Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0672302	12/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab-Warren Clinic Elm Urgent Care	2950 South Elm Place, Suite 115, Broken Arrow, 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 12/05/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director during an exit conference performed at the conclusion of the survey.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on a review of the procedure manual and interview with the laboratory director, the laboratory failed to ensure that one of one written procedure no longer in use had been discontinued. Findings include: (1) A review of the manual titled, "Procedures" identified the following procedure: (a) "Complete Blood Counts, Abbott Cell-Dyn Emerald" (2) The procedure was reviewed with the laboratory director who stated on 12/05/2023 at 03:15 pm, the laboratory discontinued the use of the Cell-Dyn Emerald analyzer in April 2023 and the procedure should have been indicated as discontinued.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 and interview with the laboratory supervisor, the laboratory failed to ensure an expired material was not available for use. Findings include: (1) On 12/05/2023 at 11:15 am, the laboratory supervisor stated CBC (Complete Blood Count) testing was performed using the Beckman Coulter DxH 520 hematology analyzer; (2) Observation of the laboratory on 12/05/2023 at 11:25 am identified one box of 10L DxH 500 Series Diluent that had exceeded the manufacturer's expiration date as follows: (a) Lot #0086170 with an expiration date of 10/29/2023 (3) Interview with the laboratory supervisor on 12/05/2023 at 11:23 am confirmed the expired materials were available for use.
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, the laboratory failed to ensure the performance specification data had been evaluated prior to implementing the new testing for one of one new test methods introduced into the laboratory. Findings include: (1) On 12/05/2023 at 03:20 pm, the laboratory director stated the laboratory began using the Cepheid GeneXpert DX analyzer to perform COVID-19, Influenza A, Influenza B, and RSV (Respiratory Syncytial Virus) testing on 10/23/2023; (2) A review of the performance specification records for the new test system identified no evidence the data had been signed and dated as approved by the laboratory prior to putting into use for patient testing; (3) Interview with the laboratory director on 12/05/2023 at 05:08 pm confirmed there was no documentation to prove the performance specification data had been reviewed and approved by the laboratory prior to putting into use. 47979 Based on a review of records and interview with the laboratory director and laboratory supervisor, the laboratory failed to utilize the demonstrated reportable range for one of one new test method. Findings include: (1) On 12/05/2023 at 11:15 am, the laboratory supervisor stated the laboratory began performing CBC (complete blood count) testing using the Beckman Coulter DxH 520 hematology analyzer on 05/23/2023; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable range: (a) Hemoglobin - 0.00 -19.40 g/dL (3) An interview with the laboratory director on 12/05 /2023 at 3:00pm confirmed the laboratory was using the following manufacturer's reportable range instead of the range that had been demonstrated by the laboratory: (a) Hemoglobin - 0.20 - 25.00 g/dL
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system

	performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory director, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for two of two function checks performed during the review period of January 2022 through the current date. Finding include: (1) On 12/05/2023 at 11:30 am, the technical consultant stated the following: (a) Urine sediment examinations were performed; (b) The specimens were processed in Horizon Mini VES centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes. (2) A review of the centrifuge function check policy titled, "Centrifuge Function Check Procedure" stated the following: (a) "To ensure the centrifuge is functioning properly in an acceptable standardized manner, its speed and timer is be checked annually"; (b) "Acceptable Limits Urine Centrifugation" - Horizon 642 VES is equivalent to 1500 rpm +/- 25 rpm; 5 minutes +/- 5 sec". (3) A review of centrifuge function check records during 2022 through the current date identified the centrifuge speed and/or timer had not been checked at the speed and times urines were processed for two of two checks performed as follows: (a) 10/29/2022 - The speed had been checked at 2511 rpm and the timer had been checked at 10 minutes; (b) 07/05/2023 - The speed had been checked at 3328 rpm. (4) The records were reviewed with the laboratory director who stated on 12/05/2023 at 04:00 pm, the laboratory had not followed their policy.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure one of two IQCP's (Individualized Quality Control Plan) included the required components; failed to perform quality control as stated in the IQCP; and failed to ensure data supported the (QC) Quality Control frequency as defined in the IQCP for one of two test systems. Findings include: REQUIRED COMPONENTS OF IQCP (1) On 12/05/2023 at 03:20 pm, the laboratory director stated the following: (a) The laboratory began using the Cepheid GeneXpert DX analyzer to perform COVID-19, Influenza A, Influenza B, and RSV (Respiratory Syncytial Virus) testing on 10/23/2023; (b) An IQCP had been developed for the test system. (2) A review of the IQCP identified a Risk Assessment and QA (Quality Assessment) plan had not been included in the IQCP; (3) The records were reviewed with the laboratory director who stated on 12/05/2023 at 04:45 pm, a Risk Assessment and QA plan had not been

	included in the IQCP. QUALITY CONTROL (1) Interview with the laboratory director on 12/05/2023 at 03:20 pm and a review of the QCP (Quality Control Plan) for the above IQCP identified the QCP required QC (quality control) testing be performed on a monthly basis; (2) A review of QC records for the testing performed from October 2023 through November 2023 identified no documentation to prove QC testing had been performed as stated in the QCP for 13 of 13 days of patient testing (QC had not been documented as performed since 10/05/2023); (3) The records were reviewed with the laboratory director who stated on 12/05/2023 at 04:55 pm, QC had not been documented as performed as shown above. DATA DID NOT SUPPORT QC FREQUENCY (1) A review of the QCP supporting documentation for the above IQCP identified the laboratory had not tested external QC materials to support the QC frequency of monthly as required by the QCP. Positive and negative QC materials for COVID-19, Influenza A, Influenza B, and RSV had been tested for 12 days (not at least 30-31 days); (2) The records were reviewed with the laboratory director who stated on 12/05/2023 at 04:55 pm, the QC had not been tested for at least 30 -31 days.