



Department  
of Health

# Vaccines for Children (VFC) Program Training Temperature Monitoring Device Calibration

Division of Vaccine Excellence  
Bureau of Vaccine Programs

SERIES 8



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Hello and welcome. This training is intended to provide guidance to New York State Vaccines for Children (VFC) providers on Temperature Monitoring Device Calibration.

# NYS VFC PROGRAM REQUIREMENTS



- All providers enrolled in the NYS VFC Program are required to use a continuous temperature monitoring device called a Digital Data Logger (DDL)
- In each storage unit where publicly-funded vaccine is stored, along with for units used for transport (non-emergency and emergency)
- With valid Certificate of Traceability and Calibration Testing
- Refer to training section “Selecting Temperature Monitoring Equipment” for required DDL features
- Providers must also have at least one back-up, calibrated continuous temperature monitoring device (DDL) with a different calibration date



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The NYS VFC Program requires all VFC providers to use a calibrated, continuous temperature monitoring device, called a Digital Data Logger (or DDL) to monitor temperatures in each unit that stores publicly-funded vaccine, including units used for transport (non-emergency and emergency).

Each device must have a current Certificate of Traceability and Calibration Testing.

Please refer to Training #7, “Selecting Temperature Monitoring Equipment” for required DDL features.

Providers are also required to have at least one-back up, calibrated, continuous temperature monitoring device (or DDL) with a current certificate of calibration. The back up device should be used in case of equipment failure or when calibration testing is due for the primary device(s). Your back-up device should have a different calibration date than your primary device.

# CALIBRATION DEFINED

- In this case, calibration is the professional measurement of the accuracy of a temperature monitoring device's readings against nationally accepted standards.\*
- Accuracy for DDLs must be within +/- 1° F (+/- 0.5° C)



[\\*CDC Vaccine Storage and Handling Toolkit](#)



Per CDC's Storage and Handling Toolkit, linked here and on the resources document provided with this training, Calibration is defined as the professional measurement of a temperature monitoring device's readings against nationally accepted standards. Accuracy for digital data loggers must be within + 1° F (+ 0.5° C)

## FREQUENCY OF CALIBRATION

- Routine calibration testing should be done every 2 to 3 years, or according to the manufacturer's suggested timeline (but no more than 3 years)
- Temperature monitoring devices can experience a "drift" over time, affecting their accuracy
- If your DDL is dropped or potentially damaged in any way, the accuracy should be checked by calibration testing
- If there is any question about the accuracy of the device, it should be replaced or sent for calibration testing



Routine calibration testing should be done every 2 to 3 years, or according to the manufacturer's suggested timeline . The calibration certificate should indicate the date the device was calibrated and the date the next calibration is due. Data loggers must have calibration dates no more than 3 years from the date last calibrated.

Temperature monitoring devices can experience a "drift" over time, affecting their accuracy. This testing ensures the accuracy of the device continues to conform to nationally accepted standards.

Mishandling a DDL can affect its accuracy. If your DDL is dropped or potentially damaged in any way, its accuracy should be checked against another calibrated DDL.

If there is any question about the accuracy of the device, it should be replaced or sent for calibration testing.

## CALIBRATION DATES

- The date the most recent calibration was performed, and the date the next calibration is due should appear on your Certificate of Calibration. It may also appear on the back or side of the device.
- If the dates do not appear on the certificate or if you did not receive the certificate, contact the manufacturer to provide a proper Certificate of Calibration.



The date the most recent calibration was performed, and the date the next calibration is due should appear on your calibration certificate. It may also appear on the back or side of the device.

If the dates do not appear on the certificate or if you did not receive the certificate, contact the manufacturer to provide a proper certificate of calibration.

# SELECTING THE RIGHT COMPANY FOR CALIBRATION

There are two acceptable types of laboratories that can perform calibration under NYS VFC requirements:

1. Laboratory with accreditation from an [International Laboratory Accreditation Cooperation \(ILAC\) Mutual Recognition Arrangement \(MRA\) signatory body](#) **OR**
  2. Non-accredited laboratory that conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
    - “Certified” does **NOT** mean that the device has been tested to meet ISO 17025 standards!
- Obtain calibration lab company from manufacturer **OR** if the vendor or manufacturer does not handle calibration, you must find an acceptable calibration laboratory;
    - ILAC has a [web resource](#) to find an acceptable laboratory



There are two types of laboratories that can perform acceptable calibration under NYS VFC requirements.

The first is a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) Signatory body. Calibration testing and traceability that is performed by a laboratory with accreditation from an ILAC MRA signatory body assures the user that testing performed meets the appropriate standard.

It is also acceptable for a non-accredited laboratory to perform the calibration as long as they state that they adhere to ISO 17025, which is the International Organization for Standardization's, General requirements for the competence of testing and calibration laboratories.

Keep in mind that even if a vendor or laboratory claims to “certify” temperature monitoring devices, this does not necessarily mean their calibration process meets ISO 17025 standards or that they are appropriately accredited.

If the vendor or manufacturer does not handle calibration, you must find an acceptable calibration laboratory. The International Laboratory Accreditation Cooperation or ILAC has a web resource you can use to look up acceptable calibration laboratories. The link can be found in the resources document provided with these trainings.

# CERTIFICATE OF CALIBRATION QUICK GUIDE

## Accredited Laboratory (Preferred)

If an accredited laboratory is performing calibration testing, one of these logos will be on the certificate of calibration:



This logo may appear on the certificate. It represents a group of accreditation organizations such as the ones whose logos appear above.

