



Vaccines for Children Thermometer Requirements and Guide

All Vaccines for Children (VFC) providers in Oklahoma are required to use Digital Data Logger (DDL) with a Certificate of Traceability and Calibration in all refrigerators and freezers used for storage of VFC vaccines. This policy came into effect January 1, 2019. Correct vaccine storage temperatures are a high priority for the VFC program to ensure that the vaccines are effective when they are administered to patients and to prevent the unnecessary loss of expensive vaccines. To ensure temperatures are correct, accurate DDL's must be used. **Continuous reading DDL's are the most effective tool to track the refrigerator/freezer temperature over time and are required by the CDC and the Immunization Service.**

This guide explains how VFC providers can meet Federal and Oklahoma requirements for vaccine storage unit Digital Data Loggers (DDL). The Oklahoma VFC program cannot endorse specific products; however, we can assist you in your research. Below you will find the requirements for the DDL's that meet the Federal and Oklahoma Standard.

Thermometer Requirements

Clinics storing VFC-supplied vaccine must:

- Use a Digital Data Logger (DDL) with a current Certificate of Traceability and Calibration in each refrigerator and freezer compartment.
- A Certificate of Traceability and Calibration guarantees the DDL's accuracy has been measured against a National Institute of Standards and Technology (NIST) or another internationally recognized standards agency.
 - The National Institute of Standards and Technology (NIST) is an agency of the U.S. Department of Commerce
- Use the calibrated DDL to read and record refrigerator and freezer temperatures each workday – and record the min/max readings of the workday.
- Keep the current Certificate of Traceability and Calibration on file with the temperature logs for a period of at least two years.
- Follow the manufacturer's recommendations for recalibration of the DDL's or replace outdated DDL's with new units that meet the requirements.
- Certificate of Calibration has no grace period for extension and is valid no longer than two (2) years per the CDC Guidelines
- Clinics must have at least one back-up DDL (i.e. a DDL not being used to monitor any other vaccine storage unit) with a current, valid certificate of calibration
- The backup DDL should have a different calibration retesting date than other DDL's to avoid requiring all DDL's to be sent out for recalibration/replacement at the same time. If the backup DDL has the same calibration retesting/replacement date, awardees/providers must have the unit retested/replaced prior to expiration, ensuring that a valid DDL is available for required temperature monitoring. Backup DDL's are usually maintained on site.

Thermometer Requirements

The Immunization Service requires the use of DDL with the following features:

Continuous monitoring	<ul style="list-style-type: none">• Provides vaccine temperatures over time• Data can be downloaded and reviewed
Probe	<ul style="list-style-type: none">• Only use probe bundled with the device
Display	<ul style="list-style-type: none">• Active temperature display that can be easily read from the outside of the storage unit• Display of current, minimum, and maximum temperatures• Low Battery Indicator
Alarm capabilities	<ul style="list-style-type: none">• Ability to trigger an alarm for temperature recordings outside of acceptable storage temperatures
Capacity	<ul style="list-style-type: none">• Memory stores at least 4,000 readings
Interval	<ul style="list-style-type: none">• Device reads and records temperatures at intervals no greater than every 15 minutes.
Certificate of Calibration Testing (Report of Calibration)	<ul style="list-style-type: none">• Name of device (optional)• Model number• Serial number • Date of calibration• Measurement results indicate unit passed test

Remember

- Ask your vendor if the DDL comes with a certificate of traceability and calibration.
- Look for a vendor that provides good customer service.
- Contact the Immunization Service if you have questions about which DDL brands and models that meet the requirements.

What is a Certificate of Traceability and Calibration?

A certificate of traceability and calibration guarantees that the DDL is accurate as measured against a National Institute of Standards and Technology (NIST) or American Society for Testing and Materials standard. When you buy a DDL, the certificate will ensure the accuracy of the DDL for a certain period of time. After that time, the DDL will need to be recalibrated or replaced. Some vendors charge for a certificate of traceability and calibration and most charge for recalibration.

What is Recalibration?

Recalibration refers to testing and adjustment of the instrument to maintain accuracy after purchase. Most manufacturers recommend recalibration every one to two years. All Instruments lose accuracy over time due to normal usage and the environmental conditions to which they are exposed. Periodic NIST certified calibrations maintain the accuracy of your instrument throughout its life. There are cases where it may be more cost effective to buy a new DDL rather than pay for a recalibration.