NOT use vaccine until the vaccine manufacturer is contacted at 1-800-637-2590 for guidance.
4. Do not discard vaccines without contacting your **immunization program** and/or **vaccine manufacturer**(s) for guidance.

Do NOT use dry ice, even for temporary storage or emergency transport. Dry ice may expose varicella-containing vaccines to temperatures colder than -58°F (-50°C).

Diluents

Diluents should be transported with their corresponding vaccines to ensure there are always equal amounts of vaccine and diluent for reconstitution. Follow manufacturer guidance for specific temperature requirements. Diluents that contain antigen (e.g., DTaP-IPV diluent used with Hib lyophilized vaccine) should be transported with corresponding vaccines at refrigerator temperature. Place an insulating barrier between diluents and coolant packs.

Refrigerate, in advance, diluents stored at room temperature before transporting in same container with refrigerated vaccines so they will not increase temperature in container.

NEVER freeze diluents, even in transport.

Multidose Vials

Only if absolutely necessary, a partially used vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained. However, a partially used vial may NOT be transferred to another provider or transported across state lines.

Monitoring Temperatures at Off-site/Satellite Facility

Immediately upon arrival at off-site/satellite facility, store vaccines at recommended temperature range in an on-site refrigerator or freezer. Place a calibrated temperature monitoring device(s) in storage unit(s) with vaccines.

Read and record temperatures a minimum of 2 times during the workday if the vaccines are stored in a refrigerator and freezer.

CDC does not recommend keeping vaccines in a transport container(s) unless it is a portable refrigerator or freezer unit. If vaccines must be kept in a transport container(s) during an off-site clinic, temperature{s) should be read and recorded at least hourly. In addition:

- Container(s) should remain closed as much as possible
- A calibrated temperature monitoring device(s) (preferably with a probe in a thermal buffer, e.g., glycol) should be placed as close as possible to vaccines
- Only amount of vaccine needed at one time (no more than 1 multidose vial or 10 doses) should be removed for preparation and administration by each vaccinator

If you have concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly), label them "Do NOT Use" and store them under appropriate conditions (set apart from other vaccines).

Immediately contact your **immunization program** and/or **vaccine manufacturer**(s) for guidance. Do NOT discard the vaccines or diluents unless directed to by your immunization program and/or manufacturer(s).

Notes:

Key Messages:

- Do not open a single-dose vial until ready to use. Once the protective cap is removed the vaccine should be used or discarded at the end of the workday.
- Multidose vials can be used until the expiration date printed on the vial unless contaminated, compromised, or there is a "beyond use date" (BUD) noted in the **package insert**.
- NEVER use partial doses from two or more vials to obtain a full dose of vaccine.
- Once a manufacturer-filled syringe is activated (i.e., syringe cap removed or needle attached), the vaccine should be used or discarded at the end of the workday.
- Diluents are NOT interchangeable unless specified by manufacturer (e.g., diluent for MMR, VAR, HZV, and MMRV). If vaccine must be reconstituted, use only diluent supplied by manufacturer for that vaccine.
- NEVER use a stock vial of sterile water or normal saline to reconstitute vaccines.
- Always check expiration dates on both diluent and vaccines to make sure neither has expired.
- Refer to manufacturer's product information/**package insert** for instructions on reconstituting specific vaccines.
- CDC recommends that providers draw up vaccines only at time of administration. If not used by the end of the workday, vaccines should be discarded.
- You should only administer vaccines that you have prepared.

Preparation for Vaccine Administration

Single-dose Vials

Single-dose vials are meant for one-time use. They do not contain a bacteriostatic (preservative) agent. Do not open a single-dose vial until ready to use. Once the protective cap has been removed, the vaccine should be used because it may not be possible to determine if the rubber seal has been punctured. Always check the vial before removing the cap to assure the correct vaccine has been selected. Unused single-dose vials without a protective cap should be discarded at the end of the workday.

Single-dose vials are meant for one-time use only. Once unsealed, discard vial at end of the workday.

Multidose Vials

Multidose vials can be entered more than once to draw up multiple doses. They do contain a bacteriostatic (preservative) agent. They can be used until the expiration date printed on the vial unless contaminated, compromised in some way, or there is a "beyond use date" or "BUD" noted in the **package insert**. Also see **Exceptions to Expiration Dates on Labels (Beyond Use Date)**.

NEVER use partial doses from two or more vials to obtain a dose of vaccine.

Manufacturer-filled Syringes

Manufacturer-filled syringes are prepared and sealed under sterile conditions by the manufacturer. Once a manufacturer-filled syringe is activated (i.e., syringe cap removed or needle attached), the sterile seal is broken. The vaccine should then be used or discarded at the end of the workday.

