Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475385	03/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab-Warren Clinic Mcalester	1401 East Van Buren, Mcalester, OK	

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	The recertification survey was performed on 03/26/2021. The findings were reviewed with the labortory director and technical supervisor/general supervisor/testing person#1 during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with a standard-level deficiency cited.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and technical consultant #2, the laboratory failed to ensure the demonstrated reportable ranges were utilized for a one of one new test method. Findings include: (1) On 03/26/2021 at 02: 30 pm, technical consultant #2 stated to the surveyor two iSTAT 1 analyzers (serial number 353689 and serial number 353107), using the Chem 8+ cartridge (includes the analytes Sodium, Potassium, Ionized Calcium, Total CO2, Creatinine, BUN, Chloride, and Glucose), were available for patient testing on 03/02/2020; (2) The surveyor reviewed the performance specification records for the analyzers. The reportable range were verified as follows: (a) Sodium (i) The laboratory verified 99-177 mmol/L (ii) The manufacturer's reportable range was 100-180 mmol/L (b) Potassium (i) The laboratory verified 2.3-7.9 mmol/L (ii) The manufacturer's reportable range was 2.0-9.0 mmol/L (c) Ionized Calcium (i) The laboratory verified 0.34-2.32 mmol/L (ii) The manufacturer's reportable range was 0.25-2.50 mmol/L (d) Total CO2 (i) The

	laboratory verified 11-42 mmol/L (ii) The manufacturer's reportable range was 5-50 mmol/L (e) Creatinine (i) The laboratory verified 0.2-17.3 mg/dL (ii) The manufacturer's reportable range was 0.2-20.0 mg/dL (f) Chloride (i) The laboratory verified 61-127 mmol/L (ii) The manufacturer's reportable range was 65-140 mmol/L (g) Glucose (i) The laboratory verified 27-597 mg/dL (ii) The manufacturer's reportable range was 20-700 mg/dL (3) The surveyor reviewed the performance specification with the laboratory director and asked if there was documentation to prove the laboratory was utilizing the reportable ranges that had been demonstrated by the laboratory; (4) On 03/26/2021 at 03:45 pm, the laboratory director stated the laboratory was using the manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory.