

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 data loggers/continuous temperature monitoring systems

Vaccine Storage Units - Pa. VFC requirements (Section 6-J)

DOH-supplied vaccine must be stored in one of the following:

- Standalone storage units required (medical/pharmaceutical grade strongly recommended for all new enrollees, and for purchases/replacements); or
- Medical/pharmaceutical grade combination units.

All new providers enrolling in the VFC program are required to use standalone refrigerators and standalone freezers for vaccine storage. Household combination units are **not** permitted for new enrollment, reactivation and/or replacement unit purchases.

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 required to use standalone freezers and standalone 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 and forced wastage of all VFC vaccine stored in the units.

- 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 all times, and will lead to disenrollment from the VFC program.

STORAGE UNITS

**Medical/Pharmaceutical Grade
Full-sized**



**Standalone Units
Refrigerator only**



Under-the-counter



Vaccine storage units must be:

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

Refrigerator: 36.0°F to 46.0°F/2.0°C to 8.0°C

Freezer: -58.0°F to 5.0°F/-50.0°C to -15.0°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 appropriate ambient temperature and sufficient space (at least four inches) around the sides and top for air circulation.

Certified Digital Data Loggers (Section 6-J)

Pa. VFC requirements

- A digital data logger/continuous temperature monitoring device with an active digital display, current min/max 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 digital data logger 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 DOH will accept a manufacturer's suggestion not to exceed two years.
- Digital data logger probes must be placed/secured in the center of each storage unit, unless specified otherwise by the manufacturer.
- VFC providers are **required** to have at least one back-up digital data logger at the provider site, with a valid and current certificate of calibration readily available on site to ensure twice-a-day temperature assessment and recordings.
- Providers are responsible for the maintenance and NIST recalibration of all digital data loggers/temperature monitoring devices. Newly purchased units and recalibrations are at the expense of the provider site.
- Digital display on outside of storage unit to allow reading temperatures without opening unit door.
- Alarm to alert out-of-range temperatures.
- Accuracy within +/-1.0°F (+/- .5°C).

- Low battery indicator.
- Continuous monitoring and recording capabilities to track and record temperatures over time.
- 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.
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes, if not more often.

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 four to seven days 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.
- Ensure that only one outlet is used for each individual storage unit.
- Have a safety-lock plug or “DO NOT UNPLUG” sign at the unit.
- Have a “DO NOT DISCONNECT” sign at the breaker box.

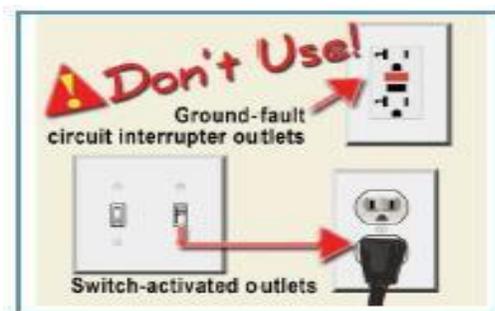


Safety-lock plug



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.
- Do not use extension cords.



Appropriately Trained Staff

Designate primary and back-up contact individuals 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 individuals;
- 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 DOH regarding any short-dated vaccines and removing expired vaccines from the viable vaccine storage units;
- Ensuring digital data loggers used inside both refrigerators and freezers are NIST certified digital data loggers with glycol/buffered probes;
- Ensuring appropriate monitoring and documentation of temperature logs;
- Notifying the DOH immediately regarding any vaccine storage and handling problems to include Incident Report 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 DOH provided vaccines; and
- Only transporting vaccine to other locations using procedures pre-approved by DOH, 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 DOH.

Designate a person to be the primary vaccine coordinator for your facility.

This person will be responsible for ensuring all vaccines are stored and handled correctly.

Appoint a second staff member to serve as an alternate in the absence of the primary coordinator (this is particularly important in case of after-hours emergencies.) Both coordinators should be fully trained in routine and emergency policies and procedures.

