

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0915945	(X3) Date Survey Completed 06/05/2026
Name of Provider or Supplier Isabella Martire Md	Street Address, City, State 8343 Cherry Lane, Laurel, MD	
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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the recertification survey completed on 05/16/2024 for not reviewing the proficiency testing (PT) provider's evaluation of each individual PT result. The laboratory's plan of correction stated this would be corrected by 06/26/2024. Based on review of PT records and interview with the office manager (OM), the laboratory failed to review the PT provider's graded results for each individual PT result in two of six PT events reviewed. Findings: 1. The laboratory was enrolled in PT for hematology and received five specimens three times per year. 2. For each PT event, the PT provider issued 1) a Cumulative Scores report that included the overall grade for each specialty and regulated analyte and 2) a Graded Results report that included all graded results for each PT sample. The Graded Results report included results for both regulated and unregulated analytes and documented if an individual analyte could not be graded by the PT provider and if not, the reason why. 3. Records from six PT events were reviewed (2024 2nd event through 2026 1st event). 4. For the 2024 3rd event, the Cumulative Scores report was reviewed but not the Graded Results report. 5. There was no documentation that the PT results from the 2025 2nd event were reviewed. 6. During the exit interview on 06/05/2026 at 12:30 PM, the OM confirmed that the Graded Results report was not reviewed for the 2024 3rd and 2025 2nd PT events.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using

the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual, the manufacturer's operator's manual, and calibration verification records and interview with the office manager (OM), the laboratory failed to ensure that a calibration verification was performed on the hematology analyzer at least once every 6 months. Findings: 1. The laboratory performed hematology testing using a CELL-DYN Emerald analyzer. 2. The "Quality Assurance Procedure" stated that "Calibration performed every 6 months, documented and records retained." 3. The "CELL-DYN Emerald Operator's Manual" (9213301B-October 2018) stated that "Calibration verification criteria include" to be performed "At least every six months." 4. Records showed that calibration verification was performed on 01/22/2025 and 09/25/2025 and had not been performed yet in 2026. 5. During the exit interview on 06/05/2026 at 12:30 PM, the OM confirmed that calibration verification was performed every nine months, not every six months as required.

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 review of the manufacturer's operator's manual, review of temperature records, and interview with the office manager (OM), the laboratory failed to document corrective actions when the humidity fell outside the manufacturer's specifications for relative humidity in 28 of 139 days recorded between 01/2025 through 05/2026. Findings: 1. The laboratory performed hematology testing using the CELL-DYN Emerald analyzer. 2. The "Environmental Specifications" section of the

operator's manual (9213301B-October 2018) listed relative humidity requirements of "80% maximum at 88 [degrees Fahrenheit]" when operating the analyzer. 3. The laboratory documented all laboratory temperature and humidity values on a temperature/humidity chart (temp chart) which listed an acceptable humidity range of 30-85%. 4. Temperature and humidity values were recorded on 139 days between 01/2025-05/2026. 5. Humidity was above the manufacturer's operating limit of 80% on six of eight days recorded in 05/2025, nine of nine days recorded in 07/2025, six of seven days recorded in 08/2025, and seven of eight days recorded in 09/2025. 6. Humidity was above the laboratory's defined limit of 85% on one of eight days in 05/2025, nine of nine days in 07/2025, and five of seven days in 08/2025. 7. No corrective actions were documented when the humidity fell outside the manufacturer's or the laboratory's defined acceptable limits. 8. During the exit interview on 06/05/2026 at 12:30 PM, the OM confirmed that corrective actions were not documented when humidity was recorded above acceptable limits.