

Vaccine Storage & Handling



Los Angeles County Immunization Program

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Objectives

- Describe current vaccine storage and handling recommendations
- Discuss the importance of maintaining the “cold chain”
- Describe preventative measures to maintain refrigerator and freezer temperatures
- List steps to protect vaccine in the event of a power outage or emergency



Importance of Vaccine Protection



- Vaccines are fragile and must be kept at recommended temperatures at all times to maintain potency
- Mishandled vaccines increase the risk that recipients will not be protected against vaccine-preventable diseases
- Vaccines are expensive

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Vaccine storage and handling is very **IMPORTANT**. Vaccines are fragile and must be kept at the temperatures recommended by the vaccine manufacturers at all times. Failure to adhere to recommended specifications for vaccine storage and handling can reduce their potency, thus resulting in an inadequate immune response and inadequate protection against vaccine preventable diseases. The Advisory Committee on Immunization Practices (ACIP) recommendations state that mishandled vaccine doses should not be counted as valid doses and should be repeated. Recalling patients to repeat vaccine doses because the vaccine has been stored improperly can damage public confidence in vaccines and reduce your patients confidence in your practice. It is better to **NOT VACCINATE** than to administer a dose of vaccine that has been mishandled.

Vaccine quality is the responsibility of **all** who handle vaccines from the time the vaccine is manufactured to the time it is administered to the patient.

Storage and handling errors are extremely expensive mistakes!.

Effect of Temperature on Vaccines

- Live vaccines
 - tolerate freezing
 - deteriorate rapidly after removal from freezer
- Inactivated vaccines
 - damaged by exposure to freezing temperatures
 - tolerate short time out of refrigeration

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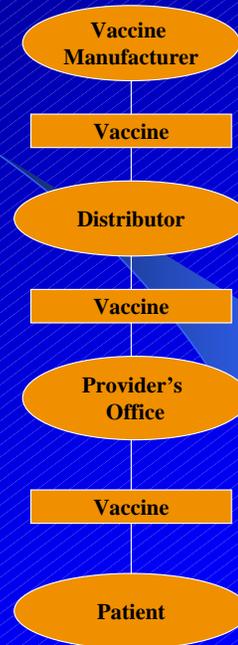


Live vaccines are extremely fragile and require freezing temperatures to maintain their potency. Vaccines such as MMRV and Varicella quickly deteriorate after being removed from the freezer, thus requiring immediate administration.

Inactivated vaccines are the exact opposite. They do not tolerate freezing temperatures and must be kept in the refrigerator at all times. Refrigerated vaccines must be maintained at 35-46°F (2-8°C) at all times.

The “Cold Chain”

- Maintenance of the “cold chain” is extremely important



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Vaccines must be stored properly from the time they are manufactured until they are administered to your patients. Excess heat or cold will reduce the potency of the vaccine, thus increasing the risk that patients will not be protected against vaccine-preventable diseases.

The system used to keep and distribute vaccine in good condition is called the “cold chain.” The cold chain has three main components; transport and storage equipment, trained personnel, and efficient vaccine management procedures. All three elements must be combined to ensure safe vaccine transport and storage.

The cold chain begins with the manufacturer and continues with the transfer of vaccine to the distributor, transfer from the distributor to the provider’s office, and ends with administration of the vaccine to the patient.

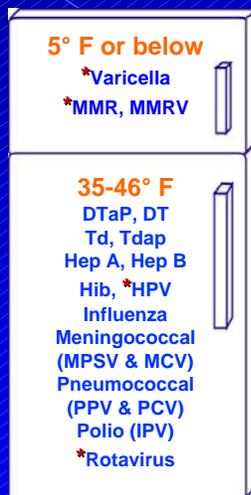
All vaccines must be inspected upon receipt and maintained during storage to ensure that the cold chain has been maintained. Proper storage temperatures must be maintained at every link in the chain.

Handle with Care

Maintain freezer temps
 $\leq +5^{\circ}\text{F}$ or $\leq -15^{\circ}\text{C}$

Maintain refrigerator
temps between
 35°F - 46°F or 2°C - 8°C

***Protect from light**



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Vaccines must be handled and stored according to the manufacturers recommendations. As previously stated, vaccines improperly stored will not protect the patient if it is inadvertently administered. Maintain proper temperatures in the refrigerator, 35 degrees Fahrenheit (F) to 46 degrees F; and the freezer temperature at 5 degrees F or colder. Aim to keep the refrigerator temperature at 40 degrees F and the freezer temperature at 0 degrees F. Adjust the thermostat as needed to reach these temperatures.

The refrigerator and freezer temperatures need to be checked twice a day, first thing in the morning and in the evening, prior to closing the clinic. Record the temperature on a temperature log sheet. If the temperature is out of the recommended temperature range take immediate action. Your facility should have a written policy on what to do when the temperature of either the refrigerator or freezer is out of range.

Store ice packs in the freezer and large jugs of water in the refrigerator along with the vaccine. This will help maintain a stable, cold temperature in case of a power failure or if the refrigerator or freezers doors are opened frequently. Also make sure that the refrigerator stays plugged-in. Post warning signs so maintenance won't unplug or turn off electricity.

If you have any questions about storing and handling vaccines please call the Immunization Program.

Vaccine Appearance

- Some vaccines may show evidence of altered potency, e.g. clumping



Improperly stored vaccine
Diminished potency



Properly stored vaccine
Full potency

- Some vaccines do not change with exposure
- Visual inspection may be unreliable

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Some vaccine may show physical evidence of altered potency when exposed to inappropriate storage conditions, such as clumping in the solution that does not go away when the vial is shaken. Other vaccines may look perfectly normal when exposed to inappropriate storage conditions. For example, inactivated vaccine exposed to freezing temperatures (i.e., 32 degrees F or colder) may not appear frozen and give no indication of loss of potency. Therefore, visual inspection of vaccine is an **unreliable** method of assuring potency.

