

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0982892	(X3) Date Survey Completed 08/02/2023
Name of Provider or Supplier Prattville Pediatric Assoc	Street Address, City, State 645 Mcqueen Smith Rd, Prattville, 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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of calibration records for the Beckman Coulter DxH 520 Hematology analyzer, a review of the manufacturer's instructions, and an interview with the Technical Consultant, the laboratory failed to ensure: (1) repeatability and reproducibility was performed and documented each time a calibration was performed; and (2) the "calibration verification" was performed after the calibration. These problems were noted to have occurred on three of three 2022-2023 calibrations. The findings include: 1. A review of calibration records for the Beckman Coulter DxH 520 Hematology analyzer revealed the following: (1) Regarding Repeatability and Carryover, the laboratory failed to perform and document these studies, as follows: (A) 2/28/2022: No documentation of Repeatability and Carryover (B) 8/18/2022: No documentation of Repeatability (C) 2/13/2023: No documentation of Repeatability (2) Regarding the "Calibration Verification", the laboratory failed to verify three of three calibration as per manufacturer's instructions. 2. A review of the Beckman Coulter DxH 520 "Instructions for Use Manual", under Chapter 11 Quality Assurance revealed, "...Calibration... ..17. Verify calibration using DxH 500 calibrator..." [page</p>

11-6] A further review of the procedure revealed instructions on how to perform the Repeatability and Carryover studies with the calibration, as follows: "...Running Repeatability..." [page 11-6] and "Running Carryover..." [page 11-8]. 3. During an interview and review of the manual on 8/2/2023 at 12:50 PM, the Technical Consultant confirmed the laboratory had failed to perform calibrations as per the manufacturer's instructions. .

D5791

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

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on reviews of personnel records, AAB (American Association of Bioanalysts) proficiency testing (PT) records, calibration records, quality assurance (QA) records, and the exit interview with the Technical Consultant, the surveyor determined the laboratory failed to follow quality assurance procedures as an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the quality of the analytic systems. These failures were noted to occur since the previous survey on 12 /14/2021. The findings include: 1. Personnel A review of the QA procedures (documented in the "Monthly Quality Assurance Checklist") revealed the laboratory failed to follow the "Personnel Policy" which specified: A) "Personnel evaluations were performed as necessary". The surveyor noted four of eight testing personnel performing patient testing on the Beckman Coulter DxH 520 with no documentation of semiannual or annual competency evaluations. (Refer to D6053 and D6054.) B) The laboratory further failed to implement QA reviews to ensure all Testing Personnel provided required educational documentation before performing patient testing. (Refer to D6045.) 2. Proficiency Testing A review of the QA procedures revealed the laboratory failed to follow the "Proficiency Testing policy" which specified, "All proficiency test results were evaluated." The surveyor noted no documentation of review for survey Event Q1-2022 until the day of the survey. The surveyor further noted Event Q3-2022 was not not printed and reviewed until the day of the survey. 3. Quality Control (QC) A review of the QA procedures revealed the laboratory failed to implement and follow "Quality Control Policies" to ensure calibrations on the Beckman Coulter DxH 520 were performed as per the manufacturer's instructions. (Refer to D5437). 4. During the exit interview on 8/2/2023 at 3:15 PM the above noted deficiencies were reviewed and confirmed with the Technical Consultant. .

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
Based on reviews of personnel files, and an interview with the Technical Consultant,

the Technical Consultant, failed to ensure two of five new Testing Personnel provided documentation of their education to ensure the minimal requirements of a High School diploma (or equivalent) were met. The Technical Consultant further failed to ensure training on the Beckman Coulter (BC) DxH 520 Hematology analyzer was performed and dated for one of five new Testing Personnel to ensure training was performed before she began patient CBC (Complete Blood Count) testing. The findings include: 1. A review of personnel files revealed no documentation of education for Testing Personnel #7 and #8. Testing Personnel must provide a High School diploma (or equivalent), or a degree in a Chemical, Physical, or Biological science before performing patient testing on the Beckman Coulter DxH 520, a moderate complexity analyzer. 2. A further review of the records revealed the training for Testing Personnel #7 was not dated. The Technical Consultant stated she did not know when the training was performed. 3. During an interview and review of the records on 8/2/2023 12:10 PM, the Technical Consultant confirmed these findings. .

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on reviews of personnel files and an interview with the Technical Consultant, the Technical Consultant, failed to ensure one new Testing Personnel had documentation of the semiannual competency evaluation. This affected one of eight Testing Personnel listed on the Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of personnel files revealed Testing Personnel #1 had training for moderate complexity testing on the Beckman Coulter DxH 520, dated 3/10/2022 and 4/11/2022. However, there was no documentation of a semi-annual competency evaluation, due the second half of 2022. 2. During an interview and review of the records on 8/2/2023 12:10 PM, the Technical Consultant confirmed these findings. .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on reviews of personnel files and an interview with the Technical Consultant, the Technical Consultant, failed to ensure three Testing Personnel had documentation of the annual competency evaluations. This affected three of eight Testing Personnel listed on the Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of personnel files for Testing Personnel who performed moderate complexity testing on the Beckman Coulter DxH 520 analyzer revealed the following: A) Testing Personnel #2 had an annual competency evaluation dated 2/28/2021, however there was no documentation of annual competency assessments in 2022 or 2023. B) Testing Personnel #3 had an annual competency evaluation dated 9/29/2021,

however there was no documentation of annual competency assessment in late 2022.
C) Testing Personnel #4 had an annual competency evaluation dated 9/22/2021, however there was no documentation of annual competency assessment in late 2022.
2. During an interview and review of the records on 8/2/2023 at 12:10 PM, the Technical Consultant confirmed these findings. SURVEYOR ID #32558 Licensure and Certification Surveyor