SECTION 4 - VACCINE STORAGE AND HANDLING

Keeping vaccines at the recommended temperature is called **maintaining the cold chain**. The cold chain begins at the manufacturer, extends to the distributor and continues in the provider site until the vaccine is administered. Proper vaccine temperature must be maintained during transit and at every link in the chain to ensure its viability.

Vaccine cold chain failure occurs when there is a break in any link of the chain. Cold chain failure may occur due to a power failure, staff error, equipment failure, etc. Preventing vaccine cold chain failure requires: properly functioning equipment, appropriately trained staff, clearly written procedures and easily accessible emergency operating protocols.

Properly Functioning Equipment

- Vaccine storage units
- Certified digital thermometers

Vaccine Storage Units (Section 6-J)

Pa. VFC requirements

PADOH supplied vaccine must be stored in one of the following:

- Stand-alone storage unit;
- Household combination unit (**must** have separate stand-alone freezer); or
- Medical grade combination unit.

Providers with PADOH approved household combination units will be given 90 days to acquire a stand-alone freezer.

- During the 90 days, the provider will not be allowed to order additional frozen VFC vaccine.
- Providers making no accommodation to acquire a stand-alone freezer within 90 days will be suspended from ordering all VFC vaccines.
- Providers will remain suspended until a stand-alone freezer is acquired.
- After one year of suspension, the provider will be disenrolled from the VFC program.

- **Effective 2017**, if a DOH approved household combination unit is not accompanied by a stand-alone freezer, providers will be immediately suspended from ordering all VFC vaccines.
    - Providers will remain suspended until a stand-alone freezer is acquired. After one year of suspension, the provider will be disenrolled from the VFC program.

CDC recommendations

CDC highly recommends medical grade units. All storage units must be approved by the VFC immunization nurse through a site visit for enrolled VFC providers. For new providers, it is strongly recommended to use medical grade stand-alone freezers and stand-alone refrigerators for vaccine storage.

CDC requirements

Absolutely **NO DORMITORY** or bar style units will be accepted. Using such units will result in an immediate suspension of vaccine ordering privileges.

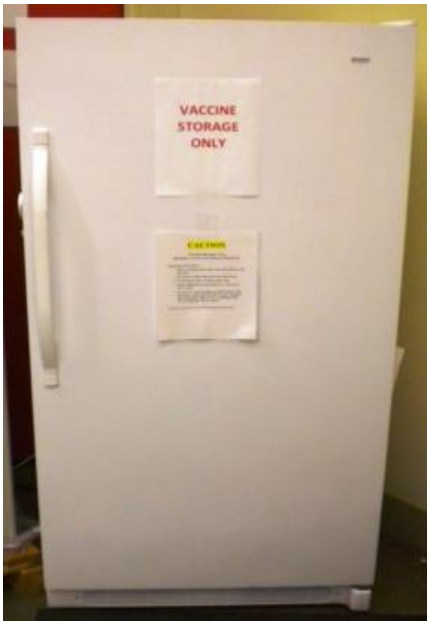
- **Effective 2016**, all vaccines stored in a dormitory style unit are considered non-viable and must be returned to McKesson Specialty Distribution. Complete and submit a Vaccine Return Form found in Section 6-F.

The use of dormitory or bar-style refrigerator/freezers is prohibited at any time.

STANDALONE STORAGE UNITS

Commercial/Household Type

Freezerless



Refrigerator only

Medical grade

Under-the-counter

Full-sized

Vaccine storage units must be:

- Able to maintain required vaccine storage temperatures year-round (Conversion Chart, Section 6-H).

  Refrigerator: 36° F to 46° F /2° C to 8° C
  Freezer: -58° F to 5° F/-50° C to -15° C)

  - Large enough to hold the year's largest inventory;
  - Defrosted on a monthly basis if freezer unit is not self-defrosting;
  - Cleaned every month to discourage bacterial and fungal growth; and
  - Placed in a well-ventilated room with sufficient space (at least four inches) around the sides and top for air circulation.

Certified Digital Thermometers (Section 6-J)

Pa. VFC requirements

- A digital data logger/continuous temperature monitoring device or a digital min/max thermometer must have an active digital display, a detachable probe encased in a biosafe buffered material, and a valid/current National Institute of Standards and Technology (NIST) certificate of traceability and calibration. **NOTE**: There is a list of thermometer manufacturers in Section 6-J.
  - VFC highly recommends a biosafe glycol-encased probe, but will accept the following buffered materials if NIST certified:
    - A vial filled with liquid (i.e., glycol, ethanol, or glycerin);
    - A vial filled with loose media (i.e., sand, or glass beads); and
    - A solid block of material (i.e., Teflon®, or aluminum).

- The best calibration is annual; however, the PADOH will accept a manufacturer's suggestion not to exceed two years.
- Thermometer probes must be placed/secured in the center of each storage unit.
- VFC providers are **required** to have at least one back-up thermometer, at the provider site, with a valid and current certificate of calibration <u>readily available</u> to ensure twice a day temperature assessment and recordings.

- **Effective 2018**, CDC will require all VFC providers to purchase a digital data logger with an active temperature display, continuous monitoring and recording capabilities, and a detachable biosafe glycol-encased/buffered material probe in all VFC storage units. Please refer to the digital data logger policy in Section 6-J.

- Providers are responsible for the maintenance and NIST recalibration of all temperature monitoring devices/thermometers. Newly purchased units and recalibrations are at the expense of the provider site.

CDC recommendations

Based on studies of temperature monitoring devices conducted by NIST in 2009, CDC recommends continuous digital data loggers with detachable probes for continuous temperature monitoring with the following characteristics:

- Digital display on outside of storage unit to allow reading temperatures without opening unit door;
- Detachable probe in a bottle filled with a glycol/buffered material, which more closely reflects vaccine temperatures, which have been found to be more thermostable than air temperature (which fluctuates with defrost cycles and opening and closing the storage unit door);
- Alarm to alert out-of-range temperatures;
- Accuracy within +/-1°F (+/-.5°C);
- Low battery indicator;
- Continuous monitoring and recording capabilities to track and record temperatures over time; and
- Display of current, as well as minimum and maximum temperatures, which indicate the coldest and warmest temperatures recorded since device was reset. Please refer to the digital data logger policy in Section 6-J.

Setting up your new equipment

- Notify the immunization nurse in your area there is to be a change in vaccine storage unit.
- Obtain and document one to two weeks of in-range temperatures and schedule a site visit to have the unit approved by an immunization nurse before using any new storage unit purchased or transferred.
- Ensure the refrigerator doors are closed properly and the unit is level and in good working order. Notify the VFC contact person immediately if problems occur.
- Advise maintenance and cleaning personnel not to unplug storage units. Post “Do Not Unplug” stickers near the outlet.
- Have a safety-lock plug or “DO NOT UNPLUG” sign at the unit.
- Have a “DO NOT DISCONNECT” sign at the breaker box.

Safety-lock plug

Use outlet covers. Post warning signs and labels.

- Do not use power outlets with built-in circuit switches and outlets that can be activated by a wall switch.
- Do not use multi-outlet power strips.

Appropriately Trained Staff

Designate primary and back-up contact persons who are responsible for:

- Ensuring the VFC Program Provider Handbook and related immunization materials are current and accessible to all staff;
- Training all staff on the proper protocols for receiving vaccine shipments in the absence of the primary and back-up vaccine contact persons;
- Ordering, receiving and storing vaccine shipments in accordance with requirements;
- Identifying and separating VFC vaccines from privately purchased vaccines;*****

- Monitoring vaccine expiration dates and weekly rotation of vaccine inventory with the shortest expiration date in front, notifying the PADOH regarding any short-dated vaccines and removing expired vaccines from the viable vaccines storage units;
- Ensuring thermometers used inside both refrigerators and freezers are NIST certified thermometers with glycol/buffered probes;
- Ensuring appropriate monitoring and documentation of temperature logs;
- Notifying the PADOH immediately regarding any vaccine storage and handling problems to include IR and Vaccine Return and Accountability Form submission for any out of range temperatures (Section 6-F);
- Developing and maintaining a maintenance/cleaning schedule for storage and handling equipment used to store PA DOH provided vaccines; and
- Only transporting vaccine to other locations using procedures pre-approved by PADOH, maintaining the vaccine cold chain (Section 6-I).

***** Clinics/practices serving both VFC and non-VFC eligible children must clearly identify and separate VFC and 317 funded vaccines from private purchased vaccines using VFC and 317 stickers provided by PADOH.

Training your personnel

Mandatory personnel training regarding proper vaccine storage and handling guidelines and vaccine administration protocols are required for the primary and back-up VFC coordinator. New coordinators must complete this training requirement during orientation to the position. All office staff (i.e., receptionists, mail handlers, nurses, medical assistants) accepting vaccine shipments or administering vaccines must be trained on vaccine management procedures.

Documentation of training must be added to the educational roster (Section 6-A) and retained for three years. Fax/email copies of the educational roster to your immunization nurse as completed annually.

The CDC required provider annual education may be met by completing one of the below options:

- Having a VFC compliance visit with the immunization nurse; or
- Requesting an annual provider training with the immunization nurse.

Or if you choose one of the following options below, it must be completed and faxed prior to Oct.1, 2016:

- Two CDC “You Call the Shots” programs (print credentials from CDC website and fax/email copies to your immunization nurse)

- Vaccines For Children (VFC) **JAN 2016**
  Scroll to bottom of page and click "continue" to start program
- Vaccine Storage and Handling **JAN 2016**
  Scroll to bottom of page and click "continue" to start program
  - The CDC provides continuing education credits at the following link:
  - http://www2a.cdc.gov/TCEOnline/help.asp

- Completion of VFC Annual Provider Training and Survey from PA VFC program
  - http://www.health.pa.gov/My%20Health/Immunizations/Vaccines-for-Children/Pages/vfc_training.aspx#.Vug9pvLD-Un

Clearly Written Procedures (Section 6-E)

VFC providers are required to:

Develop and maintain a routine **vaccine management plan**, providing guidelines to ensure the vaccine cold chain is maintained. For this plan:

- Designate staff responsible for all functions of vaccine management.
- Assign functional responsibility for executing the plan.
- Review and document personnel and functions annually.