Vaccine Storage and Handling Guidelines

- Develop and maintain detailed written Storage & Handling protocol
- Assign storage & handling responsibilities to 1 person
- Designate a back-up person
- Provide training on vaccine storage and handling

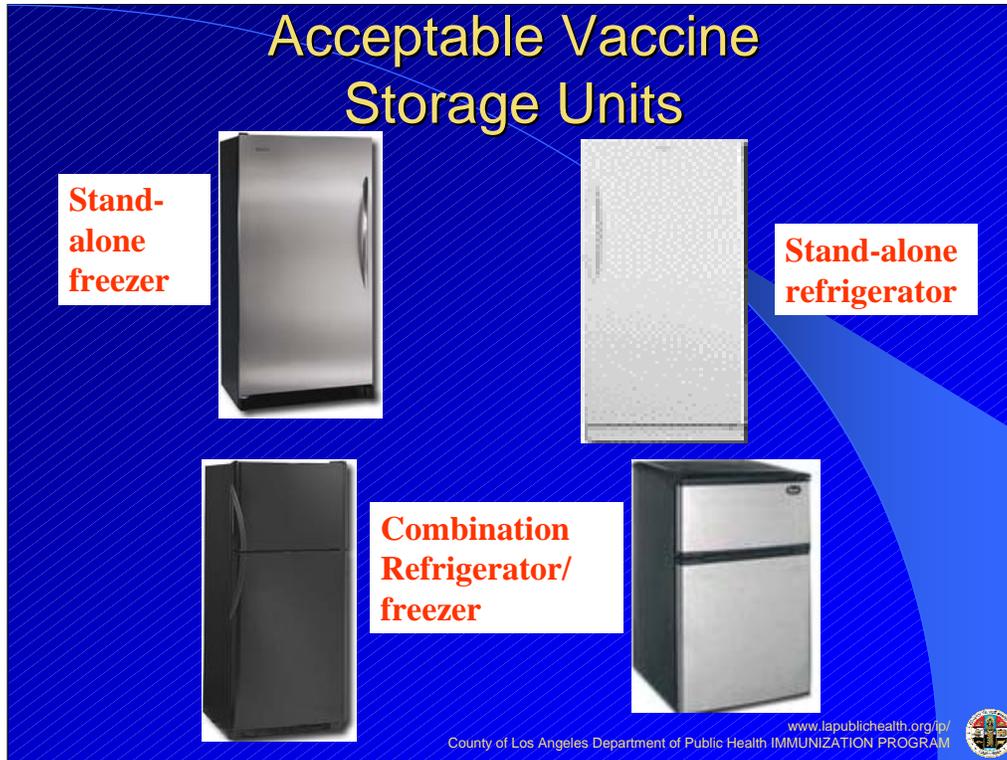
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All healthcare providers who administer vaccines should evaluate their cold chain procedures to ensure that vaccine storage and handling guidelines are being followed.

Each office should:

- develop and maintain a detailed written storage and handling protocols to address emergency situations, vaccine maintenance, ordering, and inventory control,
- assign storage and handling responsibilities to one person,
- designate a back-up person, and
- train all clinic staff on the principles of vaccine storage and handling annually



Vaccine storage and handling units must be carefully selected, used properly, and consistently monitored to ensure that recommended temperatures are maintained.

Refrigerators w/out freezers and stand-alone freezers usually perform best at maintaining precise temperatures for vaccine storage. Stand-alone units maintain consistent temperatures throughout the unit and have the maximal storage capacity.

Combination refrigerator/freezer units are acceptable if there are separate external doors for the refrigerator and freezer compartments. Combination refrigerator/freezer units sold for home use are acceptable for vaccine storage as there is a separate thermostat that controls the freezer and refrigerator. The refrigerator thermostat controls the amount of freezer air entering the refrigerator, possibly resulting in different temperature zones within the refrigerator. The coldest place is usually located at the top-shelf of the refrigerator compartment, therefore vaccines should not be stored on the top shelf near the cold air outlet from the freezer to the refrigerator.

Side by Side refrigerator/freezer units are not acceptable.

Prior to using the vaccine storage unit, providers should test the temperature in various areas of the refrigerator/freezer.

Units used to store vaccines should be less than 10 years old.

Vaccine Storage Requirements



- Maintain required temperature range year-round
- Large enough to hold year's largest inventory
- Dedicated to biologics ONLY!
- Less than 10 years old
- Have a certified calibrated thermometer inside both the refrigerator and freezer

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Any refrigerator or freezer used for vaccine storage:

- must be able to maintain the required temperature range year-round,
- must be large enough to hold the year's largest inventory, and
- must be dedicated to the storage of biologics.
- Must be less than 10 years old
- Have a certified calibrated thermometer inside both the refrigerator and freezer

Additional recommendations include:

- Wire shelving
- Locked units
- Plug locks

Food and beverages should NOT be stored in vaccine storage units.

Allow one week of twice daily documented refrigerator and freezer temperatures before using a newly purchased or repaired storage unit to store vaccines. Contact the Immunization Program Area Field Unit or VFC representative to certify your vaccine storage unit.

