

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0443241	(X3) Date Survey Completed 01/27/2025
Name of Provider or Supplier Central Family & Sports Medicine	Street Address, City, State 407 E Russell Ave, Building C, Warrensburg, MO	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's competency assessment policy, lack of competency evaluations for two of three testing personnel for 2024 and interview with the laboratory director, the laboratory failed to follow written policies for retaining competency assessment documentation. Findings: 1. The laboratory's competency assessment policy states, "File all records for a minimum of two years." 2. The laboratory did not have documentation to show the laboratory maintained personnel competency assessment records for testing personnel #1 and # 2 for 2024 3. Interview with the laboratory director on January 27, 2025 at 12:35 PM confirmed, the laboratory failed to follow the competency assessment policy.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Abbott I-Stat Chem 8+ procedure and interview with the laboratory director (LD) the laboratory failed show the current LD approved, signed and dated the procedure. Findings: 1. The laboratory did not have documentation to show the current LD approved, signed and dated the Abbott I-Stat Chem 8+</p>

procedure. 2. Interview on January 27, 2025 at 12:35 PM the LD confirmed the laboratory failed to ensure the Abbott I-Stat Chem 8+ procedure was approved, signed and dated by the current LD.

D5807

TEST REPORT

CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of reference ranges stated in the I-Stat laboratory procedure manual, two of two selected test reports, patient testing volume and interview with the laboratory director (LD), the laboratory failed to ensure test reports included pertinent reference intervals (normal values) as determined by the laboratory. Seven of seven reference ranges listed on the laboratory test report differed from those stated in the procedure manual. Findings: 1. Review of patient test report # 21389393 and # 21559831 revealed normal values for seven analytes did not match those stated in the procedure manual. Patient test reports Procedure Manual Sodium 136-145 Sodium 138-146 Potassium 3.5-5.1 Potassium 3.5-4.9 Chloride 98-107 Chloride 98-109 Glucose 65-99 Glucose 70-105 BUN 10-20 BUN 8-26 Creatinine 0.6-1.1 Creatinine 0.6-1.3 CO2 23-31 CO2 24-29 2. The laboratory provided estimated annual patient chemistry test volume of 576 tests. 3. Interview with the LD on January 27, 2025 at 12:35 PM confirmed the laboratory failed to ensure pertinent reference ranges as determined by the laboratory, were included on patient test reports.