Manufacturer-filled syringes

Reconstitution

Lyophilized (Freeze-dried) Vaccines

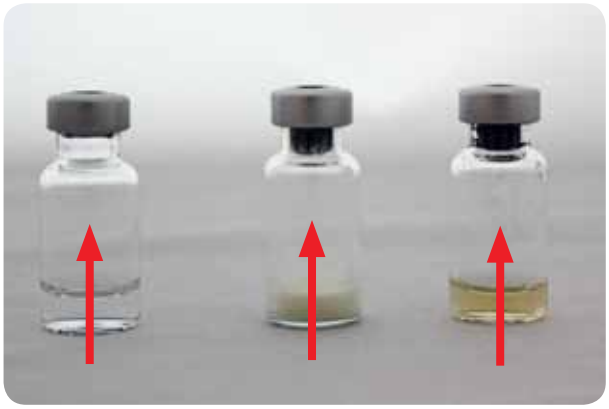
Lyophilized (freeze-dried) vaccines may be a powder or pellet that must be mixed with a liquid (diluent) in a process known as "reconstitution" before it can be administered.

Diluents

A diluent is liquid that is mixed with a lyophilized powder or pellet to reconstitute vaccine into liquid form for administration. Diluents vary in volume and composition. They are specifically designed to meet volume, pH (acid/ alkaline balance), and chemical requirements of their corresponding vaccine. Some diluents contain antigen (e.g., DTaP-IPV). Diluents are NOT interchangeable unless specified by the manufacturer (e.g., diluent for MMR, VAR, HZV, and MMRV). If vaccine must be reconstituted with sterile water or saline, use only the diluent supplied for that vaccine. NEVER use a stock vial of sterile water or normal saline to reconstitute vaccines. Always check expiration dates on both diluent and vaccines to make sure neither has expired.

NEVER administer vaccine reconstituted with the wrong diluent. If the vaccine has already been administered, contact your **immunization program** and/or **vaccine manufacturer**(s) for guidance regarding revaccination.

For general guidance on vaccine reconstitution see **Vaccine Administration**. Manufacturers' **package inserts** also contain instructions on reconstitution of specific vaccines.



Diluent + Lyophilized Powder = Reconstituted Vaccine

Predrawing Vaccines

CDC recommends that providers draw up vaccines only at the time of administration.

Problems associated with this practice

- Once vaccines are inside syringes, it is difficult to tell them apart leading to administration errors.
- Leads to vaccine waste and increases risk of storage under inappropriate conditions.
- Most syringes are designed for immediate administration, not for storage. Bacterial contamination and growth can occur in syringes with predrawn vaccine that does not contain bacteriostatic agents.
- Vaccine components may interact with polymers in plastic syringes over time, potentially reducing vaccine potency.
- Only administer a vaccine you have prepared and drawn up. If vaccine is drawn up by one person and administered by a different person, the person administering vaccine cannot be sure about what is in the syringe and its sterility. This is a quality control and patient safety issue and a best practice standard of medication administration.

CDC discourages predrawing vaccines.

Influenza Clinics and Predrawing Vaccines

Vaccine manufacturers do not recommend that vaccines be predrawn in advance of clinics because no data exist on stability of vaccines stored in syringes that have been filled by providers.

As an alternative to predrawing vaccines, CDC recommends using manufacturer-filled syringes for large immunization clinics.

Cautions if vaccine must be predrawn:

- If more than one vaccine type is to be administered, separate administration stations should be set up for each vaccine type to prevent medication errors.
- Vaccines should NOT be drawn up in advance of arriving at clinic site. Drawing up doses of vaccine hours or even days before a clinic is NOT acceptable.
- At clinic site, no more than 1 multidose vial or 10 doses should be drawn up at one time by each vaccinator.
- Patient flow should be monitored to avoid drawing up unnecessary doses.
- At end of workday, any remaining vaccine in provider predrawn syringes should be discarded.

Notes:

Vaccine Disposal

Key Messages:

- Contact **immunization program** and/or **vaccine manufacturer**(s) for policies regarding disposition of unopened vials, expired vials, unused doses, and potentially compromised vaccine.
- Open vials, activated manufacturer-filled syringes, vaccine predrawn by a provider, and broken vials and syringes are not returnable and should be appropriately discarded.
- Contact your **immunization program** or state environmental agency to ensure that your vaccine disposal procedures and any related documentation are in compliance with state and federal regulations.

Unused vaccine and diluent doses may be returnable under certain circumstances. Contact the vaccine supplier, which may be the **immunization program** and/or **vaccine manufacturer**(s), for specific policies regarding the disposition of unopened vials, expired vials, unused doses, and potentially compromised vaccine due to inappropriate storage conditions.

Open vials, activated manufacturer-filled syringes, vaccine predrawn by a provider, and broken vials and syringes are not returnable and should be appropriately discarded.

In general, most empty vaccine vials are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container.

Requirements for medical waste disposal are regulated by state environmental agencies.

Contact your **immunization program** or state environmental agency to ensure that your vaccine disposal procedures and any related documentation are in compliance with state and federal regulations.