Coordinator responsibilities:

- Ordering vaccines;
- Overseeing proper receipt and storage of vaccine deliveries;

- Documenting vaccine inventory information and organizing vaccines within storage units;
- Setting up temperature monitoring devices;
- Reading and recording storage unit temps a minimum of two times each workday;
- Reading and recording current minimum/maximum temps from a digital data logger two times each workday;
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends;
- Rotating stock at least weekly so vaccine with the earliest expiration dates are used first;
- Removing expired vaccine from storage units;
- Responding to out-of-range temperatures (temp excursion);
- Maintaining all documentation, such as inventory and temperature logs;
- Ensuring staff is properly trained;
- Monitoring operation of storage equipment and systems;
- Overseeing proper vaccine transport (when necessary);
- Overseeing emergency preparations, including plans for ensuring safety of vaccine during emergencies;
- Tracking inclement weather conditions; and
- Ensuring appropriate handling of vaccines during disaster or power outage.

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 completed educational training certificates to the VFC central office:

Fax: 717-214-7223

Email: Paimmunizations@pa.gov

In order to insure appropriate credit is given to person and facility, please include provider's PIN on each individual document.

Providers must complete the following CDC required educational modules. These two modules must be completed and faxed prior to April 1st, each year:

- CDC “You Call the Shots” programs (Print credentials from CDC website and fax/email copies to PA DOI)
 - [Vaccines for Children \(VFC\) JAN 2019](#)
Scroll to bottom of page and click "continue" to start program
 - [Vaccine Storage and Handling JAN 2019](#)
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>

If you have difficulty printing certificates:

- <https://tceols.cdc.gov/Home/Contact>
- Call 1-800-41-TRAIN.
- Email CE@CDC.gov.

* If you have any problems with the training, please do not hesitate to contact your district nurse or DOI.

Optional Training

CDC offers additional online training opportunities for providers on immunizations, storage and handling, and vaccine administration at the following link: <https://tceols.cdc.gov/>

Per provider request, a DOI nurse will perform an on-site educational visit. All education should be documented on the Education Roster (Section 6).

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 a **vaccine emergency handling procedures and disaster recovery plan**. This provides guidelines for developing emergency handling procedures and a vaccine disaster recovery plan to follow when cold storage units malfunction due to mechanical failure or natural disaster to ensure that the vaccine cold chain is maintained. For this plan, providers should:

- Identify an alternative vaccine storage facility, such as a hospital, packing plant or local pharmacy, that has proper refrigerator and freezer units, continuous temperature-monitoring capabilities with twice daily documentation (DDLs or approved continuous temperature monitoring system) and backup power (generator) where vaccine can be stored in an emergency. An alternate site with access available 24/7 is required;
- Call quarterly to make sure the alternate site is still available and will meet Pa. VFC program requirements, and document this information;
- Identify and train staff responsible to pack, monitor and move vaccine during an emergency to a safe location;
- Have a list of emergency phone numbers for local utility companies;
- Make written descriptions of floor plans and vaccine locations available;
- Establish a location of a supply of appropriate packing materials (insulated containers, bubble wrap, cardboard, frozen water bottles, digital data loggers/continuous monitoring devices, temperature logs, etc.);
- Review quarterly with date and signature of reviewer for documentation; and
- Refer to 2019 CDC Storage and Handling Toolkit, pages 25-26.

Providers can find the 2019 Storage and Handling Toolkit at the following CDC link: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Vaccine Ordering/Delivery/Receiving/Storing

Ordering the vaccine (Section 3)

- A provider must meet all recommendations and requirements to order VFC vaccine and decrease vaccine wastage. If a noncompliant provider submits an order, the order will be deleted after five business 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.
- Make sure that your delivery times are up to date in PA-SIIS.
- Providers are expected to order monthly based on patients scheduled to receive vaccine.
- 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 directly 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.