Unacceptable Vaccine Storage Units



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Dormitory style refrigerators are not acceptable for vaccine storage for the following reasons:

- ❑• Internal freezer compartment does not maintain temperature without causing refrigerated vaccines to freeze
- ❑• Dorm-style refrigerator/freezers are not designed or appropriate for storage of fragile and expensive vaccines
- ❑• Extremely limited space

Temperature Monitoring

Protect Your Vaccines: Check Temperatures Twice a Day! Mo./Yr.: _____ Days 1–15

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. **Store the vaccine** under proper conditions as quickly as possible, 2. **Call the vaccine manufacturer(s)** to determine whether the potency of the vaccine(s) has been affected, 3. **Call the immunization program at your local health department** for further assistance: (_____) _____ and 4. **Document the action taken** on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Exact Time	8:00														
F Temp	am / pm														
49°															
48°															
47°															
46°															
45°															
44°															
43°															
42°															
41°															
40°															
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30°															
29°															
28°															
27°															
26°															
25°															
24°															
23°															
Room temp															
Staff Initials	MM														

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www.immunize.org/katg_dly3039.pdf • Item # F9039 (7/02)

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Proper temperature monitoring is key to proper cold chain management. Refrigerator and freezer temperatures must be checked twice a day. Once in the morning (upon arrival)(NEXT SLIDE).

Temperature Monitoring

Protect Your Vaccines: Check Temperatures Twice a Day! Mo./Yr.: _____ Days 1–15

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. Store the vaccine under proper conditions as quickly as possible, 2. Call the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected, 3. Call the immunization program at your local health department for further assistance: (____) _____ and 4. Document the action taken on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Exact Time	9:5														
F Temp	am + pm														
Refrigerator temperature															
Freezer temp															
Room temp															
Staff Initials	NNN NNN														

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.....and once in the evening or prior to closing your clinic. One person should be assigned primary responsibility for maintaining temperature logs.

- Post a temperature log, similar to this one, on the door of the refrigerator or freezer.
- It is important to keep temperature logs for at least 3 years, unless state statutes or rules require a longer period. As the refrigerator or freezer ages, you can track recurring problems or identify how long problems have existed.

Temperature Monitoring

Protect Your Vaccines: Check Temperatures Twice a Day! Mo./Yr.: _____ Days 1–15

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. Store the vaccine under proper conditions as quickly as possible, 2. Call the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected, 3. Call the immunization program at your local health department for further assistance: () and 4. Document the action taken on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Exact Time	8:5	8:5	8:5	8:5	8:1										
F Temp	am / pm														
48°															
47°															
46°															
45°															
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3°															
Room temp															
Staff Initials	NIN	NIN	NIN	NIN	NIN	NIN	NIN	NIN	NIN	NIN	NIN	NIN	NIN	NIN	NIN

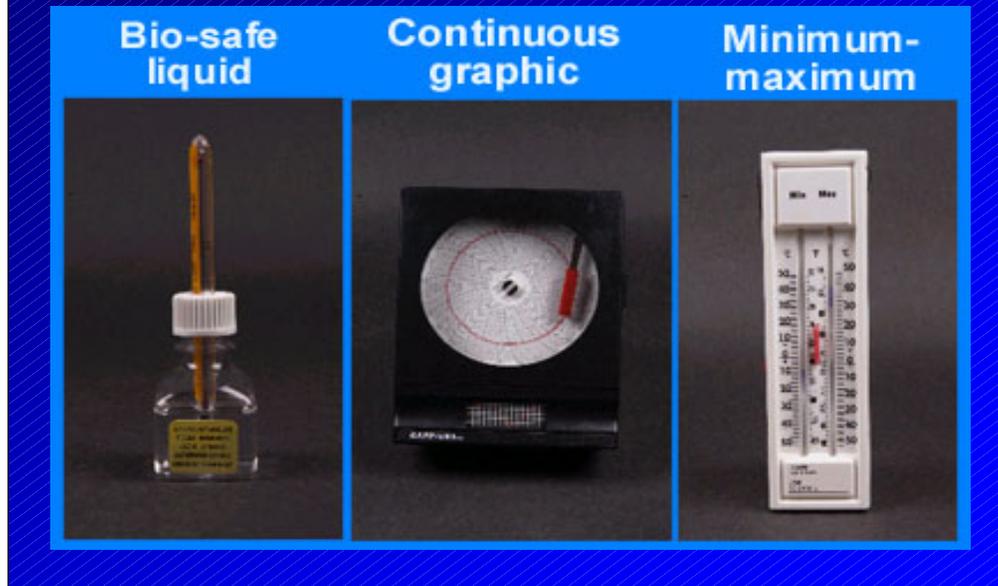
*******ALERT*****
IMMEDIATE ACTION
REQUIRED!**

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While it's important to document the temperatures, it's not enough. Equally important is taking immediate action when the temperatures fall outside the recommended ranges. Notice that the temperatures documented are in the shaded area. The shaded areas indicate the temperature is too high for the refrigerator (48 degrees F) and freezer (7 degrees F). If you notice the temperatures of your refrigerator or freezer fall within the shaded areas, contact the Immunization Program Area Field Unit or your VFC Rep immediately. If the incident occurs after hours contact your Area Field Unit/VFC the next business day.

Remember, any mishandled vaccines should NOT be administered. Separate vaccines that have been exposed to out-of-range temperatures and label with a "do not use" sign. Place in another storage unit (if available) and contact the Immunization Program for instructions. Do not use the vaccine until the viability has been verified by the Immunization Program.

Certified Calibrated Thermometers



The National Immunization Program recommends the use of certified calibrated thermometers.

All thermometers are calibrated during manufacturing. Calibrated thermometers undergo a second individual calibration against a reference standard from an appropriate agency, like the National Institute of Standards and Technology, or the American Standards of Technology and Measurement. To ensure that refrigerators and freezers are maintaining the proper temperatures for vaccine storage, each compartment should have a certified calibrated thermometer.

Fluid-filled Biosafe Thermometers

Fluid-filled biosafe liquid thermometers consist of two-parts. A glass bulb is immersed in a biosafe liquid. The liquid provides a buffer around the sensing bulb so that the reading does not fluctuate when the refrigerator or freezer door is opened or closed. These thermometers may be difficult to read and are unable to indicate temperature fluctuations outside the recommended range or a minimum/maximum temperatures.