Develop and maintain an **emergency handling plan**. For this plan:

- Identify an alternative vaccine storage facility that has proper refrigerator and freezer units, temperature-monitoring capabilities (twice daily documentation) and backup power where vaccine can be stored in an emergency. An alternate site available 24/7 is preferred.
- Call annually to make sure the alternate site is still available and will meet Pa. VFC program requirements.
- Designate staff who will be responsible for packing and moving the vaccine to a safe location.
- Have the appropriate packing material on hand at all times, including insulated containers and cold/ice packs, bubble wrap, etc.
- Have a list of emergency phone numbers for local utility companies.
- Make written descriptions of floor plans and vaccine locations available.

Develop and maintain a current written **vaccine disaster recovery plan**, providing guidelines to ensure the vaccine cold chain is maintained. The plan should include:

- Identification of an alternative storage facility, such as a hospital, packing plant or local pharmacy, with back-up power (generator) where the vaccine can be stored and monitored during an emergency;
- Identification and training of staff responsible to pack, monitor and move vaccine during an emergency;
- Location of a supply of appropriate packing materials (insulated containers, ice packs, temperature monitoring device, temperature logs, etc.);
- Identification of available transportation and location to move vaccine (secure storage facility during an emergency); and
- Annual review with date and signature of reviewer for documention.

Vaccine Ordering/Delivery/Receiving/Storing

Ordering the vaccine (Section 3)

- A provider must meet all recommendations and requirements to order VFC vaccine and to ultimately decrease vaccine wastage. If a noncompliant provider submits an order, the order will be deleted after five days unless corrective action has been taken. The provider will need to resubmit the order when compliance has been achieved. Ordering instructions are available in Section 3.
- Always tell your front office staff or supply personnel when a vaccine delivery is expected and ask them to notify the appropriate staff when it is received.
- If you have problems or need help ordering vaccine, call the VFC toll-free line 1-888-646-6864 or email questions to paimmunizations@pa.gov . Please include your VFC pin number with any communications.

Delivery of the vaccine shipment

The vaccine orders are shipped from McKesson Distribution for all vaccines except for the frozen vaccines. Frozen vaccines are direct shipped from Merck. Upon delivery, open the box immediately and inspect the contents for any potential damage that may have occurred during shipment. **If** the shipment cannot be opened and inspected immediately upon delivery:

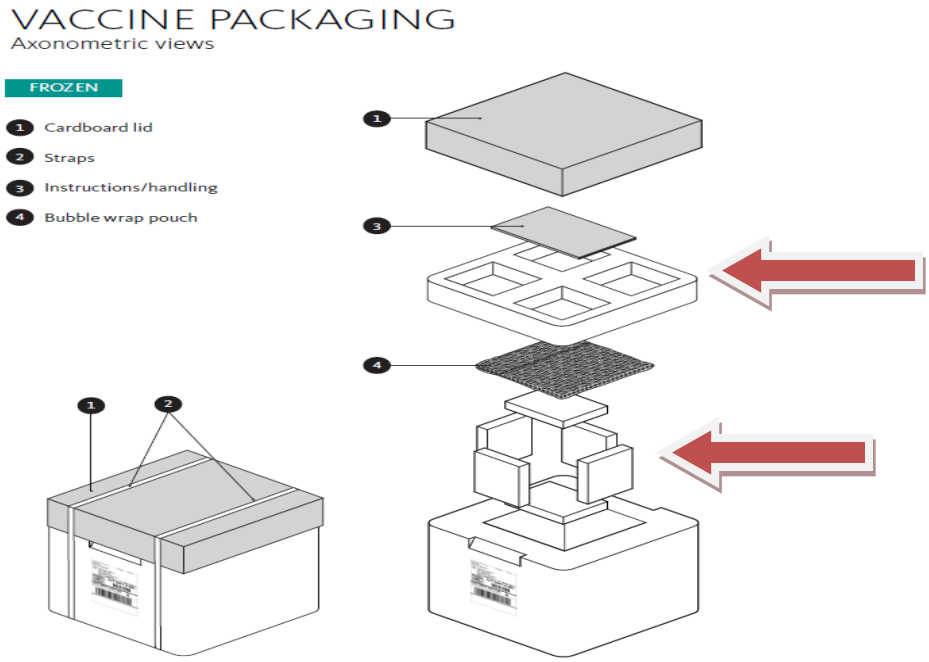
- Do not refuse delivery;
- Place the entire contents into a bag;
- Place into the proper storage unit (i.e., refrigerator or freezer); and
- Label “do not use” until inspected by designated coordinator.

McKesson shipping carton

Merck shipping carton

Providers are not required to return the empty shipping cartons to McKesson Specialty Distribution or Merck. Providers may choose to keep some for "emergency transport" or dispose of the boxes.

WHAT'S IN THE VARICELLA/PROQUAD SHIPMENTS



Merck's "Shipping Time" insert will appear inside the shipping container as 1 day, 2 days, or 4 days, indicating the number of days the vaccine shipment delivery can maintain proper temperature. The "Shipping Time" insert shown below indicates that the vaccines delivered will maintain appropriate temperatures from the shipment date that appears on an enclosed "Packing slip."

