

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0860475	(X3) Date Survey Completed 02/02/2024
Name of Provider or Supplier Cajah's Mountain Medical Associates	Street Address, City, State 1766 Connelly Springs Road, Lenoir, NC	
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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.</p> <p>This STANDARD is not met as evidenced by: Based upon review of 2022 and 2023 calibration verification records and review of the laboratory's policies and procedures, the laboratory failed to perform calibration verification activities that included a minimal value near the lower limit of the laboratory's reportable range for 5 of 18 analytes performed on the Alfa-Wasserman instrument. Findings: Review of the November 2023 calibration verification records revealed the following: 1. Five concentrations of linearity materials were used to</p>

assess the reportable range of Total Protein: 2.23, 4.70, 7.18, 9.65 and 12.13 g/dL. 2. Five concentrations of linearity materials were used to assess the reportable range of Sodium: 78.63, 109.2, 139.76, 170.33 and 200.9 mmol/L. 3. Four concentrations of linearity materials were used to assess the reportable range of Chloride: 68.3, 108.4, 148.5 and 188.6 mmol/L. 4. Five concentrations of linearity materials were used to assess the reportable range of Calcium: 1.76, 5.11, 8.46, 11.81 and 15.16 mg/dL. 5. Five concentrations of linearity materials were used to assess the reportable range of Albumin: 1.7, 3.26, 4.83, 6.4 and 7.96 g/dL. Review of the laboratory's procedure manual revealed an "ACE Axcel Reportable Range" chart. The laboratory utilizes the manufacturer's ranges as their reportable ranges. The following ranges were observed on the chart: 1. The reportable range for Total Protein is 0.4-14.0 g/dL 2. The reportable range for Sodium is 40-205 mmol/L 3. The reportable range for Chloride is 5-200 mmol/L 4. The reportable range for Calcium is 0.4-15 mg/dL 5. The reportable range for Albumin is 0.3-7 g/dL

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based upon review of 2022 and 2023 Coulter quality control records, review of September 2023 corrective action logs, review of the 9/7/23 patient test log and interview with the TC (Technical Consultant) on 2/2/24, the laboratory failed to take corrective actions to ensure that patient care was not adversely affected when 17 patients were tested and their results reported after 2 of 3 quality control values performed outside of the acceptable range for platelet on 9/7/23. Findings: Review of the laboratory's September 2023 quality control records for the Coulter instrument revealed the following: 1. The laboratory performs three levels of quality control daily for all analytes: abnormal low, normal, and abnormal high. 2. On 9/7/23, the normal and abnormal high quality control values performed outside of the acceptable range for platelet. Review of September 2023 corrective action documentation for the Coulter instrument revealed the following: 1. "New lot" was documented on 9/7/23. 2. There was no documentation of the performance or implementation of a new lot of quality controls on this date. Review of the 9/7/23 patient test log revealed that 17 patients (103202316, 103189967, 103201290, 103182261, 103175745, 103177428, 103180594, 103181627, 103183607, 103186859, 103188481, 103191655, 103198407, 103199425, 103204488, 103207065, 103202860) were tested on the Coulter instrument on that date. In interview at approximately 12:00 p.m., the TC confirmed that platelet results for the 17 patients performed on 9/7/23 have not been reviewed to ensure patient care was not adversely affected.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to

ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based upon review of 2022 and 2023 Quality Assessment records and interview with TP#1 (Testing Personnel) on 2/2/24, the laboratory failed to assess the accuracy for 3 of 4 calculations performed by the LIS (Laboratory Information System). Findings: Review of 2022 and 2023 Quality Assessment records revealed the following: 1. The laboratory assessed the accuracy of LDL (low-density lipoprotein) calculations performed by the LIS in 2022 and 2023. 2. There was no documentation that the laboratory assessed the accuracy of the following calculations performed by the LIS: a. GFR (glomerular filtration rate) b. Anion gap c. BUN(blood urea nitrogen) /Creatinine ratio In interview at approximately 1:00 p.m., TP#1 stated she checks the accuracy of only LDL calculations annually.

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based upon review of 2022 and 2023 Coulter quality control records, review of the laboratory's policies and review of the laboratory's 9/7/23 patient test log, TP#3 (Testing Personnel) failed to adhere to the laboratory's quality control policy. Findings: Review of the laboratory's September 2023 quality control records for the Coulter instrument revealed the following: 1. The laboratory performs three levels of quality control daily for all analytes: abnormal low, normal, and abnormal high. 2. On 9/7/23, the normal and abnormal high quality control values performed outside of the acceptable range for platelet. Review of the Corrective Actions policy states the following in Section "Quality Control": "When controls do not perform as expected, we will.... If controls are still not acceptable, we will notify the director that the system is inoperable...." Review on the laboratory's 9/7/23 patient test log revealed that platelet results were reported for 17 patients (103202316, 103189967, 103201290, 103182261, 103175745, 103177428, 103180594, 103181627, 103183607, 103186859, 103188481, 103191655, 103198407, 103199425, 103204488, 103207065, 103202860) when two of three quality control values performed outside of the acceptable range.