State-by-State Regulated Medical Waste Resource Locator:

http://www.hercenter.org/rmw/rmwlocator.cfm

General Vaccine Storage and Handling Guidelines

Handle with Care Poster

Routine Vaccine Storage and Handling Plan Worksheet

CDC's Temperature Excursion Checklist

NIST "Storage and Monitoring of Vaccines"

CDC Vaccine Price List

Temperature Conversion Tables

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

Vaccine Inventory Records

Sample Stock Record

Stock Record

Sample Tally Sheet

Tally Sheet

Warning Signs (can be printed and reproduced)

Do Not Adjust Refrigerator Controls (English)

Do Not Adjust Refrigerator Controls (Spanish)

Do Not Adjust Freezer Controls (English)

Do Not Adjust Freezer Controls (Spanish)

Warning! Do Not Unplug Refrigerator (English)

Warning! Do Not Unplug Refrigerator (Spanish)

Warning! Do Not Unplug Freezer (English)

Warning! Do Not Unplug Freezer (Spanish)

Do Not Unplug Refrigerator (English)

Do Not Unplug Refrigerator (Spanish)

Do Not Unplug Freezer (English)

Do Not Unplug Freezer (Spanish)

Shipping Labels (can be printed and reproduced)

Vaccine Labels for Storage Unit

Refrigerate Upon Arrival

Freeze Upon Arrival

Open Immediately: Refrigerate Upon Receipt

Open Immediately: Freeze Upon Receipt

Refrigerate—Do Not Freeze

Freeze—Do Not Refrigerate

Fragile: Handle with Care

Fragile

Perishable—Rush

Emergency Vaccine Storage and Handling Resources

Emergency Vaccine Retrieval and Storage Plan Worksheet

Emergency Management Internet Resources

Other Sources for Storage and Handling Information

Immunization Action Coalition

Vaccine Package Inserts

Immunization Action Coalition

Clinic Resources

Immunization Action Coalition

Vaccines with Diluents: How to Use Them

Immunization Action Coalition

"Ask the Experts"

State Immunization Program Websites

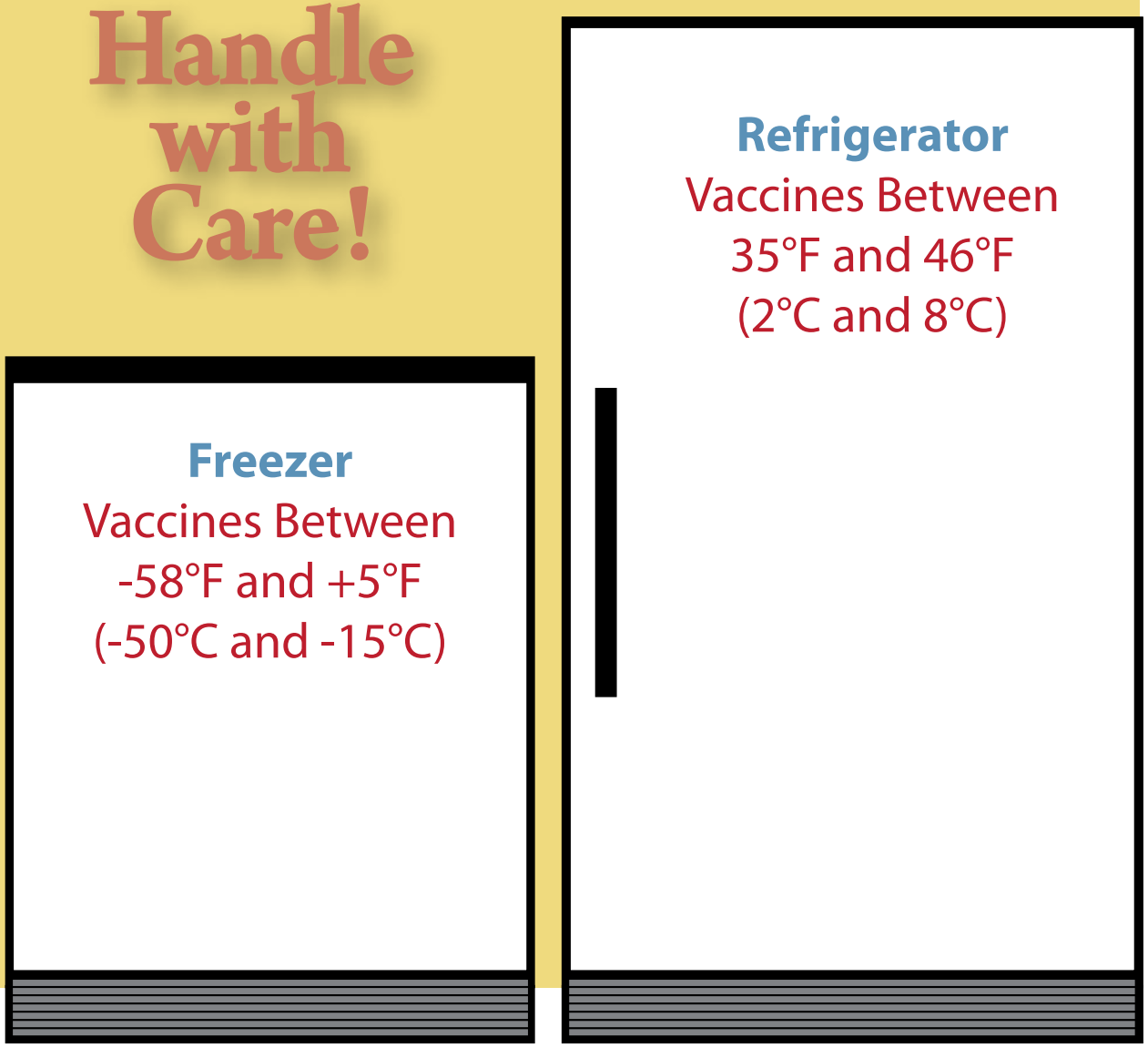
Manufacturer/Distributor Contact Information

PROTECT YOUR VACCINE
PROTECT YOUR PATIENTS

Handle with Care!

Vaccine Storage Rules

- Keep your refrigerator and freezer within the appropriate temperature ranges.
- Keep your vaccines within the appropriate temperature ranges.
- Review and record refrigerator and freezer temperatures 2 times each workday and min/max at beginning of workday.
- Take immediate action if temperatures are out of range.
- Keep vaccines in their original packages.
- Many vaccines should be protected from light (consult manufacturer's product information).
- Keep VAR, HZV, and MMRV frozen.
- Rotate your vaccine stocks.



Routine Vaccine Storage and Handling Plan Worksheet

Complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage unit. See the Vaccine Storage and Handling Plans chapter for details.

Checklist of Resources for the Routine Vaccine Storage and Handling Plan

- ❑ Up-to-date contact information
  - – Primary and alternate (back-up) vaccine coordinators
  - – Local and state health department immunization programs
  - – Manufacturers of vaccines in your inventory
  - – Refrigerator and freezer maintenance and repair companies
  - – Vaccine storage unit alarm company (if applicable)
  - – Sources for packing materials, calibrated temperature monitoring devices, and portable refrigerator/freezer units or qualified containers
- ❑ Descriptions of the roles and responsibilities of the primary and alternate (back-up) vaccine coordinators
- ❑ Policy on education and training for facility staff
- ❑ Summaries of the storage requirements for each type of vaccine and diluent in your inventory
- ❑ Protocols for vaccine storage unit temperature monitoring
- ❑ Protocols for vaccine storage equipment maintenance
- ❑ Protocols for the correct placement of vaccines within storage units
- ❑ Protocols for responding to vaccine storage and handling problems
- ❑ Protocols for vaccine/diluent inventory management
- ❑ Protocols for receiving and unpacking vaccine/diluent deliveries
- ❑ Protocols for transporting vaccines/diluents to off-site/satellite facility(ies)
- ❑ Protocols for handling vaccines/diluents prior to administration
- ❑ Protocols for proper disposal of vaccines, diluents, and supplies
- ❑ Samples of the forms used in your vaccination program

Routine Vaccine Storage and Handling Plan Worksheet

Vaccine Coordinators			
Vaccine Coordinators	Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Primary			
Alternate (Back-up)			

Resources Contact List			
Resources	Contact Person Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Local Health Department Immunization Program			
State Health Department Immunization Program			
Additional Resources	Company Name Contact Person Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Electric Power Company			
Generator Repair Company (if applicable)			
Refrigerator Repair Company			
Freezer Repair Company			
Temperature Alarm Monitoring Company (if applicable)			
Security or Perimeter Alarm Company (if applicable)			

Routine Vaccine Storage and Handling Plan Worksheet

Emergency Resources Company Name	Contact Person Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Packing Materials			
Portable refrigerator/ freezer units			
Qualified containers			
Qualified containers (alternate)			
Fillers (e.g., bubble wrap, Styrofoam pellets)			
Fillers (alternate)			
Coolant packs			
Coolant packs (alternate)			
Calibrated temperature monitoring devices			
Calibrated temperature monitoring devices(alternate)			

CDC's Temperature Excursion Checklist

1. **Checklist for general power loss**
   - ❑ Contact utility company
   - ❑ Determine if time to restoration is acceptable
   - ❑ Activate alternate generator if available
2. **Checklist for presumed storage unit malfunction (DISPOSITION OF STORAGE UNIT if Unit is too warm, too cold, too noisy, or stopped):**
   - ❑ Check circuit breakers
   - ❑ Unit plugged in
   - ❑ Door closed
   - ❑ Door seal adequate
   - ❑ Assess location of temperature monitoring devices for temperature reading
   - ❑ Record all temperatures
   - ❑ Space between vaccines for air to circulate
   - ❑ Coils free of dust
   - ❑ Temperature adjusted gradually if not set correctly (need to re-check temperatures and record every 30 minutes)
   - ❑ Unit secured and level (if unit is noisy)
   - ❑ Screws tightened (if unit is noisy)
   - ❑ Technician called
3. **Disposition of vaccines (if power not restored or if temperature does not begin to recover)**
   - ❑ Label exposed vaccines "Do NOT Use" and store under appropriate conditions (set apart from other vaccines)
   - ❑ Check temperature of alternate storage unit
   - ❑ Vaccines moved to alternate storage unit (move refrigerated vaccines first)
   - ❑ Document temperature excursion action taken and results
   - ❑ Immunization Program contacted
   - ❑ Manufacturer contacted
   - ❑ Return vaccines determined to be usable only when storage unit is stable and resume use
   - ❑ Determine disposition of vaccines that are compromised:
     - Vaccines provided through Vaccines for Children (VFC) Program and other vaccines purchased with public funds prepared for return to distributor.
     - Vaccines purchased with private funds should be disposed of in consultation with the manufacturer(s) and according to state regulations for medical waste. Replacement plans will vary.
     - If insured against losses of this type, contact insurance representative.

