Vaccines for Adults (VFA) Resource Guide

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Introduction

The Vaccine for Adults Program (VFA) is funded by Section 317 funding. The program provides vaccines to eligible adults, at no charge, through VFA enrolled clinic sites. The VFA Program covers most routine adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP). VFA eliminates or reduces cost as a barrier to vaccinating eligible adults. The program serves as an immunization safety net for uninsured or underinsured adults.

Eligibility

VFA-eligible adults must be 19 years old or older and meet the following:

- They are uninsured or underinsured.
- They meet the vaccine-specific eligibility found within Appendix B1 of the Policy and Procedure manual.

Special notes:

- Adults with Medicaid or Medicare coverage are considered insured as they are covered for all ACIP recommended vaccines.
- American Indians and Alaska Natives whose only source of health care is provided by Indian Health Service, Tribal, or urban Indian health care organization are not considered fully insured and may be vaccinated by a VFA provider if the Indian Health Service, Tribal, or urban Indian health care organization does not provide vaccines listed Appendix B1 of the Policy and Procedure Manual.

VFA vaccine administration documentation

VFA eligibility must be documented at the dose-level at every encounter. If entering this information in the provider's electronic health record, dose-level eligibility must be sent to Wisconsin Immunization Registry (WIR) via data exchange, or manually entered. Along with VFA eligibility, the provider is also required to document the following with every immunization given:

- Name of the vaccine.
- Lot number and manufacturer.
- Date given.
- Name and title of person who the administered the vaccine.
- VIS publication date and date the VIS was provided.
- The clinic's address.

VFA vaccines offered

Most vaccines recommended by the ACIP are offered through VFA. Availability of vaccines may change from year to year. Travel vaccines are not offered through VFA.

Key staff

The VFA program requires providers to have a fully trained primary and backup coordinator, with the primary coordinator located at the clinic for most operating hours. If a new coordinator is assigned, they must complete the VFA Provider Training upon hire. VFA Provider Training is available upon request, providers can send VFA Provider Training requests to VFA@wi.gov The primary and back-up coordinator must be knowledgeable of all the VFA requirements, regardless of assigned clinic responsibilities. The names and contact information of the clinic's medical directors and coordinators must be reported to the VFA Program. If there is a change in VFA staff at the clinic, these changes must be communicated to the program using the. Change of Information, F-02329 (PDF) form.

Annual and new coordinator training

The primary and back-up coordinators must complete training annually. This training should be reviewed by staff new to VFA as well. In addition, any staff responsible for the viability of the vaccine must complete the training as well (for example, staff responsible for temperature documentation).
Special Circumstance: If a VFA provider is also a VFC (Vaccines for Children) provider, VFC annual training is sufficient, and sites are not required additional annual training through VFA.

Re-enrollment

VFA re-enrollment will be conducted yearly. Sites will be notified of the VFA re-enrollment process via email to the site's contacts or coordinators. VFA annual training will be due at this time as well.

Site visits

Providers enrolled in VFA agree to participate in two types of site visits:

- Compliance Site Visits: Scheduled visit conducted every two years to offer guidance and ensure the site is meeting the VFA requirements.
- Unannounced Site Visits: Unscheduled visit that can happen at any time and serves as a spot check of proper storage and handling practices.

Record retention

All VFA documentation and records must be kept for a minimum of three years. The documents may be stored in a paper-based or electronic format. Examples of documents that should be kept include temperature logs, vaccine ordering records, training records, packing slips, borrowing forms, and re-enrollment documentation.

Wisconsin Immunization Registry (WIR)

The Wisconsin Immunization Registry (WIR) was developed to record the immunization dates of Wisconsin's children and adults, as well as to forecast when upcoming immunizations are due. All VFA providers must have a WIR account, which will be set up during VFA registration. Along with recording

patient immunization information in WIR, VFA providers use WIR to order and transfer vaccines, as well as manage their inventory. To learn more about WIR or schedule a WIR Training, please contact the WIR Help Desk.

