

Iowa Vaccines for Children Program Data Logger Requirements May 2019

The following information includes data logger requirements to be in compliance with the Vaccines for Children (VFC) Program. All VFC Program providers are required to use digital data loggers (DDL) to monitor vaccine storage units containing VFC vaccine and must meet the following requirements.

The DDL must be equipped with:

- Temperature probe that best reflects the vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, Teflon®)
- Alarm for out-of-range temperatures
- Active temperature display outside the unit that shows current, minimum and maximum temperatures
- Continuous monitoring and recording capabilities where the data can be routinely downloaded
- Low battery indicator
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes
- Recommended uncertainty of +/-0.5 °C (+/-1°F)
- A current and valid DDL Certificate of Calibration Testing which contains:
 - Model/device name or number
 - Serial number
 - Date of calibration (report or issue date)
 - Confirmation the instrument passed testing or was in tolerance
 - Recommended uncertainty of ±0.5°C (±1°F) or less

The Certificate of Calibration Testing or Report of Calibration must indicate one or more of the following items about calibration testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standard for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
- Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing Materials (ASTM) Standard E2877 Tolerance Class F or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Calibration testing should be done every one to two years or according to manufacturer's suggested timeline.

References:

CDC's Vaccine Storage and Handling Toolkit, January 2019 -
<http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>