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

°F	°C	°F	°C	°F	°C	°C	°F	°C	°F
-22	-30	21	-6.1	64	17.8	-30	-22	13	55.4
-21	-29.4	22	-5.6	65	18.3	-29	-20.2	14	57.2
-20	-28.9	23	-5	66	18.9	-28	-18.4	15	59
-19	-28.3	24	-4.4	67	19.4	-27	-16.6	16	60.8
-18	-27.8	25	-3.9	68	20	-26	-14.8	17	62.6
-17	-27.2	26	-3.3	69	20.6	-25	-13	18	64.4
-16	-26.7	27	-2.8	70	21.1	-24	-11.2	19	66.2
-15	-26.1	28	-2.2	71	21.7	-23	-9.4	20	68
-14	-25.6	29	-1.7	72	22.2	-22	-7.6	21	69.8
-13	-25	30	-1.1	73	22.8	-21	-5.8	22	71.6
-12	-24.4	31	-0.6	74	23.3	-20	-4	23	73.4
-11	-23.9	32	0	75	23.9	-19	-2.2	24	75.2
-10	-23.3	33	0.6	76	24.4	-18	-0.4	25	77
-9	-22.8	34	1.1	77	25	-17	1.4	26	78.8
-8	-22.2	35	1.7	78	25.6	-16	3.2	27	80.6
-7	-21.7	36	2.2	79	26.1	-15	5	28	82.4
-6	-21.1	37	2.8	80	26.7	-14	6.8	29	84.2
-5	-20.6	38	3.3	81	27.2	-13	8.6	30	86
-4	-20	39	3.9	82	27.8	-12	10.4	31	87.8
-3	-19.4	40	4.4	83	28.3	-11	12.2	32	89.6
-2	-18.9	41	5	84	28.9	-10	14	33	91.4
-1	-18.3	42	5.6	85	29.4	-9	15.8	34	93.2
0	-17.8	43	6.1	86	30	-8	17.6	35	95
1	-17.2	44	6.7	87	30.6	-7	19.4	36	96.8
2	-16.7	45	7.2	88	31.1	-6	21.2	37	98.6
3	-16.1	46	7.8	89	31.7	-5	23	38	100.4
4	-15.6	47	8.3	90	32.2	-4	24.8	39	102.2
5	-15	48	8.9	91	32.8	-3	26.6	40	104
6	-14.4	49	9.4	92	33.3	-2	28.4		
7	-13.9	50	10	93	33.9	-1	30.2		
8	-13.3	51	10.6	94	34.4	0	32		
9	-12.8	52	11.1	95	35	1	33.8		
10	-12.2	53	11.7	96	35.6	2	35.6		
11	-11.7	54	12.2	97	36.1	3	37.4		
12	-11.1	55	12.8	98	36.7	4	39.2		
13	-10.6	56	13.3	99	37.2	5	41		
14	-10	57	13.9	100	37.8	6	42.8		
15	-9.4	58	14.4	101	38.3	7	44.6		
16	-8.9	59	15	102	38.9	8	46.4		
17	-8.3	60	15.6	103	39.4	9	48.2		
18	-7.8	61	16.1	104	40	10	50		
19	-7.2	62	16.7			11	51.8		
20	-6.7	63	17.2			12	53.6		

Stock Record

Instructions: At the end of each month conduct a physical check of the inventory and compare it with the recorded balance, looking for any discrepancies. If the cause of a discrepancy cannot be determined and corrected, make a note of this. Start a new stock record page by recording the physical count of the previous page. Use the correct physical count for the starting balance. Use the remaining lines to record new shipments of vaccines/diluents and weekly accounts of doses used.

Vaccine Type: PPSV23 Month and Year: August 2015

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type (SDV, MDV, MFS)	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
08/02/15	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
08/09/15										1	1
08/15/15	LST	G	PPSV23	Merck	MDV	03958	02/15/14	N/A	5	3	3
08/23/15										1	2
08/29/15										0	2

* The initials of the person who unpacked and checked the vaccines/diluents upon arrival

** G = vaccines/diluents arrived in good condition
? = condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.

*** SDV = Single-dose vial
MDV = Multidose vial
MFS = Manufacture-filled syringe

† Includes number of doses administered, wasted, unusable, expired, or transferred.

†† Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used."

Vaccine Totals	7	5	2 ††

	Physical Stock Check (In Doses)	2
	Difference ("Balance" minus Physical Stock Check)	0
	Balance Carried Forward (In Doses)	2

Some state or local health department immunization programs have developed their own stock records for immunization providers. Contact program staff for information. If stock records are not available from your state or local health department or an Immunization Information System (IIS), this stock record may be used.

Stock Record

Instructions: At the end of each month conduct a physical check of the inventory and compare it with the recorded balance, looking for any discrepancies. If the cause of a discrepancy cannot be determined and corrected, make a note of this. Start a new stock record page by recording the physical count of the previous page. Use the correct physical count for the starting balance. Use the remaining lines to record new shipments of vaccines/diluents and weekly accounts of doses used.

