



**Department
of Health**

**NYS Vaccines for Children (VFC) Program
Training Series
9: Temperature Monitoring Device Calibration**

**New York State Department of Health
Bureau of Immunization**

Hello and welcome.

This training is intended to provide guidance to New York State (NYS) Vaccines for Children or VFC providers on calibration of temperature monitoring devices.

NYS VFC Program Requirements

1. Use of a calibrated, continuous temperature monitoring device:
 - In each storage unit with publicly-funded vaccine
 - With **valid Certificate of Traceability and Calibration Testing**
2. At least one back-up, calibrated continuous temperature monitoring device with different calibration date

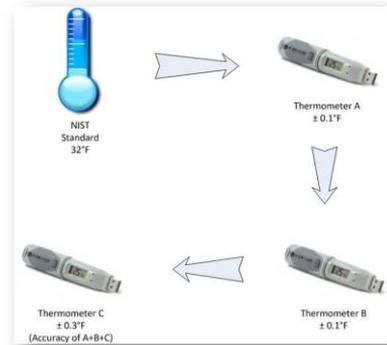


The NYS VFC Program requires all VFC providers to use a calibrated, continuous temperature monitoring device to monitor temperatures in each unit that stores publicly-funded vaccine. Each device should have a current Certificate of Traceability and Calibration Testing.

Providers are also required to have at least one-back up, calibrated, continuous temperature monitoring device 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.

What is calibration?

- Temperature monitoring device is compared to a recognized standard to certify its ability to measure accurate temperatures.
- Accuracy within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$)



A calibrated temperature monitoring device is one that has been compared to a recognized standard to certify its ability to measure accurate temperatures.

All temperature monitoring devices experience 'drift' over time. Temperature monitoring devices that have not been determined to be accurate to $\pm 1^{\circ}\text{F}$ (or $\pm 0.5^{\circ}\text{C}$) must be replaced.

Who can perform calibration?

“Certified” does NOT mean the device has been tested to meet ISO/IEC 17025 standards

- Laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body OR
- Non-accredited laboratory that states they adhere to [ISO 17025](#)*

*International Organization for Standardization (ISO) general requirements for the competence of testing and calibration laboratories



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Who can perform calibration?

There are two types of laboratories that can perform calibration acceptable 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.

Frequency of calibration

- According to manufacturer's recommendation or at least every 2 years
- Some need to be recalibrated if battery is changed
- If device is dropped or hit accidentally, check accuracy against other temperature monitoring devices.
- May be required for built-in temperature monitoring devices when storage unit is serviced



The NYS VFC program requires that all temperature monitoring devices used for monitoring publicly-funded vaccine have calibration done according to manufacturer's specification or at least every two years. If the manufacturer specifies a period less or more than 2 years long, then devices must be calibrated according to the manufacturer's specified dates.

Some battery-powered devices may need to be recalibrated when the batteries are changed. Always refer to the product insert or contact the manufacturer for information on whether a battery change necessitates recalibration.

If a temperature monitoring device is dropped or hit against the side of the storage unit, the Centers for Disease Control and Prevention or CDC recommends that at a minimum, the device be checked for accuracy against a known calibrated temperature monitoring device.

Some storage units contain built-in calibrated temperature monitoring devices. Recalibration may be required each time the unit is serviced. Built-in device calibration requires on-site calibration by a technician. Consult maintenance instructions for your storage unit for information on calibration of the storage unit's internal temperature monitoring.

Calibration Steps

1. Determine calibration due date

- Back of device
- Your equipment log book
- Current calibration certificate
- Contact manufacturer
 - If no date identified, calibration should be done at least every 2 years
- State-supplied Fridge-Tag2L data loggers are not recalibrated

2. Determine device calibration process

- Contact vendor or manufacturer
- Some vendors or manufacturers provide a simplified process
- Purchasing a new device may be cheaper



Follow the steps on this and the following 3 slides to calibrate your device.

First, find the re-calibration due date for the device. This can be found on a sticker on the back of the device, in your equipment log-book, or on the device's calibration certificate. You can also contact the manufacturer. If no due date is found and the manufacturer does not have a recommended recalibration period, perform calibration at least every 2 years.

Some temperature monitoring devices, such as the state-supplied FridgeTag2L data loggers, do not have required recalibration and are intended to be discarded after the calibration has expired.

Before purchasing a temperature monitoring device, ask the vendor if they provide re-calibration services or recommend a recalibration laboratory and obtain the details of the process. If you have already purchased a device and do not have a certificate of calibration, contact the vendor or manufacturer to determine how to have your temperature monitoring device checked for calibration.

