Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2149955	01/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab - Owasso	11610 N 137th E Ave, Collinsville, 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 01/08/2026. Standard-level deficiencies were cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, and interview with the laboratory director and testing person #2, the laboratory failed to ensure test kits were stored following the manufacturer's instructions for one of three types of i-STAT 1 cartridges observed. Findings include: (1) On 01/08/2026 at 09:20 am, the laboratory director and testing person #2 stated the laboratory performed Creatinine testing using the Abbott i-STAT 1 analyzer and Creatinine cartridge; (2) Observation of the laboratory on 01/08/2026 at 09:20 am identified one Creatinine cartridge (lot # A25322) on the laboratory counter which had not been dated; (3) Review of the manufacturer's instructions on the package identified "Room Temperature Storage" which stated the cartridges are stable up to 14 days at room temperature (18-30 degree Centigrade or 64-86 degrees Fahrenheit); (4) The findings were reviewed with the laboratory director and testing person #2 who stated on 01/08/2026 09:30 am, the cartridge had not been dated with the room temperature expiration date. 48517 Based on observation, a review of manufacturer's package insert and interview with testing person #2 and the laboratory director, the laboratory failed to ensure one of one bottle of Multistix 10 SG urine test strips and one of one K2 EDTA Vacutainer tube were stored as required by the manufacturer. Findings include: MULTISTIX 10SG TEST STRIPS (1) Observation of the laboratory on 01/08/2026 at 09:25 am, identified the following: (a) One bottle of Multistix 10 SG urine test strips, with the lid removed and

	no testing person(s) in the immediate vicinity of the strips. (2) Observation of the laboratory on 01/08/2026 at 09:50 am (thirty-five minutes later), identified the same bottle of test strips remained open on the countertop; (3) Observation of the laboratory, and interview with testing person #2 and the laboratory director on 01/08 /2026 at 11:44 am (one hour and 54 minutes later), identified the same bottle of test strips remained open on the countertop. (4) A review of the manufacturer's package insert stated, "Replace the cap immediately and tightly after removing the reagent strip". (5) Interview with testing person #2 on 01/08/2026 at 11:44 am confirmed the laboratory was not replacing the cap on the test strips between patient use. K2 EDTA VACUTAINER TUBE (1) Observation of the laboratory freezer (temperature maintained at -4 to -20 degrees Celcius)and interview with the laboratory director on 01/08/2026 at 10:40 am, identified the following: (a) One Vacutainer K2, EDTA tubes, lot # 5101429, storage temperature of 4-25 degrees Celsius. (2) Interview with the laboratory director on 01/08/2026 at 10:40 am confirmed the tube was being stored below the manufacturer's stated temperature requirements.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) 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. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, record review, and interview with the laboratory director, the laboratory failed to follow written procedures that explained the current practices and procedures being performed in the laboratory for CBC (complete blood count) controls for one of one month reviewed. Findings include: (1) On 01/08/2025 at 01:00 pm, the laboratory director stated that the laboratory performed CBC testing using the Beckman Coulter DXH520 for the following analytes, WBC (white blood cell), RBC (red blood cell), HGB (hemoglobin), HCT (hematocrit), MCV (mean cell volume), MCHC (mean corpuscular hemoglobin concentration), RDW (red blood cell distribution width), PLT (Platelets), and MCV (mean corpuscular volume); (2) A review of the laboratory's written policy titled, "Evaluation of Quality Control on Beckman Coulter Instrumentation Procedure" revealed the following: (a) "Reject run if - Any one control or combination of controls is outside the acceptable limits but within +/- 3 SD from the mean (Westgard 2-2s). (3) A review of QC (quality control) logs from 12/01 /2025 through 12/31/2025 identified the following: (a) RBC - 2-2s QC failures on 12/2 /2025 at 09:15 am and 04:55 pm, where no corrective action was documented as performed; (b) WBC - 2-2s QC failures on 12/08/2025 at 07:44 am and 04:11 pm, where no corrective action was documented as performed; (c) PLT - 2-2s QC failures on 12/10,11,12,15,16,18,19,22,23,27,28/2025, where no corrective action was documented as performed. (4) The records were reviewed with the laboratory director who stated on 01/08/2026 at 1:00 pm, the policy was not followed for Westgard 2-2s QC failures.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and

	other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, and interview with the laboratory director and testing person #2, the laboratory failed to ensure iSTAT 1 cartridges had not exceeded their room temperature expiration date for one of three cartridge types observed. Findings include: (1) On 01/08/2026 at 09:20 am, laboratory director and testing person #2 stated the laboratory performed B-type natriuretic peptide (BNP) testing using the Abbott BNP cartridge and Abbott i-STAT 1 analyzer; (2) Observation of the laboratory on 01/08/2026 at 09:20 am identified one Abbott BNP cartridge (Lot #F25203) stored at room temperature, without documentation of when they were removed from refrigeration; (3) Review of the manufacturer's storage requirements showed the following: (a) The cartridges were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The cartridges were stable at room temperature (18-30 degrees C) for 14 days. (4) Interview with the laboratory director and testing person #2 on 01/08/2026 at 09:30 am confirmed the cartridge had been placed at room temperature without a method to monitor if it exceeded the manufacturer's room temperature expiration date.