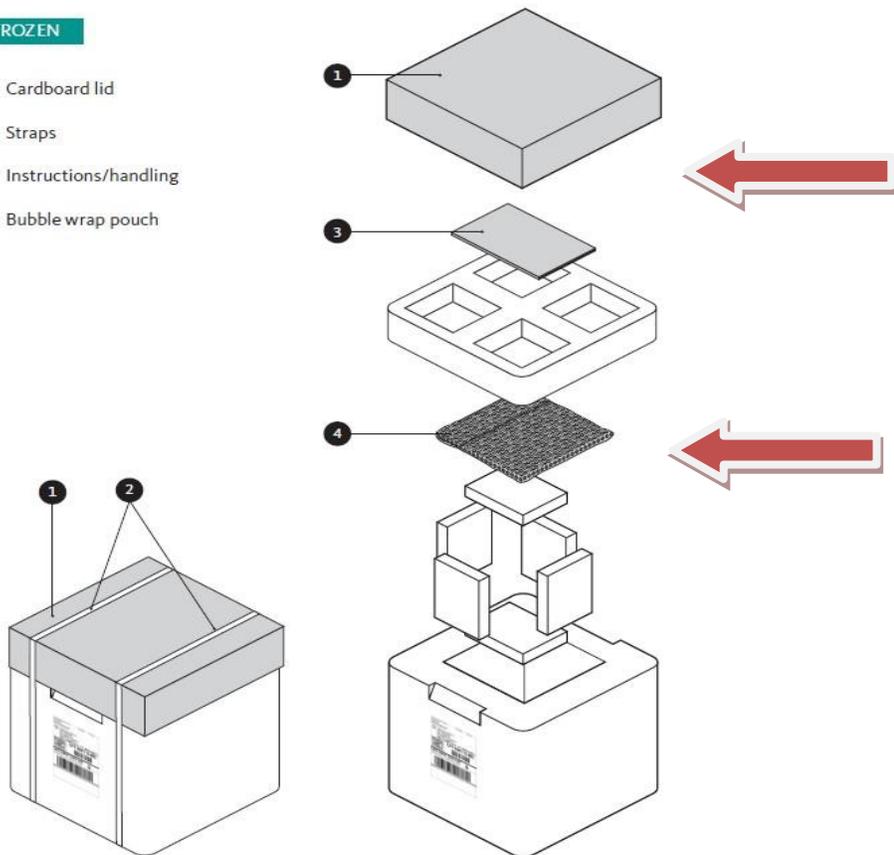
WHAT'S IN THE VARICELLA/PROQUAD SHIPMENTS

VACCINE PACKAGING

Axonometric views

FROZEN

- 1 Cardboard lid
- 2 Straps
- 3 Instructions/handling
- 4 Bubble wrap pouch



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.

1 DAY SHIPPING TIME
 Proper temperatures will be maintained 1 day from the shipment date shown on the enclosed packing slip.
FREEZE IMMEDIATELY
 Any freezer, including frost-free, that has a separate sealed freezer door and reliably maintains a temperature between -58°F and 5°F (-50°C to -18°C) is acceptable.
REPLACEMENT
 If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at 1-800-MERCK-RX (1-800-532-2579). Requests for replacement must be received by Merck within 15 days of the original shipment.

2 DAY SHIPPING TIME
 Proper temperatures will be maintained 2 days from the shipment date shown on the enclosed packing slip.
STORE PRODUCT IMMEDIATELY
 Please store product according to product package.
FROZEN PRODUCT
 Store between -58°F and 5°F (-50°C to -18°C).
REFRIGERATED PRODUCT
 Store between 36°F and 48°F (2°C to 8°C).
REPLACEMENT
 If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at 1-800-MERCK-RX (1-800-532-2579). Requests for replacement must be received by Merck within 15 days of the original shipment.

4 DAY SHIPPING TIME
 Proper temperatures will be maintained 4 days from the shipment date shown on the enclosed packing slip.
STORE PRODUCT IMMEDIATELY
 Please store product according to product package.
FROZEN PRODUCT
 Store between -58°F and 5°F (-50°C to -18°C).
REFRIGERATED PRODUCT
 Store between 36°F and 48°F (2°C to 8°C).
REPLACEMENT
 If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at 1-800-MERCK-RX (1-800-532-2579). Requests for replacement must be received by Merck within 15 days of the original shipment.