Continuous Graphic Thermometers

Continuous graphic thermometers continuously record the refrigerator/freezer thermometers 24 hours a day. If you are using a continuous recording thermometer, even though it is recording the temperatures for you, it should still be checked twice each day to make sure the temperatures are in range.

Minimum-maximum Thermometers

Minimum-maximum thermometers are available in fluid-filled or digital forms. These thermometers show the current temperature along with the minimum/maximum temperatures in the vaccine storage unit. Temperature fluctuations outside the recommended range can be detected by referring to the

Digital Thermometers



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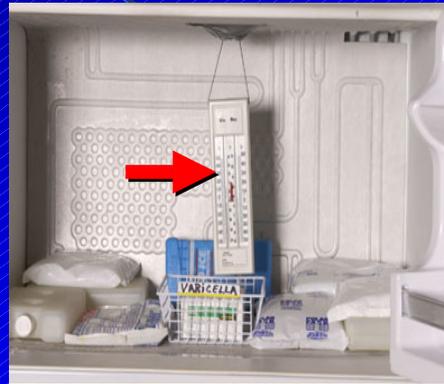
Digital thermometers are an excellent tool to monitor refrigerator/freezer temperatures. These thermometers provide both a visual (LED readout) and audio (alarm) prompt to alert for temperature variation from a pre-set range. The alarm sounds when the temperature rises above or falls below the set points. Minimum and maximum memory feature permits monitoring conditions overnight, on weekends, or for any time period, such as clinic closures during the holidays. The temperature can be displayed in Celsius or Fahrenheit (Los Angeles County Immunization Program recommends you use Fahrenheit). Remember, temperatures outside the recommended range should be corrected **immediately** and reported to the Immunization Program/VFC.

The display can be placed on the side of the refrigerator/freezer, on a counter next to the storage unit. A separate calibrated thermometer can be placed inside of the refrigerator as a back up or for use at outreach clinics.

Thermometer Placement



Refrigerator



Freezer

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Placement of temperature monitors is important. Thermometers should be placed in a central area of the refrigerator and away from coils, walls, floors, and the fan in order to obtain a true reading of the temperature.

Thermometers should be calibrated and require periodic recertification to remain accurate.

If the certified calibrated thermometer indicates an out-of-range temperature and if it is properly positioned, assume it is accurate and take immediate steps to safeguard the vaccine.

Vaccine Shipments

- Examine shipment on arrival
- Check contents against packing slip
- Check vaccine expiration dates
- Examine contents for damage
- Assure shipping time <48 hours
- Check Temperature Monitor
- Store in the appropriate compartment

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Part of the vaccine cold chain is checking the vaccine upon arrival to ensure it was transported properly. The providers should:

1. Upon receiving your vaccine shipment, examine the vaccine immediately.
2. Cross-check the contents with the packing slip to be sure they match.
3. Check the vaccine expiration dates to ensure that you have not received any vaccine that has already expired.
4. Examine the contents for any signs of damage (including physical damage to the package or vials, as well as heat or cold damage) and determine if the shipping time was less than 48 hours. If the interval between shipment from the supplier and arrival of the product at the provider's office was more than 48 hours, it could mean the vaccine was exposed to excessive heat or cold that might alter the integrity of the vaccine.
5. Check the temperature monitor included in the vaccine shipment. For Varicella vaccine, read and follow the instructions that accompany the shipment before handling. The Varicella (and MMRV) vaccine shipping container must contain residual dry ice at the time of arrival. If it does not, call the Immunization Program Field Unit immediately.
6. Store the vaccine in the appropriate compartment.

3M MonitorMark Temperature Indicator



Figure 1



Figure 2

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This is an example of one of the temperature monitors that will be placed in your vaccine shipments.

Remove the 3M MonitorMark from the shipment container upon arrival. The temperature monitor should be checked within 2 hours of shipment receipt.

For all vaccines (excluding MMR), if the index color is 0-2 (Fig. 1), store the vaccines according to the package insert and begin use.

If the index is 3-5 (Fig. 2), store the vaccines as instructed and contact the Immunization Program or VFC for further instructions. Do not use the vaccine until instructed to do so from the Immunization Program or VFC.

3M MonitorMark for MMR



Figure 1



Figure 2

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The indications for use of MMR vaccines are slightly different. If the index is 0-1, store the vaccine in the freezer and begin use (Fig. 1).

If the index is 2-5 (Fig. 2), store the vaccine in the freezer and contact the Immunization Program or VFC. Do not use the vaccine until instructed to do so by IP or VFC.

ColdMark Freeze Indicator



Figure 1



Figure 2

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The ColdMark Freeze indicator is another temperature monitor used by McKesson to ensure that the vaccines have been shipped under manufacturer-recommended guidelines.

Upon receipt of your vaccine shipment, remove the ColdMark Freeze Indicator from the shipment container. If the bulb is clear and colorless (Fig. 1), store vaccine and begin using.

If the bulb appears violet in color (Fig. 2), store the vaccine as instructed and contact the Immunization Program or VFC for further instructions prior to using.

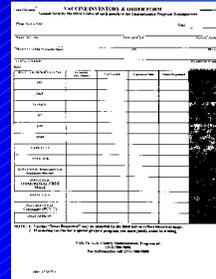


If there are any discrepancies with the packing slip, or concerns about the vaccine shipment, mark the vaccine as “DO NOT USE” and store it under proper conditions until the integrity of the vaccine is determined.

You’ll need to contact the manufacturer and the Immunization Program/State Immunization Program for further guidance.

