Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0474846	11/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab-Warren Clinic Vinita	715 N Foreman St, Vinita, 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 11/13/2020. The findings were reviewed with the laboratory director/technical consultant at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1210; D5016: Routine Chemistry 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to ensure the requirements were met for the subspecialty of Routine Chemistry. Findings include: (1) The laboratory failed to demonstrate the performance specification of reportable range for the Chem 8+ cartridge using the iSTAT 1 analyzer. Refer to D5421; (2) The laboratory failed to perform two levels of control materials each day of patient chemistry testing using the Chem 8+ cartridge with the iSTAT analyzer for 29 of 29 days of patient testing. Refer to D5447; (3) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to review and evaluate proficiency testing results for 1 of 23 events. Findings include: (1) On 11/13/2020, the surveyor reviewed 2018, 2019, and 2020 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2020 Hematology Event (i) Hematocrit - 3 of 5 results exhibited a negative bias (aa) Sample HEM-06 - SDI of -2.6 (bb) Sample HEM-07 - SDI of -2.5 (cc) Sample HEM-08 - SDI of -2.6 (ii) Hemoglobin - 4 of 5 results exhibited a negative bias (aa) Sample HEM-06 - SDI of -2.0 (bb) Sample HEM-07 - SDI of -2.0 (cc) Sample HEM-08 - SDI of -2.3 (dd) Sample HEM-10 - SDI of -3.2 (iii) Red Blood Cells - 3 of 5 results exhibited a negative bias (aa) Sample HEM-06 - SDI of -2.2 (bb) Sample HEM-07 - SDI of -2.0 (cc) Sample HEM-10 - SDI of -2.8 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory director/technical consultant. The laboratory director/technical consultant stated on 11 /13/2020 at 11:00 am the biases had not been addressed.
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 laboratory director/technical consultant, the laboratory failed to demonstrate the performance specification of reportable range for 2 of 2 new test methods. Findings include: (1) On 11/13/2020 at 09:45 am, the laboratory director/technical consultant stated the laboratory obtained a replacement Abbott iSTAT analyzer (serial number 440549) on 11/01/2019 to perform the following: (a) PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge; (b) Chemistry testing using the Chem 8+ cartridge (includes the analytes Sodium, Potassium Chloride, Ionized Calcium, CO2, Glucose, BUN, Creatinine). (2) The surveyor reviewed the performance specification records for the analyzer but could not locate records to prove the laboratory had verified the manufacturer's reportable range; (3) The surveyor asked laboratory director/technical consultant if any additional testing had been performed to verify the reportable range prior to reporting patient results. The laboratory director/technical consultant stated on 11/13/2020 at 04:10 pm the reportable range had not been verified.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director/technical consultant, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 2 of 8 months. Findings include: (1) On 11/13/2020 at 09:45 am, the laboratory director/technical consultant stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Cell-Dyn Emerald analyzer; (2) The surveyor reviewed the manufacturer's weekly maintenance requirements from the operator's manual. Under the section "Preventative Maintenance Schedule" stated: (a) "Weekly Maintenance" (i) Bleach Cleaning - "Cleaning the system with a bleach solution is performed weekly or as needed when a parameter is repeatedly rejected." (3) The surveyor then reviewed maintenance records for 8 months (January 2020 through August 2020). There was no evidence the weekly maintenance had been performed: (a) Between 01 /23/2020 and 02/04/2020; (b) Between 03/25/2020 and 04/08/2020. (4) The surveyor reviewed the records with the laboratory director/technical consultant, who stated on 11/13/2020 at 04:20 pm, the weekly maintenance had been performed but not documented as required.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director/technical consultant, the laboratory failed to perform calibration procedures as required by the manufacturer for 2 of 2 years. Findings include: (1) On 11/13/2020 at 09:45 am, the laboratory director/technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed using the Cell-Dyn Emerald analyzer; (2) The surveyor reviewed the manufacturer's instructions, contained in the operator's manual which were as follows: (a) Section 6 titled, "When to Calibrate" described the schedule and procedure for calibration of the Cell-Dyn Emerald analyzer and stated, "Calibration verification criteria include:" (i). "At least every six months" (3) The surveyor reviewed records from January 2019 through the day of the survey (11/13/2020). There was no evidence the calibration procedure had been performed between during the review period; (4) The surveyor reviewed the findings with the laboratory director/technical consultant who stated on 11/13/2020 at 04:12 pm, the calibration procedure had not been performed as indicated above.
