## Digital Data Logger Requirements

Vaccines for Children (VFC) Program providers must use digital data loggers (DDLs) to monitor temperatures in vaccine storage units containing VFC vaccine. The following requirements must be met for data loggers to be compliant with the VFC Program.

## **DDL Functionality**

Digital data loggers must be equipped with:

- Temperature probe
  - o A buffered probe is recommended for refrigerators and freezers
  - Ultra-cold monitoring requires an air-probe or other probe specifically designed for ultracold temperatures
- An active temperature display that can be easily read from the outside of the unit
- Continuous monitoring and recording with data download capability
- Logging intervals (reading rates) no less frequent than every 30 minutes
- Alarm for out-of-range temperatures
- Low battery indicator
- Current, minimum, and maximum temperature displays
- Recommended uncertainty of +/- 0.5°C (+/- 1°F) or less
- Valid Certificate of Calibration testing including
  - Mode/Device number
  - Serial number
  - Date of Calibration
  - Recommended uncertainty of +/- 0.5°C (+/- 1°F) or less
  - Confirmation of the instrument passing testing

## **Certificate of Calibration Testing**

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 completed every two to three years or according to the manufacturer's suggested timeline. Questions may be directed to the lowa VFC Program at <a href="lowaVFC@hhs.iowa.gov">lowaVFC@hhs.iowa.gov</a>.