

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1018905	(X3) Date Survey Completed 05/01/2025
Name of Provider or Supplier Family Medicine Associates Of Lincoln County, Pllc	Street Address, City, State 1531 North Aspen Street, Lincolnton, 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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of the laboratory's critical value list, review of 2023, 2024, and 2025 American Proficiency Institute (API) proficiency testing (PT) records, and interview with testing personnel (TP) 5/1 /25, the laboratory failed to test the proficiency sample in the same manner as patient specimens are routinely tested. Findings: Review of the laboratory's Proficiency Testing policy revealed "The surveys are handled in the same manner as patient samples.....Raw data printouts of PT samples must be kept with the PT records." Review of the laboratory's "Critical Value List" revealed the following ALERT VALUE parameters for Glucose: less than 50 milligrams/deciliter (mg/dl) or greater than 500 mg/dl. The "Critical Value List" stated to repeat testing for all specimens with results occurring within the listed parameters. Review of the 2025 API Chemistry Core 1st event proficiency testing records revealed that sample CH-04 contained a glucose level of 46 mg/dl, which was critically low according to the laboratory's Critical Value list. There was no repeat testing documentation found with the results for PT sample CH-04. During an interview at approximately 2:30 p.m., TP #1 verified there was no documentation of repeat testing, and confirmed the repeated critical results should be stapled to the original results.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems</p>

activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

This STANDARD is not met as evidenced by:

Based on review of 2024 and 2025 Coulter AcT diff hematology records, the absence of records, and interview with the technical consultant (TC) 5/1/25, the laboratory failed to retain calibration records for 2022 and 2023 for the Coulter AcT diff hematology analyzer. Findings: Review of 2024 and 2025 Coulter AcT diff calibration records revealed the instrument was calibrated 3/10/24, 10/28/24, and 5/1/25. There were no 2022 or 2023 calibration records available for review. During interview at approximately 11:15 a.m., the TC stated they were unable to locate 2022 and 2023 Coulter AcT diff calibration records.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the TC on 5/1/25, the laboratory failed to follow the established Competency Evaluation procedure found in the Quality Assessment Policy. Findings: Review of the Quality Assessment Policy revealed a Competency Evaluation procedure that stated, "Competency evaluations shall be the responsibility of the Lead Tech and/or Technical Consultant. The first year they shall be done every six months. Thereafter, they will be done on an annual basis.....All competencies will be documented." Review of personnel records for TP #1 revealed annual competency evaluations performed in December 2023 and December 2024, but there were no records of a competency evaluation in 2022. Review of personnel records for TP #3 revealed annual competency evaluations performed in December 2023 and December 2024, but there were no records of a competency evaluation in 2022. During an interview at approximately 10:45 a.m., the TC confirmed there were no other competency records available for review.