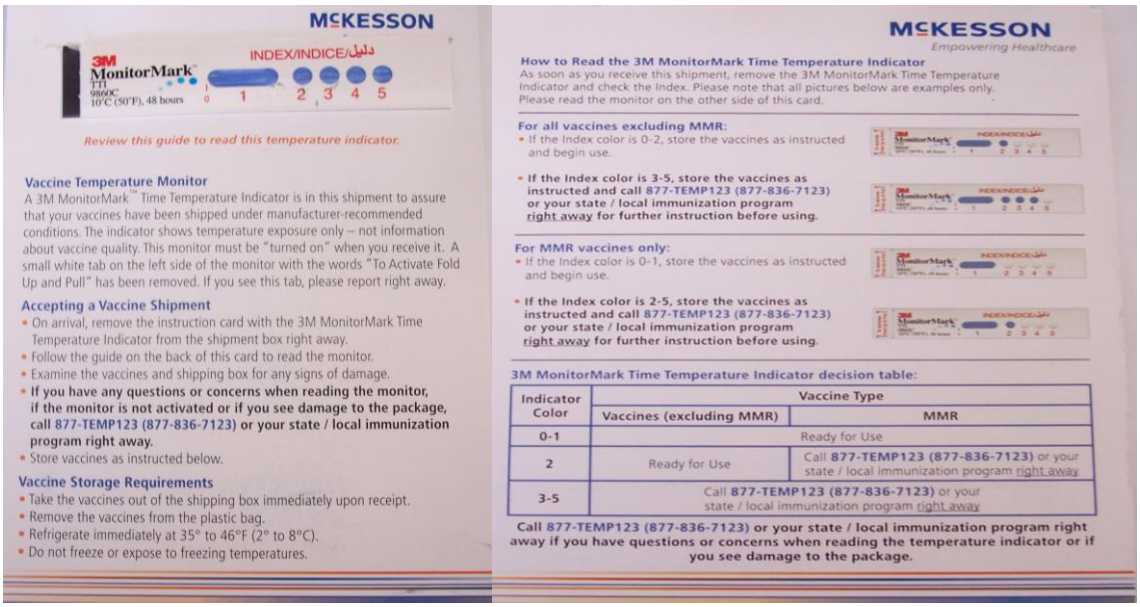
If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at **1-800-MERCK-RX** (1-800-637-2579).

1) **DILUENT** is packaged in the **lid** of the upper compartment of the shipping container.

2) **VACCINE** is in the **lower compartment** of the shipping container.

If there are any discrepancies with the packing slip or concerns about the shipment, immediately mark the vaccine and diluent as "DO NOT USE" and store them under the proper conditions.

WHAT'S IN THE MCKESSON SHIPMENTS



McKESSON

3M MonitorMark TTI 9860C 10°C (50°F), 48 hours

INDEX/INDICE/دليل

0 1 2 3 4 5

Review this guide to read this temperature indicator.

Vaccine Temperature Monitor

A 3M MonitorMark™ Time Temperature Indicator is in this shipment to assure that your vaccines have been shipped under manufacturer-recommended conditions. The indicator shows temperature exposure only – not information about vaccine quality. This monitor must be "turned on" when you receive it. A small white tab on the left side of the monitor with the words "To Activate Fold Up and Pull" has been removed. If you see this tab, please report right away.

Accepting a Vaccine Shipment

- On arrival, remove the instruction card with the 3M MonitorMark Time Temperature Indicator from the shipment box right away.
- Follow the guide on the back of this card to read the monitor.
- Examine the vaccines and shipping box for any signs of damage.
- **If you have any questions or concerns when reading the monitor, if the monitor is not activated or if you see damage to the package, call 877-TEMP123 (877-836-7123) or your state / local immunization program right away.**
- Store vaccines as instructed below.

Vaccine Storage Requirements

- Take the vaccines out of the shipping box immediately upon receipt.
- Remove the vaccines from the plastic bag.
- Refrigerate immediately at 35° to 46°F (2° to 8°C).
- Do not freeze or expose to freezing temperatures.

McKESSON
Empowering Healthcare

How to Read the 3M MonitorMark Time Temperature Indicator

As soon as you receive this shipment, remove the 3M MonitorMark Time Temperature Indicator and check the Index. Please note that all pictures below are examples only. Please read the monitor on the other side of this card.

For all vaccines excluding MMR:

- If the Index color is 0-2, store the vaccines as instructed and begin use.
- **If the Index color is 3-5, store the vaccines as instructed and call 877-TEMP123 (877-836-7123) or your state / local immunization program right away for further instruction before using.**

For MMR vaccines only:

- If the Index color is 0-1, store the vaccines as instructed and begin use.
- **If the Index color is 2-5, store the vaccines as instructed and call 877-TEMP123 (877-836-7123) or your state / local immunization program right away for further instruction before using.**

3M MonitorMark Time Temperature Indicator decision table:

Indicator Color	Vaccine Type	
	Vaccines (excluding MMR)	MMR
0-1	Ready for Use	
2	Ready for Use	Call **877-TEMP123 (877-836-7123)** or your state / local immunization program right away
3-5	Call **877-TEMP123 (877-836-7123)** or your state / local immunization program right away	

Call 877-TEMP123 (877-836-7123) or your state / local immunization program right away if you have questions or concerns when reading the temperature indicator or if you see damage to the package.