Vaccine Type: _____ Month and Year: _____

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type (SDV, MDV, MFS)	Lot Number	Expiration Date	Expiration Date After Reconsti-tution	Doses Received/ Balance Forward	Doses Used†	Balance (Doses)
	BEGINNING BALANCE FOR THE MONTH									N/A	

Vaccine Totals			††

* The initials of the person who unpacked and checked the vaccines/diluents upon arrival

** G = vaccines/diluents arrived in good condition
? = condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.

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Physical Stock Check (In Doses)	
Difference ("Balance" minus Physical Stock Check)	
Balance Carried Forward (In Doses)	

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Tally Sheet

Instructions: Place a copy of this sheet on the door of the refrigerator and freezer units in which you store vaccines. Record the week (by date or week number). Write the names of the vaccines/diluents and indicate the storage location of each vaccine/diluent in the refrigerator (R) or freezer (F). Record a tick mark for each dose of vaccine/diluent you remove from a storage unit (i.e., for each dose that is administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the appropriate stock record. Remove the completed tally sheet from each storage unit door and store in a file for future reference. Place a new copy of the tally sheet on the storage unit door.

Week: August 19-23, 2015 (Week 3)

Storage Location (R or F) *	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired **	Doses Unusable	Doses Transferred (Viable) ***	Total
F	VAR	𝍸 III (8)	I				9
R	DTaP	𝍸 𝍸 II (12)					12
R	HepB	𝍸 𝍸 II (12)					12
R	IPV	𝍸 𝍸 II (12)		II			14
R	HepA (pediatric)	II (2)					2
R	PPSV23	I (1)					1
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					

* R = Refrigerator
F = Freezer

** Some non-viable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.

*** Viable vaccine doses transferred to your state or local health department immunization program or another facility.

Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an Immunization Information System (IIS), this tally sheet may be used.

Tally Sheet

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Week: _____

Storage Location (R or F) *	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired **	Doses Unusable	Doses Transferred (Viable) ***	Total

* R = Refrigerator
F = Freezer

** Some non-viable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.

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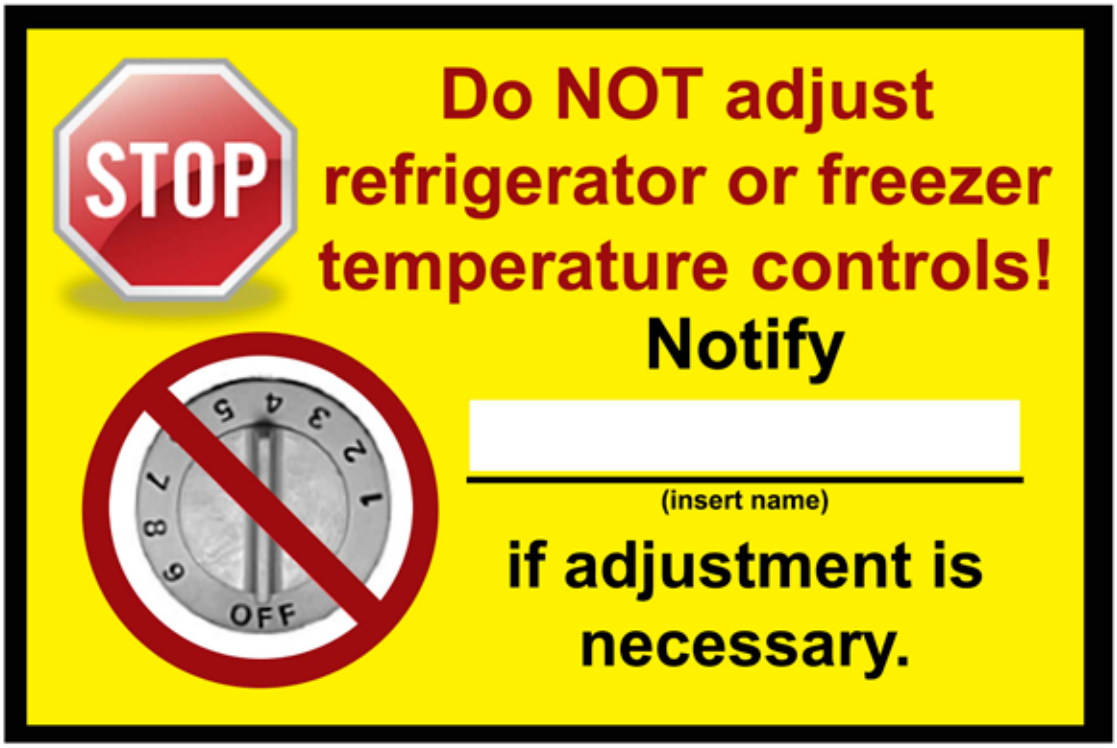
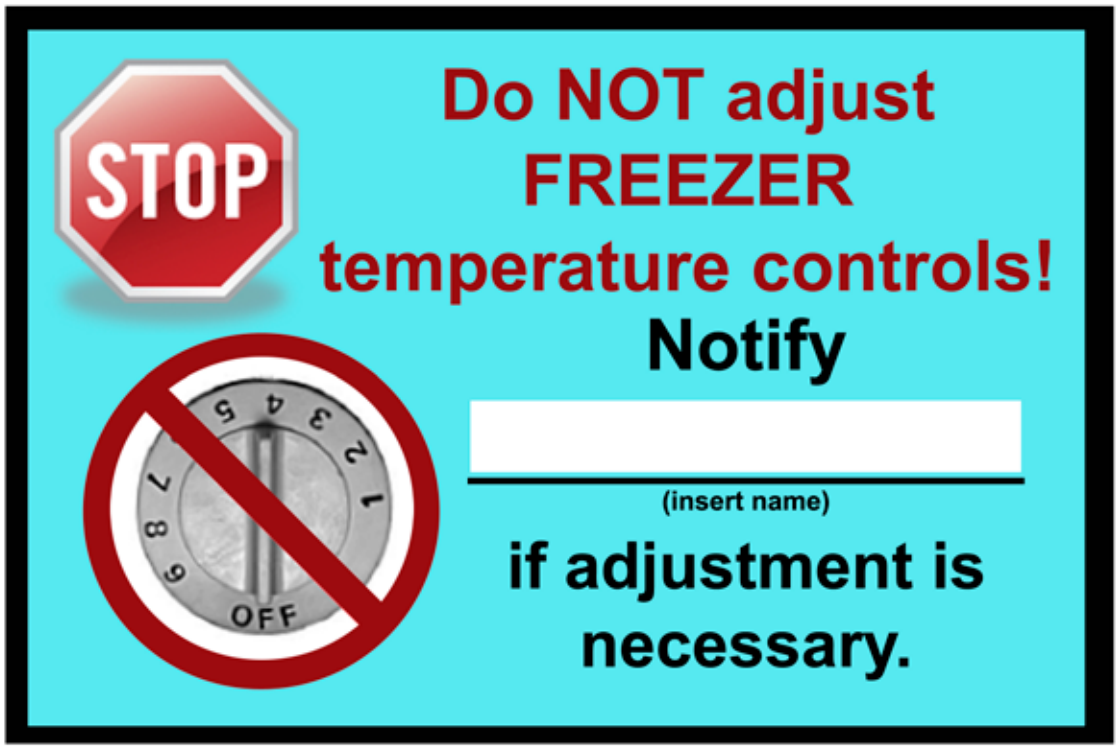
Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an Immunization Information System (IIS), this tally sheet may be used.

