Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0672302	10/26/2021
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 10/26/2021. The findings were reviewed with the laboratory director and technical consultant #2 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to retain records for at least 2 years for 2 of 3 months. Findings include: (1) On 10/26/2021 at 10:30 am, technical consultant #2 stated to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Abbott Cell-Dyn Emerald analyzer; (b) Three levels (Low, Normal, and High) of Cell-Dyn 18 Plus quality control materials were tested each day that patient testing was performed on the analyzer. (2) The surveyor reviewed Levy Jenning records between January 2021 through March 2021 with the following identified: (a) Records between 02/01 /2021 and 03/31/2021 were not available for the high level of quality control material. (3) The surveyor ask technical consultant #2 if the records between 02/01/2021 and 03 /31/2021 could be located; (4) Technical consultant #2 stated on 10/26/2021 at 03:41 pm records between 02/01/2021 and 03/31/2021 for CBC testing could not be located. Therefore, the surveyor could not determine if the records for the above months had been monitored and evaluated for shifts and trends for 2 of 3 months.
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, written policies, and interview with the laboratory director the laboratory failed to follow written quality control policies for 1 of 20 months. Findings include: (1) On 10/26/2021 at 10:30 am, technical consultant #2 stated the following to the surveyor: (a) PT/INR (Prothrombin Time/International Normalized Ratio) testing was performed in the laboratory using the PT/INR cartridge and two iSTAT analyzers (serial number 307964 and 302678); (b) An IQCP (Individualized Quality Control Plan) had been developed for the above test systems. (2) The surveyor reviewed the IQCP that had been developed for the test system. The QCP (Quality Control Plan) portion of the IQCP required 2 levels of external quality control materials be tested once every 30 days; (3) The surveyor reviewed QC (quality control) records for 20 months (January 2020 through August 2021) and identified the laboratory failed to follow the written QCP of performing quality control testing every 30 days. Quality control testing had not been performed as follows: (a) PT/INR (i) Between 06/03/2020 and 08/23/2020 (4) The findings were reviewed with technical consultant #2 who stated on 10/26/2021 at 03:40 pm, the laboratory had not performed quality control testing as required by the QCP.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with technical consultant #2, the laboratory failed to evaluate the relationship between test results using two different analyzers at least twice a year. Findings include: (1) On 10/26 /2021 at 10:30 am, technical consultant #2 stated to the surveyor PT/INR (Prothrombin Time/International Normalized Ratio) testing was performed using two iSTAT 1 analyzers (serial numbers 307964 and 302678); (2) The surveyor reviewed the written procedure titled, "Six Month ISTAT Comparison" which stated,"Every 6 months all non-waived POC iSTAT instruments on site are compared/correlated with each other."; (3) The surveyor reviewed the iSTAT comparison records between 08/02 /2019 through the day of the survey (10/26/2021) but could not locate the comparison between between the analyzers for PT/INR testing; (4) The surveyor asked technical consultant #2 if the relationship between the analyzers for PT/INR testing had been

	evaluated twice annually during the review period of 08/02/2019 through the day of the survey (10/26/2021). Technical consultant #2 stated on 10/26/2021 at 03:30 pm the relationship between the analyzers had not been evaluated during the review period.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records, written policy and procedure, and interview with technical consultant #2, the laboratory failed to perform corrective action for a quality control failure. Findings include: (1) On 10/26/2021 at 10:40 am, technical consultant #2 stated the following to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing using the Abbott Cell-Dyn Emerald analyzer; (b) Three levels of Cell-Dyn 18 Plus quality control materials were tested each day that patient testing was performed on the analyzer. (2) The surveyor reviewed the written policy titled, "Complete Blood Counts (CBC, CBCM, HEMOGRAM, HGB, HCT, PLATELET COUNT, WBC COUNT) Abbott Cell-Dyn Emerald" under the section titled, "Quality Control" stated, "To ensure the performance of the Emerald's analytical system, three levels of commercial Quality Control (L, N, and H) are to be performed at the beginning of the day after start up and prior to running patient samples;" and "9. If results falls outside acceptable limits repeat and if out, try another vial from the same lot. Do not report any patient results until all QC is acceptable."; (3) On 10/26/2021, the surveyor reviewed QC (Quality Control) records between 01/01/2021 through 01/13/2021 and identified the following QC failures: (a) Low Level (Lot# 0349) MPV (Mean Platelet Volume) tested on 01/13/2021 at 04:26 pm failed with no documented corrective action. The value obtained was 10.9 fLwith an acceptable range of 8.5-10.7 fL; (b) Normal Level (Lot# 0349) MPV tested on 01/13/2021 at 04:28 pm failed with no documented corrective action. The value obtained was 9.5 fLwith an acceptable range of 8.3-9.1 fL. (4) The surveyor reviewed the records with technical consultant #2 who stated on 10/26/2021 at 03:25 pm corrective action had not been taken and documented.