The McKesson Vaccine Temperature Monitor indicates the temperature of the vaccine and also gives vaccine storage guidance.

Receiving the vaccine

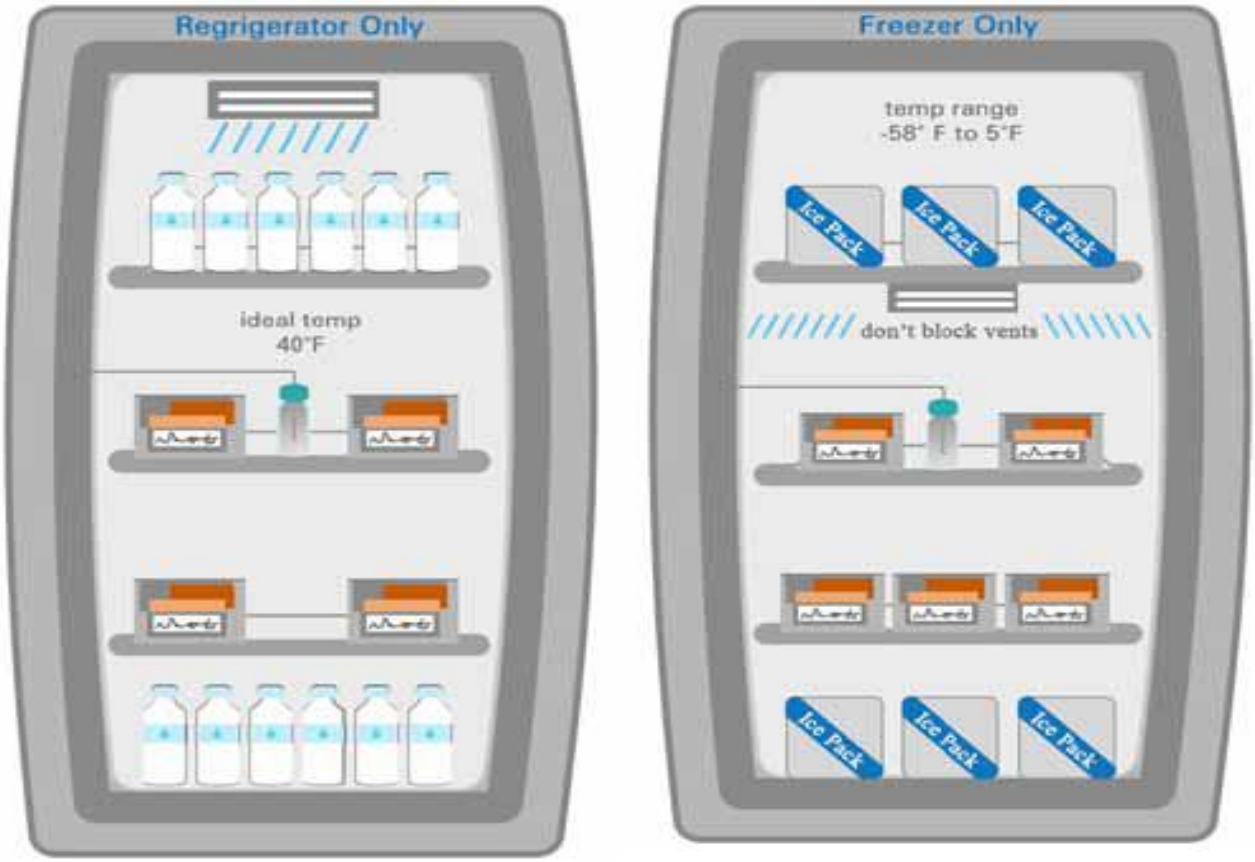
- Check the temperature indicator enclosed in the shipment to determine if the vaccines were exposed to temperatures outside of the proper range for storage and handling, and immediately notify McKesson Specialty Customer Care directly at 877-TEMP123 (877-836-7123).
- Evaluate the condition of the vaccines and ensure the vaccines are cool to the touch. If the color is odd, the package is damaged, or the vaccine seems warm, designate as "DO NOT USE" and properly store the vaccine until a determination has been made on the viability of the vaccine.
- Contact the vaccine manufacturer for further instructions if needed. Complete a Vaccine Incident Report and Worksheet form and Vaccine Return and Accountability Form, if necessary (Section 6-F). Fax forms to the PADOH at 717-214-7223.
- Compare quantities, lot numbers and expiration dates carefully; immediately advise the PADOH the same day or next business day regarding any discrepancies between the contents and the shipping invoice. Vaccine shipments must be accepted into PA-SIIS inventory. PA-SIIS participating providers should also compare the quantity, lot numbers and expiration dates with the data in the PA-SIIS.
- Re-check the shipping carton and packing materials to ensure that all vaccines have been removed from the carton.