Some vendors or manufacturers may provide a simplified process for

recalibrating your device.

In some cases, purchasing a new device may be cheaper than recalibration or may be necessary if the device cannot be recalibrated.

Calibration Steps

3. Find an acceptable calibration laboratory

- Manufacturer recommendation
- ILAC Signatory Search (web resource)

4. Request calibration services

- Give the following information:
 - Device model description or model number
 - Device serial number (if known)
 - Testing temperature ranges
 - Number of testing points (two temperature points)
 - Desired accuracy or uncertainty
 - $\pm 1^\circ$ Fahrenheit, $\pm 0.5^\circ$ Celsius



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 section at the end of this training.

When you request calibration services, provide the following information:

The device model name, description or number

Your device serial numbers, if known

Testing temperature ranges. The acceptable temperature range for refrigerators is 36-46°F or 2-8 °C, the freezer range is at or below 5°F or -15°C.

The number of points for calibration testing. Pick two temperature points within each of the ranges. These are the temperature values the lab will use to determine accuracy.

Request testing to document accuracy of plus or minus 1 degree Fahrenheit OR plus or minus 0.5 degrees Celsius.

Temperature Monitoring Device Calibration Steps

5. Back-up device

- Ensure that back-up temperature monitoring device is functional
- Place calibrated back-up device in the storage unit

6. Prepare for calibration

- Follow instructions from laboratory on proper packaging and shipping
- Built-in temperature monitoring devices require on-site calibration



Before shipping the device for calibration, make sure that the back-up device is functional (e.g., no battery change is required). Then place the back-up temperature monitoring device in the storage unit.

Finally, ship the temperature monitoring device that is due for calibration to the laboratory. Follow instructions from the laboratory on proper packaging as the device can be fragile.

If you have a built-in temperature monitoring device in your storage unit, the laboratory will need to send a technician to perform the calibration on site.

Temperature Monitoring Device Calibration Steps

7. Completing the Process

- Receive temperature monitoring device back from the calibration laboratory
- Review the calibration report/certificate
 - Verify that it includes all required information



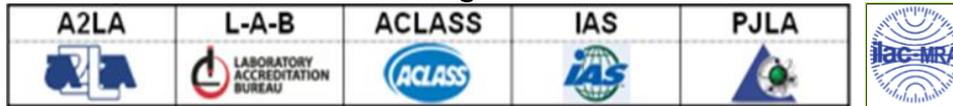
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Once you have received the temperature monitoring device back from the laboratory or anytime a new device is purchased, be sure to closely review the certificate of traceability and calibration testing, also known as a Report of Calibration. Make sure that the certificate includes the information that follows on the next slides.

Calibration Report Requirements, Part I

- **Option A: Accredited laboratory**

- Must have one of these logos



- **Option B: Non-accredited laboratory**

- Reports must contain statement that calibration testing conforms to **ISO IEC 17025 standards**



As mentioned previously, there are two types of laboratories that can perform calibration acceptable under NYS VFC requirements.

The first is a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) Signatory body.

The accredited laboratory certificate must include one the logos listed on this slide

It is also acceptable for a non-accredited laboratory to perform the calibration as long as the calibration certificate you receive states that they adhere to ISO 17025, which is the International Organization for Standardization's General requirements for the competence of testing and calibration laboratories. Adherence to ISO IEC 17025 means that a certifying laboratory keeps records in a specific way to ensure traceability, ensures continuous training of staff performing calibration and specifies how testing of calibration equipment should occur.

Calibration Report Requirements, Part II

All of the following:

- Laboratory conducting the test
 - Name
 - Address
- Device
 - Name (optional)
 - Model number
 - Serial number
- Date of calibration
- Measurement results for the device
 - Instrument testing result: *pass* or *in tolerance*
 - Documented uncertainty
 - *[within $\pm 1^\circ$ Fahrenheit ($\pm 0.5^\circ$ Celsius)]*



In addition to the requirements outlined in the previous slide, calibration certificates must include the following information:

The name and address of the laboratory conducting the test.

The device:

- Name
- Model number AND
- Serial number. – The serial number enables identification so that you know that the instrument in question is the one that is calibrated. It should be a specific number and not a range of serial numbers.