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/technical consultant the laboratory failed to follow written quality control policies for 3 of 23 months. Findings include: (1) On 11/13/2020 at 09:45 am, the laboratory director 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 the iSTAT analyzer (serial number 440549). (d) An IQCP (Individualized Quality Control Plan) had been developed for the above test system. (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 23 months (January 2019 through November 2020) 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 10/29/2019 and 12/11/2019 (ii) Between 03/25/2020 and 06/03/2020 (4) The findings were reviewed with the laboratory director/technical consultant who stated on 11/13/2020 at 02:45 pm, the laboratory had not performed quality control testing as required by the QCP.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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/technical consultant, the laboratory failed to perform two levels of control materials each day of patient chemistry testing using the Chem 8+ cartridge with the iSTAT analyzer for 29 of 29 days of patient testing. Findings include: (1) On 11/13/2020 at 01:45 pm, the laboratory director/technical consultant stated the laboratory performed chemistry testing using the iSTAT analyzer and Chem 8 + cartridge (includes the analytes Sodium, Potassium Chloride, Ionized Calcium, CO2, Glucose, BUN, Creatinine); (2) The surveyor asked the laboratory director/technical consultant if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory director/technical consultant stated an IQCP had not been written. Therefore, the surveyor determined two levels of QC (quality control) materials must

	be performed each day of patient testing; (3) The surveyor reviewed QC and patient testing records from February 2020 through March 2020. The review indicated negative and positive QC materials had not been performed 29 of 29 days of patient testing reviewed; (4) The surveyor reviewed the records with the laboratory director /technical consultant who stated on 11/13/2020 at 04:11 pm two levels of QC materials had not been performed each day of patient testing; (5) The following patient chemistry testing had been performed when two levels of QC materials had not been tested: (a) Patient #20O034VI0007 - testing performed on 02/03/2020; (b) Patient #20O035VI0004 - testing performed on 02/04/2020; (c) Patient #20O036VI0003 - testing performed on 02/05/2020; (d) Patient #20O037VI0002 - testing performed on 02/06/2020; (e) Patient #20O038VI0001 - testing performed on 02/07/2020; (f) Patient #20O041VI0008 - testing performed on 02/10/2020; (g) Patient #20O042VI0004 - testing performed on 02/11/2020; (h) Patient #20O042VI0015 - testing performed on 02/12/2020; (i) Patient #20O044VI0017 - testing performed on 02/13/2020; (j) Patient #20O045VI0001 - testing performed on 02/14/2020; (k) Patient #20O048VI0007 - testing performed on 02/18/2020; (l) Patient #20O050VI0009 - testing performed on 02/19/2020; (m) Patient #20O052VI0011 - testing performed on 02/21/2020; (n) Patient #20O055VI0001 - testing performed on 02/24/2020; (o) Patient #20O057VI0006 - testing performed on 02/26/2020; (p) Patient #20O058VI0012 - testing performed on 02/27/2020; (q) Patient #20O062VI0003 - testing performed on 03/02/2020; (r) Patient #20O063VI0006 - testing performed on 03/03/2020; (s) Patient #20O064VI0007 - testing performed on 03/04/2020; (t) Patient #20O066VI0005 - testing performed on 03/06/2020; (u) Patient #20O069VI0005 - testing performed on 03/09/2020; (v) Patient #20O070VI0008 - testing performed on 03/10/2020; (w) Patient #20O072VI0001 - testing performed on 03/12/2020; (x) Patient #20O076VI0001 - testing performed on 03/16/2020; (y) Patient #20O077VI0005 - testing performed on 03/17/2020; (z) Patient #20O078VI0005 - testing performed on 03/18/2020; (aa) Patient #20O080VI0008 - testing performed on 03/20/2020; (bb) Patient #20O085VI0002 - testing performed on 03/25/2020; (cc) Patient #20O085VI0004 - testing performed on 03/26/2020.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written procedures, and interview with the laboratory director/technical consultant, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to demonstrate the performance specification of reportable range for 1 of 1 analyzer. Refer to D5421; (b) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 2 of 8 months. Refer to D5429; (c) The laboratory failed to perform calibration procedures as required by the manufacturer for 2 of 2 years. Refer to D5437; (d) The laboratory failed to follow written quality control policies for 3 of 23