Vaccine Inventory Log

- Name of vaccine
- Number of doses
- Date received
- Condition upon arrival
- Vaccine manufacturers
- Lot numbers
- Expiration date



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Each shipment should be recorded on an inventory log. This log should include:

- the name of vaccine,
- the number of doses vaccine received,
- the date the shipment was received,
- the condition of the vaccines upon arrival,
- the name of the vaccine manufacturers,
- the lot numbers, and
- the expiration dates for each vaccine.

Providers using an immunization registry (e.g. LINK or CARE) should enter this information into the registry, with the exception of the condition upon arrival and date received.

Vaccine Inventory Control

- Conduct a monthly vaccine inventory
- Avoid stocking excessive vaccine supplies
- Monitor expiration dates
- Rotate stock to avoid waste (Put shortest dated vaccine in front)
- Never use expired vaccine or diluent
- Limit access to authorized personnel

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Vaccine inventory control is a critical part of vaccine quality management.

- As part of inventory control, providers should make an itemized account of their vaccine supply (type of vaccine and number of doses) in their refrigerator and freezer on a monthly basis to be sure they have enough vaccine to meet their needs. However, avoid stocking excessive vaccine supplies, as this leads to vaccine wastage when old vaccines expire.
- Include diluents in the stock control procedures and ensure adequate diluent supplies are available. Vaccines may only be reconstituted with the specified diluent. Diluents are not interchangeable.
- Providers should monitor the expiration dates of their vaccine and diluent supplies and rotate stock to avoid waste. Expired vaccine and diluent should never be used.
- Providers can also help protect their vaccine supply by limiting access to authorized personnel only.

Preventive Measures

- Use a plug guard or safety-lock plug
- Post a warning sign at the plug and on the refrigerator
- Label fuses and circuit breakers
- Install a temperature alarm



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To keep the refrigerator and freezer cold in good working condition, it must have power at all times.

In order to prevent the refrigerator/freezer unit from accidentally losing power e.g. unplugged or circuit breaker turned off, here are a few suggestions:

- Have a plug guard or a safety-lock plug so that the electrical cord to the unit cannot be pulled out from the outlet.
- Post a warning sign (like this one) at the plug and on the refrigerator. You can order this type label or the “Do Not Unplug” label from the IP or it can also be downloaded from the IAC website.
- Label the fuses and circuit breakers to alert janitors and electricians not to unplug the vaccine storage unit or turn the power off from the circuit breaker.
- And finally, you may want to install a temperature alarm to alert staff to after-hours emergencies, particularly if large vaccine inventories are maintained.

Preventive Measures

- Remove vegetable bins and replace with bottles of water to stabilize refrigerator temperature
- Keep extra cold packs or blue ice in the freezer



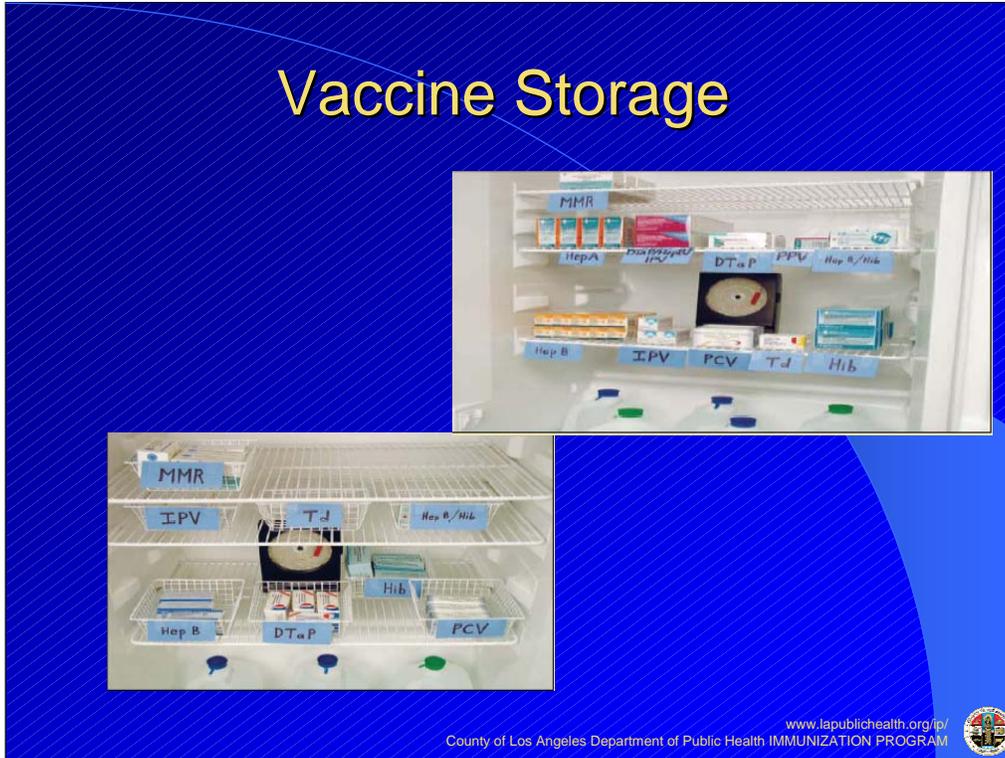
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Providers are encouraged to place water bottles in the storage bins or doors of the refrigerator to stabilize the temperature in the refrigerator. This liquid bulk helps keep the temperature stable, particularly when the refrigerator is being opened and closed.

The same principle applies to the freezer. Store extra cold packs or blue ice in the freezer. Not only will they help keep the temperature stable with frequent opening and closing of the door, they will also help keep the temperature stable in the event of a power failure.

Vaccine Storage



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Vials should not be removed from original boxes and stored in baggies or bins.

- Vials out of packaging could cause administration of the wrong vaccine, as vials look similar.
- MMR, VARIVAX, Proquad, RotaTeq, and GARDASIL prescribing information instructions state to

“Protect from Light.”

- Removing vials from the package increases the risk of inappropriate exposure to light.
- Exposure to light may inactivate the vaccine viruses and/or affect vaccine potency.
- Vaccine manufacturers have no data to ensure the viability of products removed from the original packaging and stored in baggies or bins.

Vaccine Storage Tip: Organize the refrigerator by attaching vaccine name labels directly to the

shelves on which each vaccine type is positioned (pictured above), or label trays or open-weave

baskets (which allow air flow) according to the vaccines they contain (pictured below).

Vaccine Storage

Never store vaccines in the door of the refrigerator or freezer



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- Providers should also never store vaccines in the door of the freezer or the refrigerator, as the temperatures in the doors are not stable.
- Do not let the vaccine touch the sides of the refrigerator. Store vaccines in the middle of the refrigerator and never on the top shelf as the top shelf is the coldest part of the refrigerator.
- Avoid letting the refrigerator or freezer doors stand open unnecessarily. Not only does this affect the temperature of the unit, it also exposes the vaccines to light (which can affect the potency of MMR, HPV, Rotavirus and varicella vaccines).

Vaccine Storage After Opening or Reconstitution

- Multi-dose vials
 - Contain a bacteriostatic agent
 - Can be used until the expiration date unless contaminated
 - Must be dated and initialed after opening

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Multi-dose vials of vaccine contain a bacteriostatic agent and can be used until the date of expiration, unless they become visibly contaminated. All multi-dose vials must be labeled with the date the vial was opened and the initials of the person who opened it. In the event the refrigerator temperatures/freezer temperatures are out-of-range, this information will be important in determining the viability of the remaining doses in the vial.

Vaccine Storage After Opening or Reconstitution

- Single dose vials
 - do **NOT** contain a bacteriostatic agent
 - once opened use or discard at the end of the clinic day
- Reconstituted vials
 - Consult package insert for life of vaccine once reconstituted

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Single-dose vials do NOT contain a bacteriostatic agent. Once opened, they must either be used or discarded at the end of the clinic day.

With regards to reconstituted vaccine, once vaccines are reconstituted with a diluent, their shelf life is limited and they should be kept cold. The life of each reconstituted vaccine varies from product to product. MMR must be used within 8 hours after reconstitution whereas Varicella vaccine must be used within 30 minutes after reconstitution. Check the package insert for specific time limits.

“Pre-filling” Syringes

- May result in vaccine administration errors, vaccine wastage, and possible bacterial growth
- Use manufacturer-supplied prefilled syringes (e.g., flu outreach and back-to-school clinics)
- Discard syringes at end of the clinic day

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•The Immunization Program strongly discourages filling syringes in advance because this increases the risk for administration errors. Once in the syringe, it is difficult to tell which vaccine is which. Pre-filling syringes also leads to vaccine wastage. Unused syringes you have pre-filled must be discarded at the end of the clinic day. Finally, pre-filling syringes may result in bacterial growth in the vaccines that don't contain preservatives (such as vaccines supplied in single-dose vials)

•As an alternative to pre-filling syringes yourself, consider using manufacturer-supplied pre-filled syringes for large immunization clinics (e.g. flu clinics).

•Syringes (other than those filled by manufacturer) are designed for immediate administration and NOT for vaccine storage. However, if you have a reason to draw up more than one dose of vaccine, you should only pre-fill a few syringes at a time which you will administer, while someone else is pre-filling a few syringes he or she will administer.

To reiterate: any syringes of vaccine, NOT pre-filled by the manufacturer, should be discarded at the **END OF CLINIC DAY**.

The screenshot shows the CDC National Immunization Program (NIP) website. The main heading is "Emergency Preparedness" with the URL www.cdc.gov/nip/news/vacc_weather_emerg.htm. The page features a navigation menu with options like "Public NIP Home", "Health Care Professionals", "Partners", "Media", and "Informacion en Espanol". The main content area is titled "Emergency Procedures for Protecting Vaccine Inventories" and includes a sidebar with a "NIP Site Search" box. The text discusses the importance of vaccine inventories and provides specific instructions for emergency preparedness.

Emergency Procedures for Protecting Vaccine Inventories

The [Vaccines For Children \(VFC\) program](#) maintains vaccine inventories in the field valued at over \$150 million dollars. To protect this national vaccine inventory and minimize the potential monetary loss from natural disasters or other emergencies, immunization facilities should develop Standard Operating Procedures (SOPS) to safeguard their vaccine inventories.

Emergency procedures should address the protection and/or retrieval of vaccines at both the depot and provider level. Projects should have the ability to routinely communicate during normal operations and quickly communicate action plans during emergencies or anticipated emergencies with all providers receiving public purchased vaccines.

When states, local officials, or providers have reasonable cause to believe that emerging conditions will disrupt vaccine operations, **emergency procedures should be implemented IN ADVANCE OF THE EVENT.**

In advance of the emergency, all providers should:

- Identify an alternative storage facility (hospital, packing plant, state depot, etc.) with back-up power (generator) where the vaccine can be properly stored and monitored for the interim,
- Insure the availability of staff to pack and move the vaccine,
- Maintain the appropriate packing materials (insulated containers, ice packs, dry ice for Varicella/MMR vaccine, etc.) and,
- Insure a means of transport for the vaccine to the secure storage facility.

It is critical that every clinic have a written emergency vaccine retrieval and storage plan. The most important part of this plan is to identify a location with a backup generator where providers can move their vaccine in the event of an emergency, such as an equipment failure, power outage, or natural disaster. Consider contacting the local hospital, Red Cross, or long-term care facility as a backup site. Information to assist in developing a written plan is available on the NIP website shown on the screen. If you do have any emergency e.g. power failure, please contact your Area Field Unit to inform them of the emergency.