The calibration certificate should also include the date of calibration (this is usually the date of the report or issue date)

The calibration certificate should include measurement results for the device. Each test result should indicate that the device passed, with either a “pass” or “in tolerance” testing result. When the certificate shows testing results of “pass” or “in tolerance,” it shows the temperature monitoring device for which it was

issued will accurately read temperatures. If the certificate shows results of “fail” or “not in tolerance”, the temperature monitoring device must be replaced. The measurement result should also document uncertainty within the suitable limits, which are $\pm 1^{\circ}\text{F}$ or -0.5°C .

Sample Calibration Report/Certificate

ICL CALIBRATION LABORATORIES, INC.

ISO/IEC 17025 and ANSI/NCSL Z540-1 accredited
 The specialists in ASTM and laboratory thermometers & hydrometers
 Members: ASTM, API, NCSL, ASQ, NQMI

1501 Decker Avenue, Suite 110 Stuart, FL 34984 USA
 Tel: 772 286 7710 1-800-743-4647
 Fax: 772 286 8737 E-mail: sales@icllab.com
 Internet: www.icllabs.com

Setting new standards in calibration excellence!

CALIBRATION REPORT FOR THERMOMETER

Report No. U173289 Page 1 of 2 SO: 123456

THE INSTRUMENT DESCRIBED BELOW WAS EXAMINED AND TESTED IN ICL'S ISO/IEC 17025 ACCREDITED CALIBRATION LABORATORY, USING NIST TRACEABLE REFERENCE STANDARDS, IN ACCORDANCE WITH ICL'S ISO/IEC 17025 CALIBRATION PROCEDURE REFERRED TO BELOW. THIS CALIBRATION MEETS THE REQUIREMENTS OF ISO/IEC 17025, ANSI/NCSL Z540-1:1994, WHICH SUPERCEDES AND REPLACES MIL-STD 45662A1, AND THE ISO-9000 AND QS-9000 SERIES OF QUALITY STANDARDS.

CUSTOMER INFORMATION

SAMPLE CUSTOMER
 STREET ADDRESS
 CITY, STATE ZIP

PURCHASE ORDER NUMBER: NOT AVAILABLE

SUBMITTED BY: SAMPLE COMPANY

DATES

DATE REPORT ISSUED: 08-16-2011

INSTRUMENT INFORMATION

THERMOMETER ASTM 12F INSCRIPTION: LSW

MODEL: 10012F-C RANGE: 6-215F DIVISIONS: .5 °F IMMERSION: TOTAL

ENGINEERING UNITS: degrees Fahrenheit

SERIAL NUMBER: XXXX

ACCURACY TOLERANCE (maximum scale error permitted by ASTM E 11): +/- 0.25F

RESULTS OF PHYSICAL EXAMINATION

THIS INSTRUMENT WAS EXAMINED UNDER A POLARIZED LENS AND STRAINS IN THE GLASS, IF ANY, WERE JUDGED TO BE MINIMAL AND OF NO DETRIMENT TO THE FUNCTION OF THE INSTRUMENT.

THE CAPILLARY OF THIS THERMOMETER WAS EXAMINED UNDER MAGNIFICATION WITH RESULTS AS FOLLOWS: NO FOREIGN MATERIAL, MOISTURE, OR OTHER EVIDENCE OF CONTAMINATION WERE DISCOVERED. NO DISCERNABLE CAPILLARY IRREGULARITIES WERE NOTED.

IT WAS DETERMINED THAT THIS INSTRUMENT IS IN GOOD WORKING ORDER AND IS THEREFORE SUITABLE FOR CALIBRATION.

CALIBRATION PROCEDURE USED: ICL Procedure 01, which is based upon ASTM E 77, NBS Monograph 150 & NIST SP 250-23

RESULTS OF CALIBRATION

NOTE: The indications of this instrument cannot be adjusted or modified by ordinary means; accordingly, the readings given in the table below should be considered, in effect, to be both "As Found" and "As Left" readings.

TEST TEMP	READING	CORRECTION	ACCEPT LIMIT*	P/M/F	UNCERTAINTY
-6.00°F	-6.00°F	0.00°F	0.246°F	PASS	0.12°F
15.00°F	14.95°F	+0.05°F	0.246°F	PASS	0.12°F
31.00°F	31.95°F	+0.05°F	0.246°F	PASS	0.12°F
32.00°F	31.90°F	+0.10°F	0.246°F	PASS	0.12°F
60.00°F	60.05°F	-0.05°F	0.246°F	PASS	0.12°F



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Here is an example of a calibration certificate.