In addition, the following information must be included on the certificate:

- Name and address of laboratory conducting the test
- Name of device (enables product identification)
- Model number (enables product identification)
- Serial number (enables product identification)
- Date of calibration (Report or Issue Date)
- Measurement results for the device
  - Instrument pass or in tolerance testing result
  - OR
  - Documented uncertainty [must be within  $\pm 1^\circ\text{F}$  ( $\pm 0.5^\circ\text{C}$ )]

## Non-accredited Laboratory

If a non-accredited laboratory is performing calibration testing, the following information must be included on the certificate:

- Statement that calibration testing conforms to ISO IEC 17025 standards
- Name and address of laboratory conducting the test
- Name of device (enables product identification)
- Model number (enables product identification)
- Serial number (preferred)
- Date of calibration (report or issue date)
- Calibration expiration date
- Measurement results for the device
  - Instrument pass or in tolerance testing result
  - OR
  - Documented uncertainty [must be within  $\pm 1^\circ\text{F}$  ( $\pm 0.5^\circ\text{C}$ )]



Here are some “cheat sheets”, to help determine if a calibration certificate is acceptable. Accredited laboratories will have one of the logos seen on the left, in addition to the items listed below. Refer to the lists of items on the right to determine if the calibration from a non-accredited laboratory is acceptable.

# SAMPLE CERTIFICATE OF CALIBRATION

**ABC**  
**Calibration Lab**

123 Calibration St. City, State 12345

  **Certificate of Calibration**

Report Number: 12345-999  
Equipment: Resistance 1, 200  
Report Issue Date: September 1, 2023  
Calibration Due: September 1, 2025

Manufacturer: XYZ Company  
Model: ABC-123  
Serial Number: 123456789  
Calibration Exp. Date: September 2025

The certificate applies only to the piece of instrumentation which has been calibrated in accordance with the published specifications. The requirements specified in this certificate are subject to the United States Department of Commerce National Institute of Standards and Technology (NIST) and Foreign Mutual in the International System of Units (SI).

ABC Calibration Laboratory is accredited to ISO/IEC 17025:2017. This Calibration Laboratory is certified at the highest level of accreditation. All measurements are made by the NIST traceable methods. Uncertainty shall be determined at a 95% confidence level. All measurements are made in accordance with the NIST Handbook 44-100, and all measurements are made in accordance with the NIST Handbook 44-100. The certificate may be used in court proceedings and is not to be used for any other purpose. All measurements are made in accordance with the NIST Handbook 44-100.

**Calibration Environment:** Temperature: 21.1 °C (±0.1 °C) Humidity: 45.3 %

**Method:** NIST 44-100

**Notes:** None

**Calibration Information:**

As Found Date:	Ref. Value	As Found	Diff.	Spec.	Uncertainty	Result
Temperature	5.0 °C	5.0 °C	0.0 °C	+0.5 °C	±0.001 °C	Pass

**As Found Accuracy:** In Tolerance  
**As Left Accuracy:** In Tolerance

**Standards Used for Calibration:**

ACCUMCO Model 170104 or 1701 Model 170101-02, Serial Number 12345, Serial Number 67890, Calibration due 03/2025

Calibrated By: John Doe  
Title: NIST-44-100 Calibration Technician

Approved By: Jane Doe  
Title: Calibration Lab Supervisor

This Certificate Report shall not be reproduced or used in any way without the written consent of ABC Calibration Lab.  
ABC Calibration Lab - 123 Calibration St. - City, State, NY 12345 - (123) 456-7890

Here is a sample certificate from an accredited laboratory.



Note the logos and other listed information.



This is a sample calibration certificate from an accredited laboratory. Note the logos and other listed information.

# CALIBRATION PROCESS

1. Contact the manufacturer for calibration company recommendations or search on ILAC's site (see resources on prior slides) to find a calibration laboratory
2. Provide the DDL specifications and desired accuracy or uncertainty (+/- 0.5°C or +/- 1°F) to determine if the company can provide what is required
3. Place a certified backup DDL with current calibration in the storage unit, before sending your data logger out for calibration
4. Follow the company's packaging and shipping instructions\*
5. Receive the recalibrated device back from the company and verify that a valid certificate of calibration is included in the package
6. Note the date the next calibration is due
7. Keep the current calibration certificates on file and be prepared to make available upon request

\* Units with built-in DDLs require on-site calibration services



The DDL manufacturer should be able to provide information on recommendations for recalibration of your data logger. They will need to know the accuracy or uncertainty requirements (within + 1° F (+ 0.5° C)) Before sending your data logger out for calibration, you must place a certified calibrated back-up data logger in your storage unit, as the unit must be constantly monitored.

When the data logger is returned, look for the calibration certificate in the box. If not included, immediately call the company and request it to be emailed or faxed.

Calibration certificates must be made available upon request from the NYS VFC Program

Units with built in data loggers require on site calibration services.

## CALIBRATION OR NEW PURCHASE?

1. Purchasing a new DDL is sometimes less expensive than having an existing device recalibrated. Weigh your options.
2. Some DDLs are not built to be recalibrated and are designed to be discarded when the calibration expires (the NYS-supplied Fridge-Tag® 2L is one example).



Inquire about the cost of calibration versus the cost of purchasing a new data logger. Purchasing new is often less expensive than having an existing device recalibrated.

Some data loggers are not built to be recalibrated. Please keep in mind that the NYS supplied Fridge-Tag® 2L DDLs may not be recalibrated.

**THANK YOU!**



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Thank you for your participation in this training on Temperature Monitoring Device Calibration. As always, any questions can be sent to [nyvfc@health.ny.gov](mailto:nyvfc@health.ny.gov).