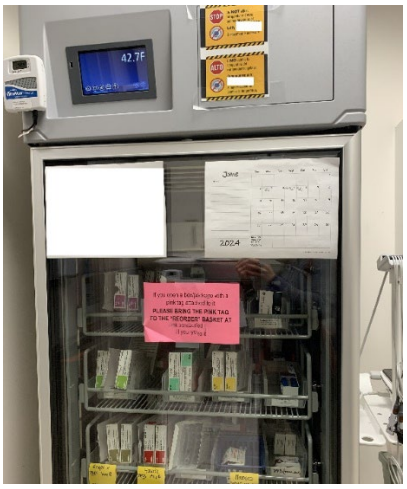
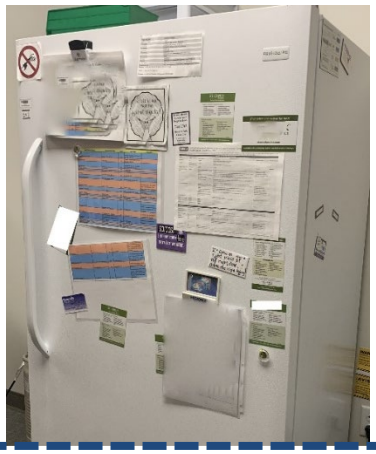
- The WIR Help Desk hours are 7:30 a.m. to 4:30 p.m., Monday through Friday.
- Phone #: (608) 266-9691
- Email: dhswirhelp@wisconsin.gov

Vaccine storage units

All VFA providers are required to properly store and handle vaccines. This starts by having the proper storage and monitoring equipment that is set up correctly, maintained appropriately, and repaired as needed.

Vaccine storage unit type

The VFA program recommends the following vaccine storage unit types (in order of preference): pharmaceutical grade/purpose-built units, commercial units, and household units. A dorm-style may never be used to store vaccine.

Pharmaceutical Grade	***Commercial***	***Household***
Best	*Good*	*Discouraged*
Designed for storage of biologics, including vaccines, they maintain temperatures more consistently.	Units not built for vaccine storage and instead intended for commercial food use.	Unit built for food storage with compressors less powerful than commercial units.
		

Commercial and household units can look similar. You can use the manual to distinguish between the two by looking at compressor size and performance.

Pharmaceutical grade units

- These units can be stand-alone or combination units. The units can vary in size from a compact, under-the-counter style to a large stand-alone unit.
- These units have good temperature recovery when the unit has been opened to get vaccines and nearly all the internal space in the unit can be used to store vaccines. Use water bottles in open space unless the manufacturer states not too.
- Pharmaceutical grade units do include vending or doorless style units. Please contact the VFC program to see if your unit meets VFC program requirements.

Commercial grade units

- These are acceptable but may not provide consistent temperatures as well as purpose-built units, and they are not built for vaccine storage.
- Vaccine cannot be stored in the doors, vegetables bins, or on the floor of these units and water bottles must be used for temperature maintenance.

Household units

- If you are using a combination household unit, only the refrigerator section can be used for vaccine storage. A separate, stand-alone freezer must be in use.
- Vaccine cannot be stored in the doors, vegetables bins, or on the floor of these units and water bottles must be used for temperature maintenance.
- If a temperature excursion occurs the program may request a provider obtain a new vaccine storage unit that is either a purpose-built or commercial unit.

Dorm-style units

- Not an acceptable unit for vaccine storage at any time.
- A dorm-style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

Storage unit size

Storage units must have enough room to store the largest inventory a provider location might have at the busiest point in the year without crowding to promote good airflow. The unit should have enough room to store routine vaccine plus additional room for seasonal vaccines when applicable.

The following guidance can be used to estimate size needs:

Public (on-hand) + private (on-hand) = Current Inventory X1.25 = maximum doses

> 2,000 doses	May need two units
1000-2000 doses	40 cu ft
900-1000 doses	36 cu ft
801-900 doses	23 cu ft
701-800 doses	17-19.5 cu ft
400-700 doses	11-16.7 cu ft
100-399 doses	4.9-6.1 cu ft

Storage unit location

The storage units should be in a well-ventilated location where there is good air circulation. The ideal room temperature is between 68°F and 77°F.

Storage unit setup

Basic setup requirements

- All storage units must have a temperature monitoring device that is a digital data logger.
- Protect the power source for all storage equipment by using "Do Not Disconnect" warning labels at the electrical outlet and circuit breaker.
- Storage units must be plugged into an electrical outlet. Power strips are not allowed to be used.
- Never store food or beverages in the unit with vaccine.