As you can see, this calibration examination certificate clearly displays an ILAC accreditation logo at the top right. Directly beneath the logo is the laboratory's name and address information.

The date of calibration is listed as the report issue date on the certificate.

Next, the certificate clearly identifies the name of the device, the model number and the serial number.

The bottom of the certificate indicates the temperatures at which the device was tested, a passing designation and the degree of uncertainty, which should always be less than the required + or - 1° Fahrenheit (or + or - 0.5 Celsius) for each test.

VFC **Certificate of Calibration Quick Guide**

A Certificate of Calibration (also known as a Report of Calibration) must include key pieces of information. Information required on the certificate depends on whether the laboratory performing calibration testing is an accredited or non-accredited laboratory.

Before sending your device for calibration, check with the calibration company to verify required information will be included on your certificate.

Accredited Laboratory

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

A2LA



L-A-B



ACLASS



IAS



PJLA



This logo may appear on the certificate

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 (*optional*)
- Model number (*enables product identification*)

<http://eziz.org/assets/docs/IMM-1119.pdf>



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The California Department of Health's Vaccines for Children Program has developed a quick guide which gives a checklist of things to look for on a calibration certificate.

Visit the resources slide at the end of this training to access this guide.

Calibration Steps

Additional Steps/Documentation

1. Contact laboratory

- For report clarification as needed
- Sign up for notification system for next calibration

2. File copy of each report of calibration

- With other VFC records
- Store with Routine Vaccine Storage and Handling Plan
- Make available upon request



After reviewing the certificates of calibration, contact the laboratory that performed the calibration if you have any questions about any of the items that appear or for follow up information. Some vendors have a notification system in place to remind you when your device is due for its next recalibration.

File the calibration certificate along with other VFC related items in with your routine vaccine storage and handling plan. You should have a certificate for each calibrated temperature monitoring device. A monitoring device with current calibration is required for each storage unit that holds publicly-funded vaccine. You must also have a current calibration certificate for your backup temperature monitoring device.

Be prepared to show each certificate of calibration to a NYS VFC Program representative upon request and/or during site visits.

Key Messages

- Temperature monitoring devices must be calibrated by a laboratory that is ILAC-accredited or adheres to ISO 17025 .
- Certified does not mean calibrated!
- Temperature monitoring devices should be calibrated according to manufacturer specifications, or at least every 2 years
- A valid calibration certificate/report is required for each temperature monitoring device (including backup). Review the report to ensure it meets all requirements.
- Purchasing a new calibrated device may be cheaper than recalibration, in some cases.
- State-supplied Fridge-Tag2L data loggers do not require recalibration (discard when calibration expires).
- Contact the NYS VFC program with questions at 1-800-543-7468 or nyvfc@health.ny.gov



Here are the key messages for this training module:

First, remember that certified does not mean calibrated. Only an accredited laboratory or a laboratory who adheres to ISO 17025 standards can perform appropriate calibration testing of your temperature monitoring equipment.

Temperature monitoring devices should be calibrated on a schedule according to manufacturer specifications, or at least every 2 years. Calibration may also need to be performed when the device battery is changed.

You must have a valid calibration certificate or report of calibration available for each device used to monitor temperatures inside a unit that stores publicly-funded vaccine.

Closely review all calibration certificates to ensure they meet the requirements that are outlined in this training.

Be sure to review prices for calibration prior to your purchase. In some cases, purchasing a new replacement calibrated temperature monitoring device may be cheaper than calibration testing or recalibration.

If you have any questions about calibration please contact the NYS VFC program at the phone number or email address in this slide.

Resources

NYS Vaccines for Children (VFC) Program

Temperature Monitoring Device Requirements

http://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/temp_monitor_device_guidance.pdf

International Standards Organization (ISO)

General requirements for the competence of testing and calibration laboratories

http://www.iso.org/iso/catalogue_detail.htm?csnumber=39883

International Laboratory Accreditation Cooperation

ILAC MRA Signatory Search (search for an accredited laboratory)

<http://ilac.org/signatory-search/>

California Department of Public Health, EZIZ

Checklist for temperature monitoring device Certificate of Traceability and Calibration

<http://eziz.org/assets/docs/IMM-1119.pdf>



Here is a listing of available resources.

Additional Training Webinars for NYS VFC Providers

**Next: NYS VFC Program Training Series #10:
Monitoring Vaccine Storage Unit Temperatures**



There are a number of additional trainings available.

The next training in this series is #10: Monitoring Vaccine Storage Unit Temperatures