	months. Refer to D5445; (e) The laboratory failed to perform two levels of control materials each day of patient chemistry testing using the Chem 8+ cartridge with the iSTAT analyzer for 29 of 29 days of patient testing. Refer to D5447.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure performance specification procedures for a new test system was adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 6 of 27 events. Refer to D6016; (3) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (4) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory director failed to ensure performance specification procedures for a new test system was adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the performance specification of reportable range had been demonstrated for a new test method. Refer to D5421.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as

	required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 6 of 27 events. Findings include: (1) On 11/13/2020, the surveyor reviewed 2018, 2019, and 2020 proficiency testing records. It was identified for 6 of 23 events, the attestation statements had been signed approximately 2-4 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Microbiology Second event of 2019 - The samples had been tested on 07/02/2019 and the attestation statement had not been signed by the laboratory director until 09/17/2019; (b) Microbiology First event of 2020 - The samples had been tested on 02/13/2020 and the attestation statement had not been signed by the laboratory director until 06/10/2020; (c) Chemistry Core First event 2020 - The samples had been tested on 02/03/2020 and the attestation statement had not been signed by the laboratory director until 09/22/2020; (d) Chemistry Core Third event 2020 - The samples had been tested on 09/02/2020 and the attestation statement had not been signed by the laboratory director until 11/05/2020; (e) Hematology /Coagulation First event 2020 - The samples had been tested on 03/23/3030 and the attestation statement had not been signed by the laboratory director until 06/10/2020; (f) Hematology/Coagulation Second event 2020 - The samples had been tested on 07 /24/2020 and the attestation statement had not been signed by the laboratory director until 11/05/2020; (2) The surveyor reviewed the findings with the laboratory director /technical consultant and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens. The laboratory director/technical consultant stated on 11/13/2020 at 04:28 pm the attestation statements had not been signed in a timely manner as shown above.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to perform two levels of control materials each day of patient chemistry testing using the Chem 8+ cartridge with the iSTAT analyzer for 29 of 29 days of patient testing. Refer to D5447.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written procedures, and interview with the laboratory director/technical consultant, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated

	specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 3 of 5 competency evaluations performed. Findings include: (1) On 11/13/2020, the surveyor reviewed records for 5 persons performing moderate complexity testing in 2018, 2019 and 2020. The records showed the evaluations for 3 of 5 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 07/11/2019 and 11/15/2020 evaluations had been performed by testing person #1 (this person had earned an Associates Degree in Science); (b) Testing Person #3 - The 09/06/2019 and 11/15/2020 evaluations had been performed by testing person #1; (c) Testing Person #4 - The 09/06/2019 and 11/15/2020 evaluations had been performed by testing person #3. (2) The surveyor reviewed the records with the laboratory director /technical consultant explained that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory director/technical consultant stated to the surveyor on 11/13/2020 at 10:10 am, the above evaluations had been performed by an individual who did not meet the educational qualifications of a technical consultant.