Vaccine Storage & Handling Resources

- CDC National Immunization Program (NIP)

www.cdc.gov/nip/menus/vaccines.htm

- Immunization Action Coalition (IAC)

www.immunize.org

- B-71 www.lapublichealth.org/ip

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There are also other useful storage and handling resources available on the NIP website. Additionally, the Immunization Action Coalition website has an online catalog that contains a number of useful documents you can download (e.g. temperature logs in Fahrenheit and Celsius)

**Vaccine Storage & Handling Self Assessment
2007**

Instructions: Complete the checklist below with all immunization staff to ensure your office is in compliance with Vaccines for Children (VFC) Vaccine Storage and Handling principles. New providers should use this checklist as a guide in preparing for the storage of VFC Vaccines. For questions or assistance, please contact your Area Field Unit.

<input checked="" type="checkbox"/> VACCINE MANAGEMENT PRACTICES
<input type="checkbox"/> 1. Have written Policies and Procedures for vaccine storage and handling, including a plan for cold-chain problems (too hot, too cold, power failure) that are routinely reviewed with staff.
<input type="checkbox"/> 2. A trained person is in charge of the vaccines and a trained back-up person is designated.
<input type="checkbox"/> 3. Have an appropriate refrigerator and freezer, defined as: ___ Meets LACIP Vaccine Storage Equipment Chart recommendations ___ Has the capacity to meet the maximum vaccine storage needs (including Influenza seasons). ___ Is designated for the storage of vaccines (no food or drink).
<input type="checkbox"/> 4. Have a Certified, Calibrated Thermometer placed centrally in each unit. ___ The battery is changed every 6 months. ___ A back-up thermometer is also located centrally in each unit and referenced, as needed.
<input type="checkbox"/> 5. Temperatures are logged at the start and end of each business day on VFC Temperature Log (IMM-652). ___ The refrigerator temperature is maintained between 35-46° F (2-6°C), (Aim for 40° F) ___ The freezer temperature is maintained below 5° F (-15°C), (Aim for 0°F) ___ Action is taken if the temperature goes out of range. ___ The temperature logs are kept on site for 3 years.
<input type="checkbox"/> 6. Keep vaccine supply to a minimum by ordering only the quantity needed and on a regular basis, as allowed by VFC ordering frequency.
<input type="checkbox"/> 7. The refrigerator and freezer set up and the placement of vaccines is appropriate. ___ Vaccines are stored only on the shelves, in the center of the unit, and away from the walls and cold air vents. ___ Vaccines are kept in original manufacturer boxes and placed to allow air circulation around the boxes. ___ Rotate stock so the vaccine with the earliest expiration date is placed in the front to be used first. ___ Water bottles are placed in the bottom of the refrigerator or door away from the air vents. ___ Frozen packs are in the freezer or door away from air vents.
<input type="checkbox"/> 8. A "Do Not Unplug" sign is next to the refrigerator electrical outlet and circuit breaker box.
<input type="checkbox"/> 9. Maintain accurate vaccine inventory. ___ VFC vaccines are distinguished from privately purchased vaccines. ___ Notify the VFC Program at least 3 to 6 months before the vaccine expiration date if it cannot be used in time.
<input type="checkbox"/> 10. The VFC website is accessed for important VFC communications, current forms, and immunization resources, www.vfcca.org .

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The Vaccine Storage and Handling Self-Assessment tool can be used to assist providers in determining if they are in compliance with Vaccine for Children (VFC) Vaccine Storage and Handling principles. This tool can assist new providers in preparing their clinic site for the storage and handling of vaccines. For a copy of the tool, Contact the Los Angeles County Immunization Program.

Don't Be Guilty of These Errors in Vaccine Storage and Handling

The following are frequently reported errors in vaccine storage and handling. Some of these errors are much more serious than others, but none of them should occur. Be sure your clinic or practice is not making errors such as these.

Error #1: Designating only one person in the office to be responsible for storage and handling of vaccines, instead of a rotation of staff.

It is important to train at least one back-up person to learn proper storage and handling of vaccines. This back-up person should be familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, how to properly record refrigerator and freezer temperatures, and what to do in case of an equipment problem or power outage.

Error #2: Recording temperatures only once per day.

Temperatures in the units throughout the day. If any persons in the refrigerator and freezer should be checked in the beginning and end of the day to determine if the unit is getting too cold or too warm. Ideally, you should have a continuous thermometer that measures and records temperatures all day and at night. Also, expensive alternative temperature monitoring systems are available. It's also a good idea to record the room temperature in your temperature log in case there is a problem with the refrigerator or freezer temperature. This information is helpful to the vaccine company's telephone consultant in ascertaining whether your vaccine can still be used.

Error #3: Recording temperatures for only the refrigerator or freezer.

If your facility stores multiple vaccines, you should have thermometers in both the refrigerator and the freezer. Rather than buying cheap thermometers that may not accurately measure the temperatures, buy quality thermometers that will last for years.

Error #4: Documenting out-of-range temperatures on vaccine temperature logs and not taking action.

Documenting temperatures is not enough—acting on the information is even more important. So, what should you do? Notify your supervisor whenever you have an out-of-range temperature. Subsequent actions vary widely by vaccine type, location and their duration. If they are still viable, check the condition of the unit for problems. Are the units tight? Have someone fix or call on the cold? After you have made the equipment, document the date, time, temperature, what the problem was, the action you took, and the results of the action. Backup the temperature logs too. Call maintenance or a repair person if the temperature is still out of range.

Error #5: The going away temperature logs at the end of every month.

It is important that you keep your temperature logs for at least three years. As the refrigerator ages, you can track recurring problems. If

temperatures have been documented out of range, you can determine how long this has been happening in order to take appropriate action. It's also good to have a log for a new refrigerator.