Storing the vaccines

Proper storage and handling of vaccine is important not only for the shelf life and effectiveness of a vaccine, but for the safety of the person receiving the vaccine as well.

Vaccines must:

- Be stored away from cold air vents and coils;
- Have space between vaccines for circulation;
- Be stored with the shortest expiration date in front;
- Be organized and labeled by type (VFC, 317, private);
- Have different vaccine with similar packaging stored in separate locations in the unit to avoid errors in identification;
- Be stored with water bottles in refrigerator; and
- Be stored with water bottles/coolant packs in freezer.



Vaccines must never:

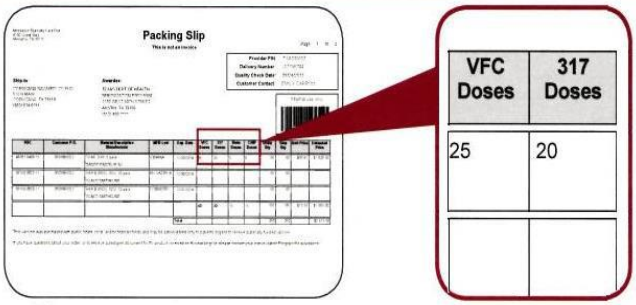
- Be stored with food and beverages because this practice results in frequent opening of the door and destabilization of the temperature;
- Be stored with medications or other biologic products, unless placed below the vaccines on a different shelf to prevent contamination of the vaccines;
- Be stored on the door or floor of the unit; or
- Be stored in crisper drawers. (Remove the crisper drawers and add water bottles.)

Separating and Storing Your Vaccine Stock

1 How to identify vaccine by public funding type

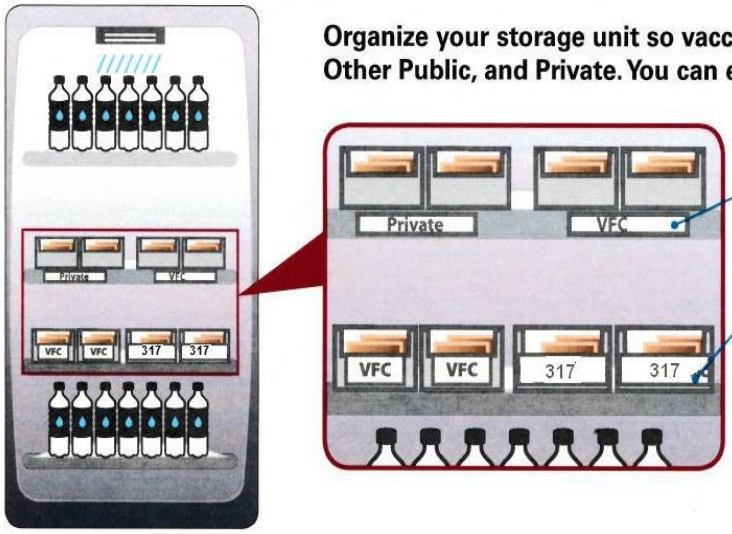
There are 2 types of public funding:

- VFC
- 317



The funding type for each public vaccine is listed on the shipment's packing slip. Your private vaccines come in a separate shipment and must be stored apart from public vaccines.

2 How to store vaccine with only one fund type in a box



Organize your storage unit so vaccines are separated by VFC, Other Public, and Private. You can either:

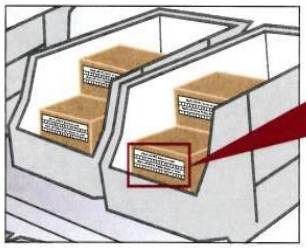
- Label the storage unit shelf.

OR

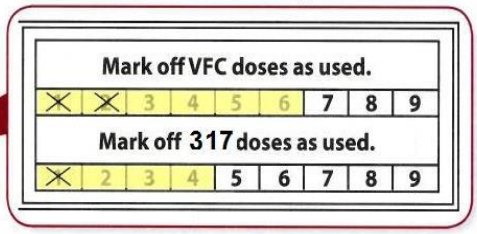
- Label the bins.

Place the vaccine in the proper bin.

3 How to store vaccine with more than one fund type in a box



Store these boxes in a separate bin. To keep track of your use:



1. Label the box of single-dose or multi-dose vials.
2. Highlight the number of doses from each funding type.
3. Mark off vaccine as you use it.

Be sure you don't cover important information such as vaccine name and lot number. Always keep vaccines in their original packaging with the lid closed to protect them from light.

Documentation requirements

Temperature log requirements

Temperatures are to be checked twice daily (current, minimum and maximum) and recorded on the PADOH supplied temperature log with your PIN preprinted on it. Temperature logs are to be retained at the provider site for three years and must be made available upon request for review by PADOH staff.

