

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2154250	(X3) Date Survey Completed 01/08/2025
Name of Provider or Supplier Liberty Mountain Pediatrics	Street Address, City, State 4600 Hwy 280 S, Suite 103, Birmingham, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), the laboratory failed to ensure the Laboratory Director (or designee) signed the PT attestation statements. This was noted for two of the six events reviewed from the date of the last survey, 12-22-2023 through the date of the current survey, 01-08-2025. The findings include: 1. A review of the 2023-2024 API PT Hematology records revealed the Laboratory Director (or designee) did not sign the attestation statements for the following PT events: a) 2023 Hematology/Coagulation-2nd Event b) 2024 Hematology/Coagulation-2nd Event 2. The PM and TP1 confirmed the above findings during the exit conference on 01-08-2025 at 1:46 PM.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), the laboratory failed to document the PT evaluation review for one of the six</p>

events reviewed from 2023-2024. The findings include: 1. A review of the API PT records revealed no documentation of the PT performance review from the Laboratory Director, or designee, for the 2024 Hematology/Coagulation-3rd Event. 2. The PM and TP1 confirmed the above findings during the exit conference on 01-08-2025 at 1:46 PM.

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 lack of Hematology calibration records, the Horiba Hematology User Manual, and an interview with Practice Manager (PM) and Testing Personnel 1 (TP1), the laboratory failed to ensure the Hematology analyzer was calibrated per the manufacturer's instructions. No calibration documentation was available for review from the date of the last survey, 12-22-2022, through the date of the current survey, 01-08-2025. The findings include: 1. A review of Hematology calibration records revealed Horiba Micros 60X had no calibration performed and documented from 2022-2025. 2. A review of the Horiba ABX Micros 60 Hematology Analyzer User Manual, under the Quality Assurance, 2.1 General Recommendations for Calibration revealed, "The calibration on Horiba Medical instruments is an exceptional procedure, which must be carried out particularly in case of certain technical interventions ..." 3. 2. The PM and TP1 confirmed the above findings during the exit conference on 01-08-2025 at 1:46 PM.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:
Based on a review of the personnel records and an interview with the Practice Manager (PM) and Testing Personnel 1 (TP1), the Technical Consultant (TC) failed to ensure three of the three Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report) had competency assessments which included the six minimal regulatory requirements. The surveyor noted six of the six requirements were missing from the annual and semi-annual competencies. The findings include: 1. A review of

the 2023-2024 personnel records revealed the TP competency assessment for Hematology specialty had no documentation of six of the six minimal regulatory requirements. The surveyor noted the six missing requirements are as follows: (1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing, (2) Monitoring the recording and reporting of test results, (3) Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. (4) Direct observation of performance of instrument maintenance and function checks. (5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (6) Assessment of problem-solving skills. 2. The PM and TP1 confirmed the above findings during the exit conference on 01-08-2025 at 1:46 PM.