Error #6: Storing vaccines in the wrong part of the refrigerator (e.g., vegetable bin, plastic container, the door, bottom, or near the cold or outer doors on the freezer).

The temperatures in these areas are often significantly warmer than the temperatures in the body of the refrigerator. Always place a vaccine in the middle in open, labeled containers, so that air can circulate around the vaccine.

Error #7: Storing varicella vaccines in a door-in-style refrigerator.

Vaccines must be stored in a freezer that has its own internal door separate from the refrigerator. Remember how handy it is to get the temperature to 45°F in a door-in-style refrigerator's freezer, you want to make sure that the temperatures in the freezer, and not just probably freeze the rest of your vaccines in the refrigerator!

Error #8: Inadvertently leaving the refrigerator or freezer door open or leaving inadequate seals.

Make sure to close the unit doors tightly each time they open them. Also, check the seals on the doors on a regular schedule, and if there is any indication the door seal may not be sealing properly, have it replaced. The cost of replacing a seal is much less than replacing a box of potent doses of vaccine or vaccine doses.

Error #9: Discarding multi-dose vials 18 days after they are opened.

Check the date of your vaccine's expiration. All out of multi-dose vials of vaccine have preservatives in them and can be used until the expiration date on the label has three, six, twelve, or 24 months. However, you must discard multi-dose vials of non-preserved vaccine (e.g., meningococcal, yellow fever) if they are not used within a defined period after reconstitution. Refer to the vaccine package inserts for additional information.

Error #10: Not having emergency plans for a power outage or natural disaster.

There are several steps to take in a disaster. Develop a plan that identifies a refrigerator with a backup generator in which to store vaccine in the event of a power outage or natural disaster. Consider contacting a local hospital or other facility to be your back-up location if you should need it.



www.immunize.org/publicat • Item #P286 (2/08)

Immunization Action Coalition • 1573 Sully Avenue • St. Paul, MN 55104 • (651) 647-9029 • www.immunize.org

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Another excellent resource in the IAC online catalog is a one page list entitled “Don’t Be Guilty of These Errors in Vaccine Storage and Handling.” It reviews the top ten reported vaccine storage and handling errors.

This error list and the checklist can be posted on your refrigerator so that everyone who uses vaccines in your clinic will be aware of proper storage and handling guidelines, as well as problems and errors to avoid.

Storage and Handling Take-Home Messages

- Colder is NOT better for inactivated vaccines
- Maintenance of the cold chain is vital to proper vaccine storage and handling.
- Out of range temperature readings require IMMEDIATE action
- It is estimated that >\$100 million worth of vaccine is exposed to freezing temperatures each year in the United States

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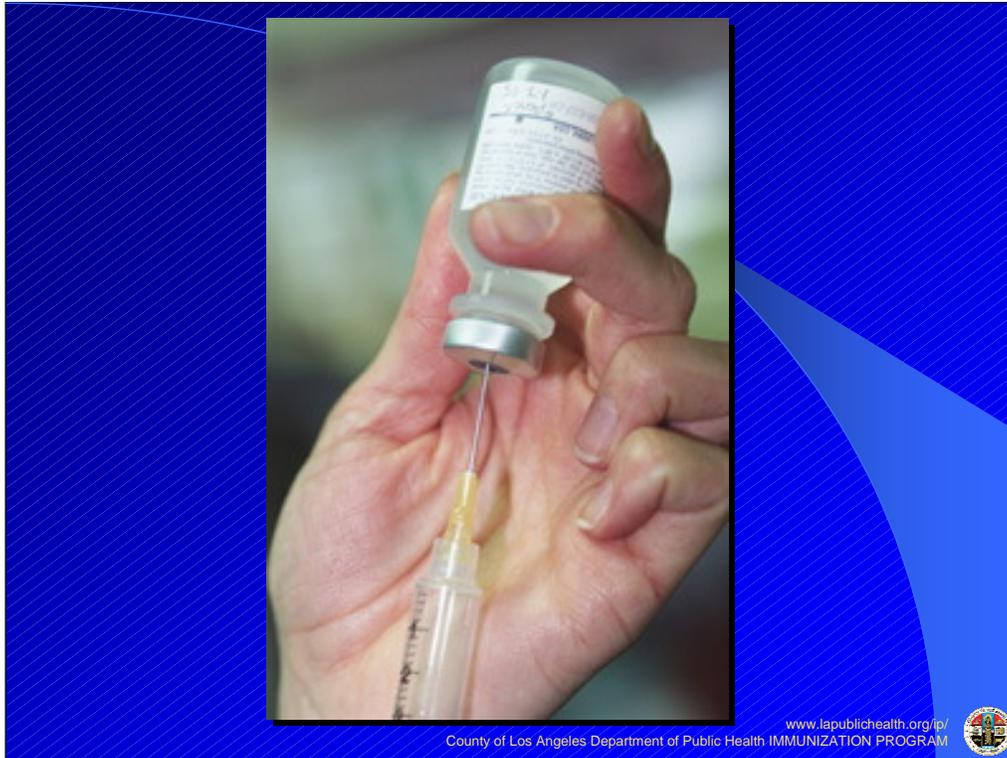


An estimated 17% to 37% of providers expose vaccines to improper storage temperatures. Refrigerator temperatures are more commonly kept too cold than too warm.

Maintenance of the cold chain is the core principle in proper vaccine storage and handling.

Out-of-range temperature readings require IMMEDIATE action.

It is estimated that more than \$100 million worth of vaccine is exposed to freezing temperatures each year in the United States.



In order for patients to be protected by vaccines, vaccines must be stored and handled with care. With a few simple steps and good practices to maintain proper vaccine storage and handling, we can ensure that the full benefit of immunization is realized.



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