Key points to remember when completing your monthly temperature log:

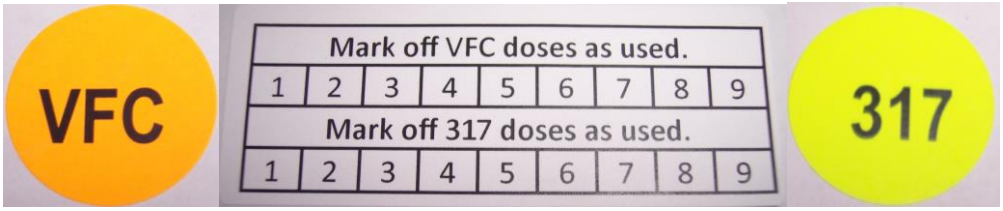
- Temperature logs must include provider name, pin number, and month and year.
- Include in daily documentation time when temperatures were checked and initials of staff checking the current, minimum and maximum temperatures.
- Manually check and document temperatures twice a day on the temperature log regardless of whether a continuous reading or alarmed units are in use.
- If vaccine temperatures have not been documented for more than 72 hours, contact the manufacturers to ascertain the vaccine viability.
- If the office is going to be closed for a period of time other than holidays or weekends, move the vaccines to the alternate delivery site where they can be monitored and temperatures documented twice daily.
- If the manufacturer states vaccine viability is uncertain and there is any question regarding the vaccine utilization, contact the PADOH.
- If vaccine temperatures are out of recommended ranges for less than 30 minutes during temperature logging, take immediate action to correct the problem and document the action taken on Step 3 of the temperature log or attach an explanation of action taken.
- For temperatures that are determined to be out of range for more than 30 minutes, mark the vaccine “do not use,” store appropriately, and notify the vaccine manufacturer immediately. Complete and submit the Vaccine Incident Report and Worksheet (Section 6-F) to PADOH within five days of incident. Fax to 717-214-7223.
- Submit a copy of the Vaccine Return and Accountability Form to request a return label for shipping unopened vials of expired/wasted vaccines. This is for Federal Excise Tax Credit.

Maintaining your inventory

- Store and rotate vaccines weekly according to expiration dates. Use vaccines with the shortest expiration dates first.
- Identify any vaccines that will **expire within 90 days.** Contact your immunization nurse for assistance.

- If vaccines are within 90 days of expiration and cannot be used, they may be transferred to a participating VFC provider. Contact your immunization nurse to properly coordinate such transfers.

- Separate vaccines by funding source: VFC, 317 and private. This can be achieved by labeling:
    - Separate bins;
    - Individual vials/syringes; and
    - Vaccine boxes.



Vaccine accountability

PADOH must account for all vaccines. This accountability is achieved through:

- Adhering to the manufacturer's recommended storage and handling;
- Administering vaccine properly (injection site, recommended schedule, etc.);
- Ensuring authorized personnel track doses administered and reconcile vaccine inventory in PA-SIIS (Section 5) in the site's Electronic Medical Records or on the PA VFC Dose Tracking Form (Section 6-D);
- Rotating inventory weekly according to expiration date;
- Reporting expired/wasted vaccines (Section 6-F); and
- Limiting thermostat adjustments to the primary and back-up vaccine contact persons.

A warning sign must be posted on the storage unit.

Vaccine borrowing

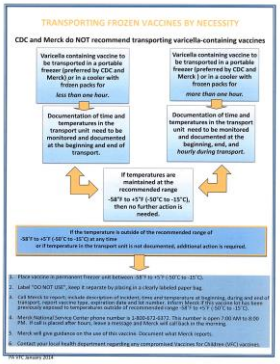
Two-directional borrowing between VFC and private-stock vaccine must be documented on the VFC Vaccine Borrowing Report (Section 6-D). The VFC Vaccine Borrowing Report must be completed and kept at the provider site for review by the immunization nurse during VFC site visits. Borrowing should **only** occur when there is a lack of appropriate stock vaccine (VFC or provider-purchased) due to unexpected circumstances, such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff who calculated ordering time incorrectly. The reason **cannot** be provider-planned borrowing from either the private stock or the VFC stock. VFC providers who are suspended from ordering vaccine may **not** borrow vaccine to compensate vaccine inventory.

Transporting vaccine

Occasionally, clinics have more vaccine than they can use before it expires. In these situations, transferring vaccine to another clinic to use is a good option. For assistance with this process, please contact the immunization nurse in your area. The transferring site is responsible for ensuring the vaccine is properly shipped or transferred and will be held responsible until the vaccine is appropriately and safely accepted by the receiving facility.

The following documents **should be reviewed prior to transporting vaccines (Section 6-I):**

- “Transporting Vaccines” (Vials/syringes must remain in original packaging.)
- “Transporting Frozen Vaccines by Necessity”
- “Vaccine Hourly Monitoring Report”



When transporting/transferring vaccines in ordinary vehicles, use the passenger compartment – NOT the trunk.

Varicella-containing vaccines are fragile. The CDC **<u>strongly discourages</u>** the transport of varicella-containing vaccines. If these vaccines must be transported, the manufacturer must be contacted to ascertain whether or not the vaccine is acceptable for use.