Do Not Adjust Refrigerator Controls (English)



Do Not Adjust Refrigerator Controls (Spanish)

Do Not Adjust Freezer Controls (English)



Do Not Adjust Freezer Controls (Spanish)

Warning! Do Not Unplug Refrigerator (English)

WARNING!

Do not unplug the REFRIGERATOR or break circuit. Expensive vaccine in storage.

In the event of electrical problem, immediately contact:

_____

Warning! Do Not Unplug Refrigerator (Spanish)

¡AVISO!

No desconecte el REFRIGERADOR ni corte el circuito. ¡Contiene vacunas caras!

Si hay un problema con la electricidad, comuníquese inmediatamente con:

_____

Warning! Do Not Unplug Freezer (English)

WARNING!

Do not unplug the FREEZER or break circuit. Expensive vaccine in storage.

In the event of electrical problem, immediately contact:

_____

Warning! Do Not Unplug Freezer (Spanish)

¡AVISO!

No desconecte el CONGELADOR ni corte el circuito. ¡Contiene vacunas caras!

Si hay un problema con la electricidad, comuníquese inmediatamente con:

_____

Do Not Unplug Refrigerator (English)

Do Not Unplug Refrigerator (Spanish)

Do Not Unplug Freezer (English)

Do Not Unplug Freezer (Spanish)

Refrigerate Upon Arrival

Freeze Upon Arrival

Open Immediately: Refrigerate Upon Receipt

Open Immediately: Freeze Upon Receipt

Refrigerate—Do Not Freeze

Freeze—Do Not Refrigerate

Fragile: Handle with Care

Fragile

Perishable—Rush

Emergency Vaccine Retrieval and Storage Plan Worksheet

In advance of an emergency, complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage units. See the Vaccine Storage and Handling Plans chapter for details.

Checklist of Resources for the Emergency Vaccine Retrieval and Storage Plan

- ❑ Designated primary and alternate (back-up) vaccine coordinators with emergency contact information
- ❑ Emergency staff contact list in order of contact preference
- ❑ Specifications of vaccine storage unit (type, brand, model number, serial number)
- ❑ Alternate vaccine storage facility(ies)
- ❑ Written protocols, vehicles, and drivers for transporting vaccines to and from alternate vaccine storage facility(ies)
- ❑ Written instructions for entering your facility and vaccine storage areas in emergency if building closed. Instructions should include building security/after-hours access procedure, floor diagram, and locations of the following:
  - Alarms (including instructions for use)
  - Doors
  - Flashlights
  - Spare batteries
  - Light switches
  - Keys
  - Locks
  - Circuit breakers
  - Packing materials
- ❑ Calibrated temperature monitoring devices
- ❑ Portable refrigerators and freezers
- ❑ Qualified containers
- ❑ Appropriate packing materials to safely transport or temporarily store vaccines
- ❑ Written protocol for vaccine packing refrigerated vaccines
- ❑ Written protocol for vaccine packing frozen vaccines
- ❑ Written protocol for vaccine transport
- ❑ Written protocol for appropriately storing vaccines at alternate storage facility
- ❑ Up-to-date list of manufacturers' telephone numbers

Emergency Vaccine Retrieval and Storage Plan Worksheet

Vaccine Coordinators			
Vaccine Coordinators	Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Primary			
Alternate (Back-up)			

Emergency Staff Contact List*			
Name	Title	Telephone Numbers (home, cell, pager)	E-mail Address
1.			
2.			
3.			
4.			
5.			
6.			

