

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1021708	(X3) Date Survey Completed 05/24/2024
Name of Provider or Supplier Family Medical Group Of Texarkana, Llp	Street Address, City, State 2101 Galleria Oaks, Texarkana, TX	
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
D0000	An onsite survey conducted 05/24/2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory verification documentation, laboratory chemistry test menu, and confirmed in interview the laboratory failed to ensure that patient reference ranges were appropriate for the laboratory's patient population with the implementation of the new chemistry analyzer put into use for patient testing starting May 2023. The findings included: 1. Review of the laboratory provided implementation binders for the Abbott Ci4100 chemistry analyzer put into use May 2023 did not include documentation of a reference range verification for chemistry testing performed on the analyzer before it was put into use for patient testing. 2. Review of the laboratory test menu included the following 35 chemistry analytes: Albumin, alkaline phosphatase, ALT, AST, Bilirubin direct, bilirubin total, urea, calcium, total T4, free T4, TSH, Ferritin, PSA, Vitamin D 25-OH, SHBG, creatin, potassium, total protein, sodium, triglycerides, uric acid, UIBC, PSA, Vitamin B-12, chloride, cholesterol, HDL, CO2, Creatinine, glucose, iron, magnesium, A1C, 2Gen testosterone, Microalbumin 3. In an interview on 5/24/2024 at 13:20, in the office, testing personnel (TP) 1 confirmed the laboratory did not verify patient reference</p>

ranges were appropriate on the new Abbott Ci4100 Chemistry analyzer before it was put into use.