

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0311095	(X3) Date Survey Completed 07/23/2024
Name of Provider or Supplier Mountain Region Family Medicine, Pc	Street Address, City, State 444 Clinchfield Street, Suite 2300, Kingsport, TN	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance Plan, review of proficiency testing records, and staff interviews, the laboratory failed to follow its written policy for proficiency testing result review in 2023 and 2024. The findings include: 1. A review of the laboratory's Quality Assurance Plan revealed the following statement, "We will evaluate the results of our proficiency testing (PT) with the laboratory director within one week of their return from the PT program." 2. A review of the proficiency testing records for 2023 3rd Event and 2024 1st Event revealed missing final evaluation results for both events. 3. Interview on 07.23.2024 at 12:30 p.m. with the Technical Consultant and Lab Manager confirmed the above survey findings.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)</p>

The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the final patient test reports, the laboratory procedure manual, and staff interview, the laboratory procedure manual failed to include the established reference ranges currently in use by the laboratory. The findings include: 1. Observation of the laboratory on 07.23.2024 at 9:30 a.m. revealed the EPOC Blood Analysis System (serial #49701) in use for patient testing. 2. A review of the final patient test reports for two of two patients (#1 and #2) on 06.12.2024 and 06.13.2024, revealed the following reference ranges: "Sodium epoc": 134-145 mmol/L "Potassium epoc": 3.5-5.1 mmol/L "Ionized Ca epoc": 1.12-1.32 mmol/L "Chloride epoc": 98-108 mmol/L "CO2 epoc": 22-32 mmol/L "Glucose epoc": 70-99 mg/dL "BUN epoc": 8-23 mg/dL (Male) "BUN epoc": 5-18 mg/dL (Female) "Creatinine epoc": 0.8-1.3 mg/dL (Male) "Creatinine epoc": 0.5-1.0 mg/dL (Female) "eGFR Afr Amer": >59 mL/min/1.73m² "eGFR Non Afr Amer": >59 ml /min/1.73m² 3. Review of the EPOC laboratory procedure revealed the following ranges, which were different than the ranges on the final patient test report. Sodium: 138-146 mmol/L Potassium: 3.5-4.5 mmol/L Ionized Ca: 1.15-1.33 mmol/L Chloride: 98-107 mmol/L CO2: 23-30 mmol/L Glucose: 74-100 mg/dL BUN: 8-26 mg/dL Creatinine: 0.51-1.19 mg/dL eGFR: no reference range present 4. Interview with the technical consultant on 07.23.2024 at 12:30 p.m. confirmed that the manufacturer's reference ranges in the procedure manual had not been updated with the established reference ranges currently used by the laboratory. Word Key: Ca= Calcium CO2 = Carbon Dioxide BUN = Blood Urea Nitrogen eGFR = estimated Glomerular Filtration Rate Afr Amer = African American