*** List contacts in order of preference. Determine whether all or certain persons on the list should be contacted or if the first person reached is sufficient. Include the primary and alternate (back-up) vaccine coordinators on the list.**

Vaccine Storage Unit Specifications			
Type of Unit (Refrigerator or Freezer)	Brand	Model Number	Serial Number
1.			
2.			
3.			
4.			
5.			

Emergency Vaccine Retrieval and Storage Plan Worksheet

Emergency Resources Contact List			
Emergency Resources	Company Name Contact Person Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Additional Staff (to move and pack vaccine)			
State Health Department Immunization Program			
Local Health Department Immunization Program			
Electric Power Company			
Emergency Generator Repair Company (if applicable)			
Emergency Generator Fuel Source (if applicable)			
Refrigerator Unit Repair Company			
Freezer Unit Repair Company			
Temperature Alarm Monitoring Company (if applicable)			
Security or Perimeter Alarm Company (if applicable)			
Weather Service			

Emergency Vaccine Retrieval and Storage Plan Worksheet

Alternate Vaccine Storage Facility(ies)			
Emergency Resources Company Name/Address	Contact Person Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
1.			
2.			
3.			
4.			

Transportation to Alternate Vaccine Storage Facility(ies)*			
Emergency Resources Name/Address	Contact Person Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Refrigeration Company			
Refrigeration Company (alternate)			
Private Vehicle			
Private Vehicle (alternate)			

Emergency Vaccine Retrieval and Storage Plan Worksheet

Emergency Resources Company Name	Contact Person Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Packing Materials			
Portable refrigerator/ freezer units			
Portable refrigerator/ freezer units (alternate)			
Qualified containers			
Qualified containers (alternate)			
Fillers (e.g., bubble wrap, Styrofoam pellets)			
Fillers (alternate)			
Coolant packs			
Coolant packs (alternate)			
Calibrated temperature monitoring devices			
Calibrated temperature monitoring devices (alternate)			

Emergency Management Internet Resources

Three National Oceanic and Atmospheric Administration (NOAA) websites provide up-to-date information on U.S. weather:

http://www.nws.noaa.gov/
http://www.nhc.noaa.gov/
http://www.goes.noaa.gov/

The Federal Emergency Management Agency (FEMA) offers a wide range of information on disaster preparedness:

http://www.fema.gov/index.shtm

The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions:

http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm147243.htm

Manufacturer/Distributor Contact Information

Manufacturer / Distributor Websites	Telephone Number/E-mail	Products
Acambis http://www.pharmamedtechbi.com/companies/199300028	800-332-2181	Smallpox
Berna http://crucell.us.com/	800-533-5899	Typhoid
Centers for Disease Control and Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.html http://www.cdc.gov/laboratory/drugservice/index.html	404-639-3670 drugservice@cdc.gov	Distributor for diphtheria antitoxin, smallpox vaccine
CSL Limited (Merck Distributor) https://www.merckvaccines.com/	800-637-2590	IIV
Emergent BioSolutions http://www.biothrax.com/	877-246-8472 productsafety@ebsi.com	AVA
GlaxoSmithKline (GSK) http://www.gskvaccines.com/	https://www.contactus.gsk.com/callback.html or 1-888-825-5249	DTaP, DTaP-HepB-IPV, DTaP-IPV, HepA, HepB, HepA-HepB, Hib, Hib-MenCY, HPV2, IIV, RV1, Tdap
Massachusetts Biological Labs http://www.umassmed.edu/massbiologics/	800-457-4626	Td
MedImmune http://www.medimmune.com/	877-633-4411 medicalinformation@medimmune.com	LAIV
Merck & Co., Inc https://www.merckvaccines.com/	800-637-2590	HepA, HepB, Hib, Hib-HepB, HPV4, HZV, MMR, MMRV, PPSV23, RV5, VAR

Manufacturer / Distributor Websites	Telephone Number/E-mail	Products
Novartis http://www.novartisvaccines.com/us/index.shtml	877-683-4732 Vaccineinfo.us@novartis.com	IIV, JE, MCV4, Rabies
Pfizer/Wyeth http://pfizerpro.com/	800-438-1985	PCV13
Protein Sciences http://www.flublok.com/professionals.html	http://www.flublok.com/contact.html	IIV3
Sanofi Pasteur https://www.vaccineshoppe.com/	800-822-2463	DT, DTaP, DTaP-IPV/Hib, Hib, IIV, IPV, MCV4, MPSV4, Rabies, Td, Tdap, TT, Typhoid, YF