Example of a labeled outlet

Temperature requirements

- Refrigerator: Store between 2°C to 8°C or 36°F to 46°F
- Freezer: Store between: -15°C to -50°C or 5°F to -58°F

Vaccine placement requirements

- Keep private and public vaccines clearly labeled and separated.
- Vaccine must be stored in the original packaging or amber colored bags with the following information: vaccine name, lot number, expiration date, and the NDC number from the box.
- Place vaccines with the earliest expiration date in front of those with a later date.

The picture on the right gives an example of what proper vaccine storage looks like in a pharmaceutical-grade unit.

☐ Vaccine is stored in the original packaging.

☐ Vaccine is separated by stock-type

- Private vaccine labeled yellow.
- Public vaccine labeled red.

☐ Vaccine is well organized.

☐ Vaccine is stored in bins that allow for airflow.

New storage unit setup and routine maintenance

New unit setup

It may take two to seven days to stabilize the temperature in a newly installed or repaired refrigerator and two to three days for a freezer.

Before using a unit for vaccine storage, check and record the minimum and maximum temperatures each workday. Once you have two consecutive days of temperatures recorded within the recommended range, your unit is stable and ready for use.

Recommended routine maintenance

Regular maintenance of vaccine storage units is recommended to ensure proper operation and to maintain temperatures suitable for vaccine storage. Suggested maintenance includes:

- Clean the inside of the storage unit.
- Check door seals and hinges.

- Clean coils or remove dust as needed according to manufacturer's recommendations.
- Prevent frost build-up, defrost freezer according to manufacturer's recommendations.
- Check drain pans, if applicable.
- Test back-up generator, if applicable.

Digital data loggers (DDL)

It is required of all VFA providers to have a calibrated temperature monitoring device in each storage unit. The VFA program requires all temperature monitoring devices be digital data loggers (DDL).

Digital data loggers (DDL) requirements

To meet VFC requirements, the digital data logger must have the following features:

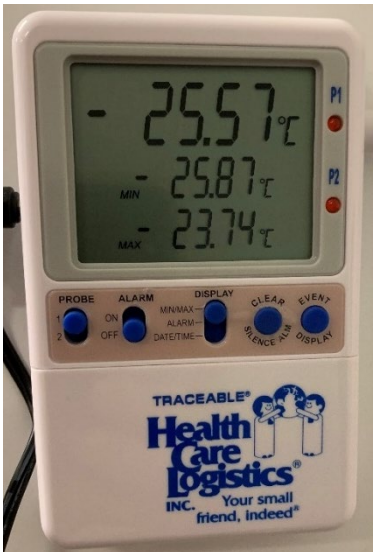
- An active display that can be read from outside the unit and display the minimum, maximum, and current temperature.
- The capacity for continuous monitoring and recording capabilities, where the data can be routinely downloaded and analyzed for review.
- A buffered probe that reflects vaccine temperature (see image on page 3 for examples)
- An alarm for out-of-range temperatures. The alarm can be audible or email, text, or call alerts.

Understanding your DDL

A wide range of digital data loggers are available that have different mechanisms for logging of the temperature data. The two groups available are manual downloads and automatic data downloads.

DDL with manual download

Temperature data usually stored in device's internal memory until downloaded by USB or docking station.



DDL with Wi-Fi/cloud

Models usually send temperature data directly to the cloud or other online application.

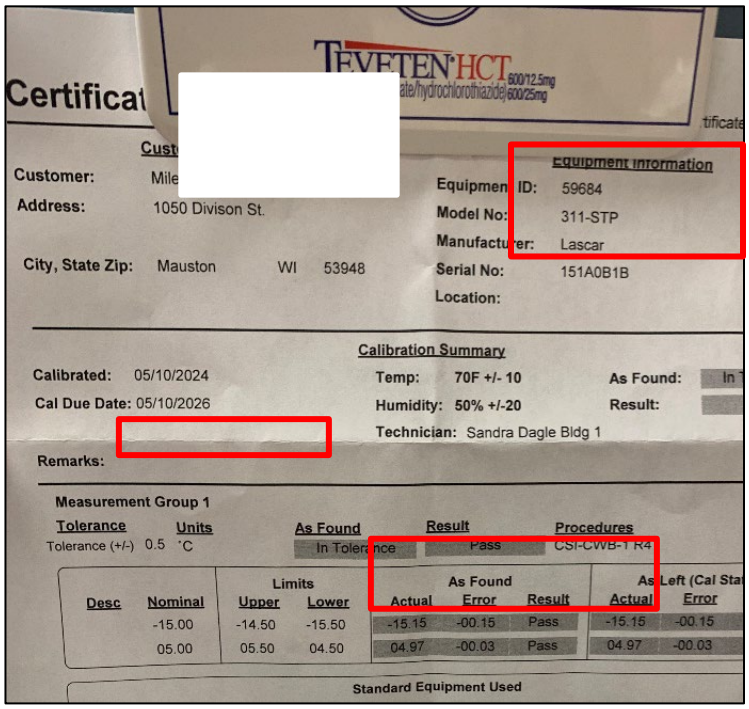
Regardless of the DDL you use, understanding how your device works is critical to temperature monitoring. When learning how to use your device focus on the following:

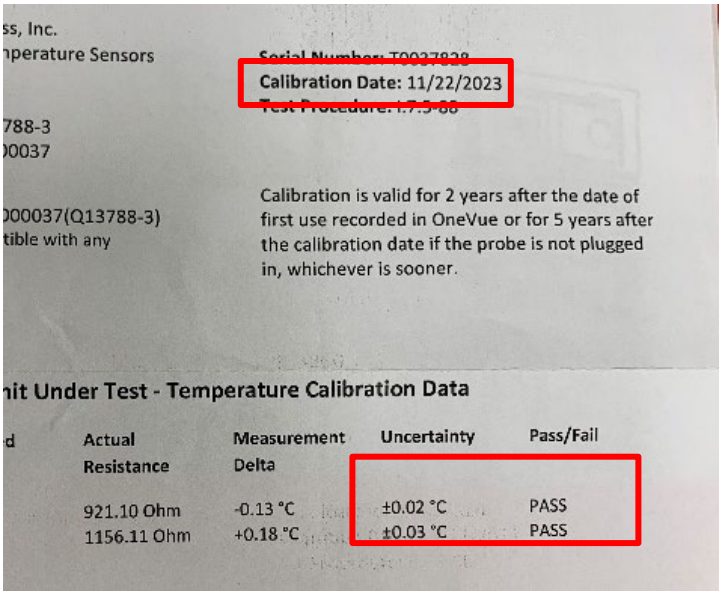
- Understand the digital display.
  - Locate the current, minimum, and maximum readings.
  - Understand what all buttons and icons on the display mean.
- Know how to retrieve and save the temperature data, for example manual download or accessing the cloud.
- Understand how to or when the device resets the minimum and maximum temperatures.
- Understand when your device needs to be recalibrated and how-to recalibrate it.
- Have manufacturer training materials or user guides available.

Certificate of calibration

All DDLs need to have a current and valid certificate of calibration. Calibration testing is required to assure the accuracy of a temperature monitoring device and should be done at least every three years or according to the manufacturer's suggested timeline. Certificates of Calibration must include the following:

- Model/device number and serial number.
- Date of calibration (report or issue date).
- Confirmation the instrument passed testing (or the instrument in tolerance).





Calibration date, due date, and first use date

Different devices may have different recommendations and language referring to when a DDL needs to be calibrated. All certificates will have a calibration date. This is the date the device was last calibrated. Some certificates will provide a due date (see above). This is the date the DDL must be calibrated by. If no date is provided, the DDL must be re-calibrated at a minimum every three years.

Some DDLs base the re-calibration date on the date the probe is first installed, referred to the first use date. See the example to the left. The device must be re-calibrated two years after first use.

DDL use and placement

- All vaccine storage units must have a digital data logger.
- All VFC providers must have at least one back-up DDL. The back-up temperature monitoring device should be stored outside of the storage unit until needed and should have a different calibration date than other DDLs to avoid requiring all DDLs to be sent out for recalibration at the same time.
- Providers who transport vaccine must have a DDL that can be used during transport of vaccine.
- Ensure appropriate logging interval is setup. At a minimum the DDL must log temperatures at least every 30 minutes.
- Probe must be placed in the center of the storage unit; the only exception is for units with a built-in port that dictates probe placement.

DDL probe placed in dedicated probe location of a pharmaceutical grade unit.

DDL probe placed in the center of the storage unit.

Temperature monitoring

Monitoring storage unit temperatures is critical to maintain the viability of the vaccine. At a minimum, the following is required:

- Check temperatures once a day, preferably in the morning.
- Document the minimum and maximum temperatures and then reset the unit*****.
- Document current date, time, and name (initial) of the person checking the temperatures.

