

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0892637	(X3) Date Survey Completed 03/03/2022
Name of Provider or Supplier Pediatric Care Center	Street Address, City, State 304 East 4th Street, Anniston, AL	
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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to document investigation and corrective actions to determine the underlying cause of unsuccessful performance for a non-regulated analyte, MCV (Mean Corpuscular Hemoglobin) when the first of two failures occurred (2019 Event #3 and 2020 Event #1). The findings include: 1. A review of API PT records revealed the laboratory received failing scores of 40% for MCV in the 2019 Event #3 survey, and 0% for MCV in the 2020 Event #1 survey, resulting in unsuccessful performance for a non-regulated analyte. 2. A review of the corrective action for the 2019 Event #3 failure was to repeat the PT specimens. There was no indication the severe negative SDI (Standard Deviation Index) bias was noted in the returned PT evaluation, or any additional investigation was implemented to determine the underlying cause of the failure, and prevent recurrence of the problem in the next survey. 3. During the exit summation on 3/3/2022 at approximately 1:50 PM, the surveyor asked the Technical Consultant if any additional corrective action (such as a calibration) was implemented after the MCV failure in the 2019 Event #3 survey. The Technical Consultant checked his notes in the December 2019 and January 2020 Quality Assurance records, and confirmed no additional corrective actions were implemented. .</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (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 (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (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 reviews of the Abbott Cell Dyn Emerald Hematology analyzer records and Operator's Manual, and an interview with the Testing Personnel, the surveyor determined the laboratory failed to perform calibrations as per manufacturer's instructions in 2019 - 2021. The findings include: 1. A review of Abbott Cell Dyn Emerald records revealed documentation of calibrations on the following dates: A) 1/15/2019 and February 2019 (Acceptable calibrations reviewed during the previous survey on 7/23/2019) B) 4/21/2020 (fourteen months later) C) 1/26/2021 (nine months later) D) 10/6/2021 (eight and a half months later) 2. A review of the Abbott Cell Dyn Emerald Operator's Manual, Section 6 "When to Calibrate", on page 6-3 revealed, "... Calibration verification criteria include: When indicated by Quality Control data ... At least every six months ...". 3. A review of the 2/8/2020 through 3/10/2020 QC records revealed a negative bias in all three levels of QC for MCV (Mean Corpuscular Hemoglobin). The surveyor further noted the laboratory received a failing score of 40% for MCV on the 2019 Event #3 proficiency testing survey performed on 11/20/2019, and a score of 0% for the 2020 Event #1 survey performed on 3/18/2020. [Refer to D5221 and D5783.] 4. During an interview on 3/3/2022 at 11:40 AM, the surveyor asked how often Emerald calibrations should be performed; the Testing Personnel answered, "Every six months". The surveyor reviewed the survey dates above and asked if the laboratory had any documentation of calibrations the second half of 2019 and 2020. The Testing Personnel thought she had performed other calibrations, however she was unable to locate any additional documentation during the on-site survey. .

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on reviews of the API (American Proficiency Institute) proficiency testing (PT) records, Abbott Cell Dyn Emerald Hematology quality control (QC) and quality assurance (QA) records, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to implement additional corrective actions and monitor effectiveness after the 2019 Event #3 PT failure. The problem was unresolved from November 2019 until April 2020. In addition, the laboratory failed to implement corrective actions and monitor to ensure calibrations were performed every six

months, as per manufacturer's instructions from 2019 until October 2021. The findings include: 1. A review of API PT records revealed the laboratory received a failing score of 40% for MCV (Mean Corpuscular Hemoglobin) in the 2019 Event #3 survey; testing was performed on 11/20/2019. The corrective action for the failure was to repeat the PT specimens. [Refer to D5221.] 2. A review of the Cell Dyn Emerald Hematology cumulative QC records for the period 2/8/2020 through 3/10/2020, revealed several days when the testing personnel was unable to obtain values within the acceptable ranges for the Low control. The surveyor noted a severe negative bias for MVC (Mean Corpuscular Hemoglobin) in all three QC levels on the Levy-Jennings charts. 3. A review of API PT records revealed the laboratory received a failing score of 0% for MCV in the 2020 Event #1 survey; testing was performed on 3/18/2020. 4. A review Abbott Cell Dyn Emerald Hematology analyzer calibrations revealed no documentation of calibration from February 2019 until April 2020 (fourteen months later); the laboratory had failed to follow the manufacturer's requirements to perform calibrations every six months. [Refer to D5437.] 5. A review of the February 2020 QA records revealed the Technical Consultant noted the problem with the Low Hematology QC level, and recommended "Recal [recalibrate] when unable to get an in range value". However, no calibration was performed until after the second PT failure on 4/21/2020; the surveyor further noted the laboratory failed to implement additional corrective actions and monitor to ensure calibrations were performed every six months as per manufacturer's instructions from April 2020 through October 2021. [Refer to D5437.] 6. During the exit summation on 3/3/2022 at approximately 1:50 PM, the surveyor reviewed and confirmed the above noted findings with the Technical Consultant. SURVEYOR ID #32558 Licensure and Certification Surveyor