

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0936836	(X3) Date Survey Completed 11/06/2025
Name of Provider or Supplier Pediatrics In Brevard	Street Address, City, State 255 N Sykes Creek Parkway Ste 104, Merritt Island, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Pediatrics in Brevard PA on November 6, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency cited as follows:
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to identify and document corrective actions for temperatures out of range for the refrigerator for five days of operation of the laboratory from 09/20/2023 to 11/06/2025. Findings Included: 1. A tour of the laboratory on 11/06/2025 at 9:20 AM, revealed hematology controls were stored in the laboratory refrigerator. 2. Review of the package insert for the Cell-Dyn 18 Plus Control (hematology controls) noted "Cell-Dyn 18 Plus Control should be tightly capped and stored at 2 - 10 Degrees C" (Celsius). 3. Review of the Laboratory Temperature Log for the refrigerator showed the temperatures were below 2 degrees C with no correction action documented for the following 5 days: 06/05 /2024 recorded 1 degrees C 09/18/2025 recorded 0 degrees C 09/22/2025 recorded 1 degrees C 09/23/2025 recorded 1 degrees C 09/24/2025 recorded 1 degrees C 06/05</p>

/2024 recorded 1 degrees C 4. Review of the procedure titled, General Laboratory Procedures noted, "Refrigerator, freezer, and room temperatures and relative humidity are checked and recorded. If out of range, provide corrective action. 5. Review of the Monthly Laboratory Quality Assurance Checklist for June 2024, showed "11 days corrective action not documented." Review of the Monthly Laboratory Quality Assurance Checklist for September 2025 showed, "1 day corrective action not documented." No further information indicating corrective action taken for the refrigerator temperatures out of range was recorded on the quality assurance checklists. 6. On 11/06/2025 at 10:22 AM, Technical Consultant B acknowledged the temperatures were out of range and corrective action taken was not documented.