WHAT'S IN THE MCKESSON SHIPMENTS

McKesson
3M MonitorMark
 TTT
 9660C
 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.

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 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 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 DOH at 717-214-7223.
- Compare quantities, lot numbers and expiration dates carefully; **contact the DOH immediately (the same day or next business day) if there is any discrepancy between the contents received 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 and diluents have been removed from the carton.
- Single dose vaccines are packaged in amber bag in lid of upper compartment of shipping container.

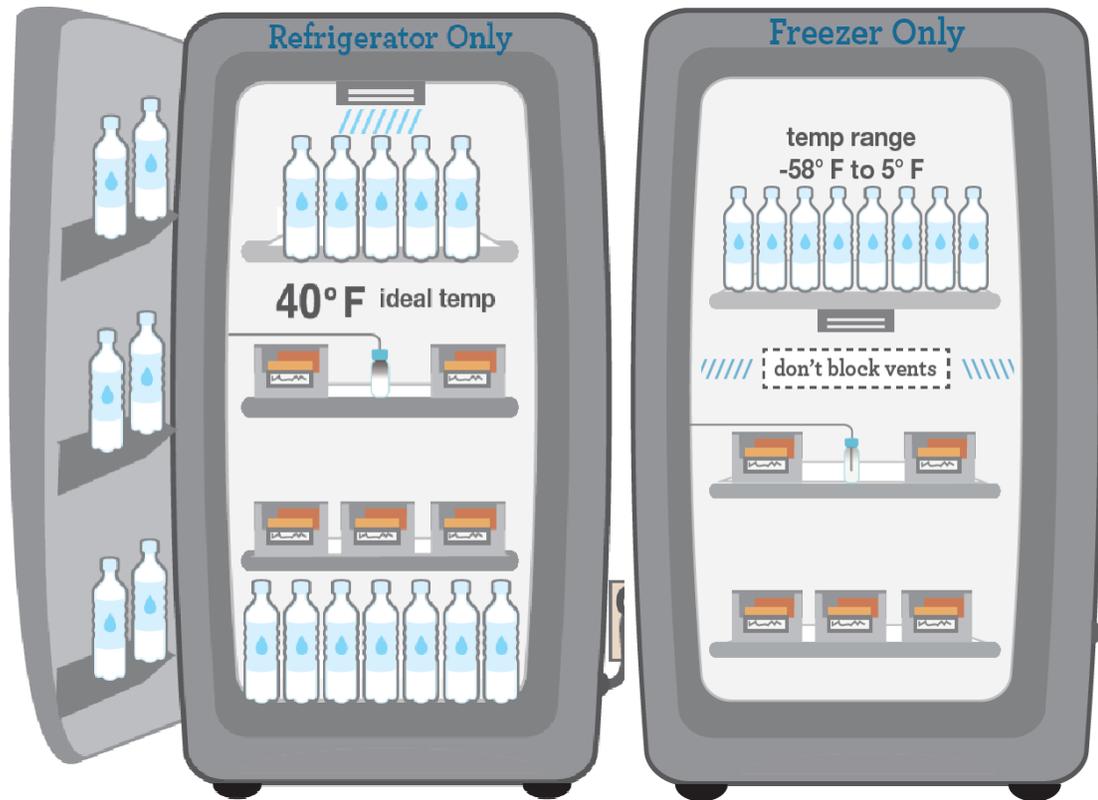
Storing the vaccines

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

Be sure to store vaccine in a well-ventilated room with appropriate ambient temperature and sufficient space (at least four inches) around the sides and top for air circulation.

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 unless specified otherwise by refrigerator manufacturer;
- Be stored with water bottles in freezer unless specified otherwise by freezer manufacturer



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.)



Defrosting manual-defrost freezer units

- Check for frost build-up; if frost exceeds 1 cm or the manufacturer's given limit for frost build-up, follow manufacturer's directions for defrosting unit;
- Frost will build up quickly, when unit's door is open and closed frequently;
- If unit requires defrosting every month or more often than every month, check seals on unit's door and call a technician if needed;
- Always have another storage unit available that is able to maintain correct vaccine temperature, to place vaccine in while defrosting freezer unit.