Expired and wasted vaccines

Unopened vials of all expired/wasted vaccines, including influenza vaccine, should be returned to McKesson Specialty Distribution within six months after the expiration date. However, vaccines that have expired more than 6 months previously will still be accepted. Diluent is not a vaccine and does not need to be returned**.** When nonviable product needs to be returned to McKesson Specialty Distribution, the provider should remove it from the storage unit, label “Do Not Use” and complete and fax the Vaccine Return and Accountability Form (Section 6-F) to 717-214-7223 (attention: Vaccine management) to initiate the request for a return label. A Vtrcks return ID number will be emailed to the primary VFC contact for each vaccine return request. The ID number must be recorded on a copy of the vaccine return form and placed in the box to be mailed back with the expired/wasted vaccines.

Providers can receive the UPS return label several ways:

- By email from uoltsupport@ups.com to a single email address, within one to three hours after return data is received at McKesson;
- By routine U.S. mail – seven to 10 business days; or
- By UPS driver at scheduled pick-up time.

Sample of email message

The email reads:

UPS Label Delivery, 1Z2R40000097600007

UPS Returns Label Delivery

This notice tells you that a UPS shipper has sent you an electronic label.

You can print and use this label to include in your outbound shipment or send it to the consignee. The label will be available for only 30 days. If label is not received within 30 days, the process must be repeated.

Note: When retrieving your label below, we will provide you with both a UPS returns label and commercial invoice if the invoice was prepared by the original shipper.

View UPS returns documentation instructions

Retrieve your shipment label.

If vaccines are wasted as a result of a power outage, failure to properly store, temperatures out of range, etc., the Vaccine Incident Report and Worksheet Form (Section 6-F) must be completed and forwarded to the PADOH by fax or email within five days following the incident. Failure to complete these forms will result in immediate suspension of vaccine ordering. Providers will be informed of saved/wasted vaccine doses and cost with every incident report.

Vaccine Adverse Event Reporting System (VAERS)

The National Vaccine Injury Compensation Program (VICP) is a federal “no-fault” system designed to compensate individuals or families of individuals who have been injured by childhood vaccines administered by private or public providers. VAERS, operated by the Food and Drug Administration (FDA) and the CDC, must be notified of any vaccine-related adverse event by completing a VAERS reporting form (Section 6-F). Reporting an adverse advent to VAERS does not initiate a claim for compensations; a petition must be filed with VICP to start a claim for compensation.

Vaccine Cold Chain Failure

Suspected vaccine cold chain failure – <u>Providers Shall</u>:

- Refer to the Vaccine Disaster Recovery Plan and the VFC Provider Handbook for vaccine management guidance.

- Contact the appropriate vaccine manufacturers within one workday of a suspected vaccine cold chain failure, to determine viability of the vaccine. Be prepared to provide:
    - Vaccine name;
    - Lot number;
    - Expiration date;
    - Number of doses at risk;
    - Documented refrigerator and freezer temperatures; and
    - Duration of exposure to out of range temperature.
- Complete and submit the Vaccine Incident Report and Worksheet Form (Section 6-F) and fax to the PADOH at 717-214-7223 within five days of a suspected cold chain failure.

Confirmed vaccine cold chain failure – <u>Providers Shall</u>:

- Notify Division of Immunizations (DOI) by completing the Vaccine Incident Report and Worksheet Form within five days of confirmation of the vaccine cold chain failure. The Quality Assurance staff will assist you if needed at 1-888-646-6864.
- Review refrigerator/freezer temperature logs to verify whether other "out of range" temperatures occurred that could indicate other periods of cold chain failure; submit copies with the incident report to DOI.
- Complete a Vaccine Return and Accountability Form (Section 6-F).
- Return unopened vials of all expired/wasted vaccines, including influenza vaccine, within six months to McKesson Specialty Distribution in a prepaid McKesson shipping container. Complete the Vaccine Return Form found in section 6 of the VFC Provider Handbook and fax to 717-214-7223; a vaccine return label from McKesson Specialty Distribution will be emailed/mailed to the provider site. When the label arrives, enclose a copy of the Vaccine Return Form with the expired/wasted vaccines in the box and set out for UPS to pick up.
- Any new refrigerator/freezer equipment purchased must be approved by the VFC program through a site visit by the immunization nurse, prior to storing vaccine.
- Within fourteen workdays of confirmation of vaccine cold chain failure, review office databases, registries, patient charts to identify those persons receiving vaccines during the identified cold chain failure period(s) and determine who needs to be revaccinated.

- Within twenty-one workdays of confirmed cold chain failure, prepare and submit a Corrective Action Plan to the Division of Immunizations Quality Assurance staff outlining the steps to identify, recall and revaccinate patients who had received potentially compromised vaccine.
- Within six weeks of confirmation of cold chain failure, contact identified patients and/or guardian of children by telephone or written correspondence with the following information:
    - Purpose of recall;
    - Explanation of need for revaccination;
    - Information about available clinics and times for revaccination; and
    - Scheduled appointments to revaccinate persons who were vaccinated during the cold chain failure timeframe.

- Document appropriate vaccination information on the patient's medical record and/or immunization record.
- Instruct parent/guardian of a revaccinated child to provide revaccination information to the child's school and/or childcare facility.
- Keep an ongoing log of the number of persons revaccinated and the number of doses of each vaccine administered.
- Submit interim status report and/or final report (Section 6-F) as directed by PADOH.

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