

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0982096	(X3) Date Survey Completed 06/24/2025
Name of Provider or Supplier Preferred Pediatrics At Snowden Inc	Street Address, City, State 331 Park Hill Drive, Fredericksburg, VA	
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 Preferred Pediatrics at Snowden on June 24, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows:
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, Cell-Dyn Emerald's Operator's Guide, calibration records, quality control records, lack of documentation and interviews, the laboratory failed to follow their established policy to run quality control (QC) after calibration of the Cell-Dyn Emerald for two (2) of 2 calibrations from 1/2025 until 6/2025. The findings include: 1. Review of the laboratory's policies and procedures revealed a statement, "Calibrate CBC every 6 months-see CBC manual for detailed instructions." 2. Review of the Cell-Dyn Emerald hematology analyzer's Operator's Guide revealed a statement, "Abbott recommends you, run controls: ... After calibration (confirmatory step)." 3. Review of the laboratory's calibration records for the Abbott Emerald revealed calibrations were performed on 01/28/2025 and 06/10/2025. Further review of the calibration records revealed a lack of post-calibration QC for 01/28/2025 and 06/10/2025. The surveyor requested to review the post-calibration QC for the 2 above listed calibration events. The laboratory provided no documentation for review. 4. In an exit interview with the laboratory manager on June 24, 2025 at 12:15 PM, the findings were confirmed.</p>

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the Cell-Dyn Emerald's operator's manual, hematology calibration records, and interview, the laboratory failed to perform the Cell-Dyn Emerald calibration procedures every six months from July 27, 2023 up to the date of the survey on June 24, 2025. The findings include: 1. Review of the Cell-Dyn Emerald's operator's manual the Abbott Emerald hematology analyzer, revealed a section, "When to Calibrate", with a statement, "Calibration verification criteria include: When indicated by Quality Control data; After major maintenance and service procedures; At least every six months." 2. Review of the hematology calibration documents for the Abbott Emerald analyzer from July 2023 up to the date of the survey on June 24, 2025 revealed calibration procedures performed on 12/13/2023, 6/20/2024 (6 months), 01/28/2025 (7 months) and 6/10/2025 (5 months). The surveyor requested to review additional calibration procedures for the above mentioned time frame. The laboratory provided no further documentation for review. 3. In an exit interview with the laboratory manager on June 24, 2025 at 12:15 PM, the findings were confirmed.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(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.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies and procedures, quality control (QC) records, lack of documentation and interviews, the laboratory failed to document the corrective actions taken when the QC peer comparison reports identified issues with the QC material used to verify the accuracy of the Abbott Cell-Dyn Emerald hematology analyzer for six (6) of twenty-two (22) months reviewed from July 2023

until May 2025. The findings include: 1. Review of the laboratory's Streck STATS peer comparison reports for the Abbott Cell-Dyn Emerald QC from July 2023 until May 2025 revealed reviews by the Laboratory Director for the 22 months from July 2023 until May 2025. 2. Further review of the comparison report revealed the following statements, "S.D.I (Standard Deviation Index)Report: This report is a graphical presentation of your laboratory's data on the current lot. The S.D.I. allows you to inspect results from many different tests at the same time, without having to consider different units and the actual magnitude of the change in the units of the test. In general, any S.D.I. of greater than 2.0 or less than -2.0 deserve some attention because your method shows a systematic difference from the group." and "Important Notes: SDI values greater than 2.0 or less than -2.0 are displayed in white on a dark background." 3. Review of the STATS peer comparison reports revealed the following months and parameters with an SDI less than minus (-) 2.0: August 2024-White Blood Cell Count (WBC) November 2024-WBC March 2025-WBC, and Mean Corpuscular Hemoglobin Concentration (MCHC) April 2025-WBC, MCHC May 2025-WBC Review the peer comparison reports revealed the following month and parameters with an SDI greater than 2.0, December 2024 -Mean Corpuscular Volume (MCV). 4. Review of the laboratory's corrective action documentation from July 2023 until May 2025 revealed a lack of documentation of the actions taken when the SDI was greater than 2.0 and less than -2.0 for the following months: August 2024, November 2024, December 2024, March 2025, April 2025, and May 2025 . The surveyor requested to review documentation of the investigation/corrective actions taken for the months listed above. The laboratory provided no documentation for review. 5. In an exit interview with the laboratory manager on June 24, 2025 at 12:15 PM, the findings were confirmed.