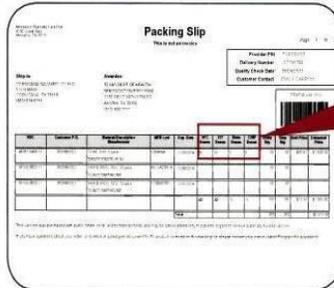


Separating and Storing Your Vaccine Stock

1 How to identify vaccine by public funding type

There are 2 types of public funding:

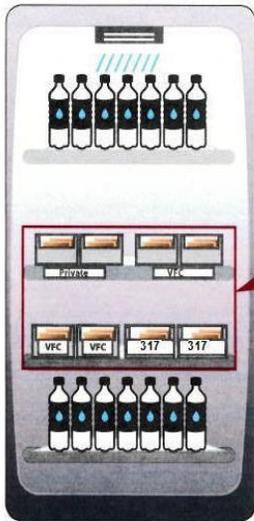
- VFC
- 317



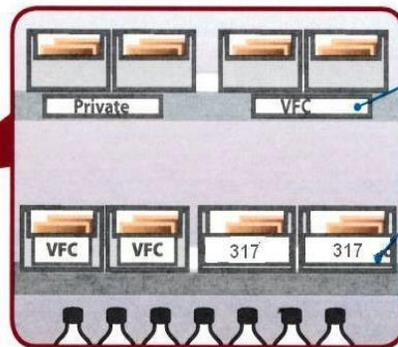
VFC Doses	317 Doses
25	20

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:



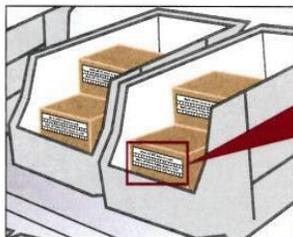
Label the storage unit shelf.

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:

Mark off VFC doses as used.								
×	×	3	4	5	6	7	8	9
Mark off 317 doses as used.								
×	2	3	4	5	6	7	8	9

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 DOH supplied temperature log with your PIN 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 DOH staff.

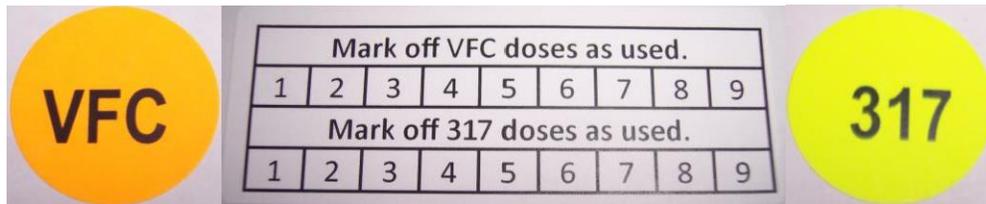
Key points to remember when completing your monthly temperature log:

- 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;
- Temperature readings should not be rounded up. Record exactly what is displayed on the digital data logger/continuous temperature monitoring device. If your minimum temperature is **36.24°F** it should be written as such and **not 36.0°F**.
- Once temperatures have been documented, follow instructions provided by manufacturer of temperature monitoring device to clear the temperature data on the display.
- If vaccine temperatures will not be documented for more than 72 hours, contact PA DOI for guidance.
- 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 PA DOI.
- 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.
- Any time temperatures are out of range, it should be indicated on the temperature log, with corrective action documented.
- 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. **You must also complete and submit the Vaccine Incident Report and Worksheet (Section 6-F) to DOH 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.

- Notify your local immunization nurse as well. This must be done in conjunction with notifying DOI.

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

DOI 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;
- Ordering only vaccine needed for the patients scheduled to receive immunizations in the next month.
- Reporting all expired/wasted vaccines (Section 6-F); and
- Limiting thermostat adjustments to the primary and back-up vaccine contact individuals.

Vaccine borrowing

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. Failure to follow proper borrowing protocol may lead to disenrollment.

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.

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. VFC cold chain protocol must be maintained at all times.