*****Once the minimum and maximum temperatures have been recorded, the unit should be reset to capture the minimum and maximum temperatures for the next 24-hour period. Not resetting the unit after each reading could cause inaccurate monitoring and leave the vaccine vulnerable to out-of-range temperatures.

Data from the DDL must be downloaded and reviewed weekly or monthly, or if a temperature excursion is identified. The logs should be reviewed for temperature excursions that were missed or temperature trends that could indicate a storage unit performance issue. These logs should be kept electronically for a minimum of three years—the same as the paper temperature logs.

Best practice for temperature monitoring is to set up the logging interval at 30 minutes. A longer interval time may increase the likelihood that a temperature excursion could be missed. All investigations regarding a possible excursion must be documented.

Vaccine management plan

Maintain a current and complete vaccine management plan that includes routine and emergency storage and handling situations. The plan must include the following:

- Current coordinators and staff training.
- Proper storage and handling practices.
- Plan for when receiving vaccines.
- Emergency planning.
- Vaccine ordering and inventory management practices.
- How to handle wastage or expired vaccines.
- Date updated and signed.

At a minimum, the plan must be updated annually.
Keep the vaccine management plan in a location that is easily accessible by staff, ideally near the storage units.

Temperature excursions

When the DDL is reading outside of the recommendation range or the minimum or maximum indicates the temperature was out of range at some point, this is considered a temperature excursion and action needs to be taken immediately.

- Notify staff as needed and label the vaccine "do not use."
- Obtain and document the details of the excursion.
    - Download and review the temperature data. Determine the highest/lowest temperature and the duration of the excursion.
    - Collect the vaccine information of all vaccines in the unit (lot number, expiration dates) using the Emergency Response Worksheet.
- Contact the manufacturer and obtain determination reports. These reports determine if the vaccine is viable.
- Next steps:
    - Complete the Wisconsin Immunization Program's Temperature Excursion Incident Report, F-02257 (Word) and send the report to the VFC program at vfc@wi.gov.
    - Keep all documentation related to the excursion in your files for three years.
    - If the vaccine is viable, attempt to correct the issue to prevent future excursions if applicable.
    - If the vaccine is not viable, remove the non-viable vaccine from the unit to prevent accidental use.

Vaccine transport

Vaccine must be shipped directly to your clinic and transporting vaccine is not recommended, however there are a few specific circumstances when vaccine may be transferred.

- Emergency transport: This includes necessary transport during power outages, natural disaster, or equipment. See more about Packing Vaccines for Transport During Emergencies.
- Transport to another clinic to avoid wastage: Transporting vaccines directly from provider to provider to prevent wastage or expiration of vaccines before use.
- Transport to an off-site clinic (for local and Tribal health departments only): Transporting vaccines to conduct immunization clinics outside of the clinic location (for example, influenza clinic). If you need to transport vaccine, please see the Wisconsin Vaccine Transport Requirements Hand-out for proper procedures.

Vaccine returns

All VFA vaccines that expire or are spoiled must be returned. Instructions are available on the Vaccine Return—Request for Authorization to Return, F-02287 (PDF) . Returns must be completed within six months of the expiration date/spoil date. Never store spoiled or expired vaccine in the storage unit. The vaccine should be removed immediately and stored outside the unit until the vaccine is returned.

Borrowing

Vaccine borrowing is when you use a privately purchased vaccine to immunize a VFA-eligible patient or use VFA-funded vaccine to immunize a privately insured patient to prevent missed opportunities. Borrowing should not become a routine practice. Proper inventory practices should be implemented to prevent borrowing. Use the Vaccine Borrowing Report, F-03196 (PDF) if borrowing occurs.

***Providers are not permitted to borrow VFC (Vaccines for Children) vaccine to immunize an adult nor should a VFA (Vaccines for Adults) vaccine be used to immunize a child.**

Restitution

Restitution is when vaccines become non-viable due to clinic negligence. If this occurs, your clinic must replace VFA vaccines with privately purchased vaccine dose for dose. To learn more, view Wisconsin's Vaccine Restitution Policy.

Fraud and abuse

All providers agree to operate within the VFA program in a manner intended to avoid fraud and abuse.

- Fraud is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.
- Abuse occurs when provider practices are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

Vaccine availability

The Vaccines for Adults Program is funded by 317 funding. Adult vaccine is not guaranteed. Adult vaccine availability is dependent on available funding.

Contact Information

VFA program contact information.

Email: VFA@wi.gov