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 Monitoring Report”



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

Varicella-containing vaccines are fragile. The CDC **strongly discourages** the transport of varicella-containing vaccines. If these vaccines must be transported, the manufacturer must be contacted to determine if the vaccine is acceptable for use.

Expired and wasted vaccines

Unopened vials of **all** vaccines that are expired or have been exposed to out-of-range temperatures, including influenza vaccine, must be returned within six months after the expiration date. However, vaccines that have expired for more than six months will still be accepted. When non-viable vaccine needs to be returned, provider must:

- Remove vaccine(s) from the storage unit and label “Do Not Use”;
- 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 processed and emailed to the primary VFC contact for each vaccine return request;
- Record the ID number on a copy of the vaccine return form. A VTrckS return ID number will be processed and emailed to the primary VFC contact for each vaccine return request. The 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; and
- Return all unopened vials of vaccines. Unopened vials of all vaccines, including influenza vaccine, should be returned to McKesson Specialty Distribution within six months after the expiration date. However, vaccines that have expired for more than six months will still be accepted.

***Diluent is not a vaccine and is not returnable.**

***Opened multi-dose vials (including polio and influenza) are also not returnable.**

These must be accounted for on the **Non-Viable, Non-Returnable** form

Providers can receive the UPS return label several ways:

- By email from pkginfo@ups.com to a single email address, within one to three hours after return data is received at McKesson;
- By UPS driver at scheduled pick-up time – used especially if you do not have routine UPS service.

Note: If label is not received within 30 days, the process must be repeated.

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 in your outbound shipment or send it to the consignee. The label will be available for 30 days.

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](#)

Note: 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, listing all vaccines exposed to temperature excursion and forwarded to the DOH 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:

<https://vaers.hhs.gov/>.

- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see <https://www.hrsa.gov/vaccine-compensation/index.html>).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

Vaccine Cold Chain Failure

Suspected vaccine cold chain failure – Providers must:

- 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;
- Request all viability research information be sent from the vaccine manufacturers to the provider, and include with incident report to DOI;
- Complete and submit the Vaccine Incident Report and Worksheet form and fax to the VFC Program at 717-214-7223 within five days of a suspected cold chain failure; and
- 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 temperatures

Confirmed Vaccine Cold Chain Failure - Providers must:

- 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 any other periods of cold chain failure and submit copies with the incident report to DOI.
- Complete a Vaccine Return Form found in the VFC Provider Handbook, section 6. A form is attached and may be copied for use by provider sites.
- Unopened vials of all expired/wasted vaccines, including influenza vaccine, must be returned, preferably within six months, to McKesson Specialty Distribution. Complete the Vaccine Return Form found in section 6 of the VFC Provider Handbook and fax to 717-214-7223 at the Division of Immunizations, and 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 a 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 in the unit.
- Within 14 workdays of confirmation of vaccine cold chain failure, review office databases, registries, and patient charts to identify those individuals receiving vaccines during the identified cold chain failure period(s) and determine who needs to be revaccinated.
- Within 21 workdays of confirmed cold chain failure, prepare and submit a Corrective Action Plan to Division of Immunization staff outlining the steps to identify, recall and revaccinate patients who received potentially compromised vaccine.
- Within six weeks of confirmation of cold chain failure, contact identified patients and/or guardians of children by telephone or written correspondence and inform them of the following information:
 - ✓ Purpose of recall;
 - ✓ Need for revaccination;
 - ✓ Information about available clinics and times for revaccination; and
 - ✓ Set appointments to revaccinate individuals who were vaccinated during the cold chain failure timeframe.
- Provide DOI with copy of patient revaccination notification letter template, without patient personal information. If notifying by telephone, please provide copy of script provider staff will use for notification of revaccination.
- 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 child care facility.
- Keep an ongoing log of the number of individuals revaccinated and the number of

doses of each vaccine administered

- Submit interim status report and/or final report (Section 6-F) as directed by DOH.

Pennsylvania Department of Health
Division of Immunizations
Room 1026, Health and Welfare Building
625 Forster St.
Harrisburg, PA 17120
Fax: 717-214-7223