Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2149955	03/27/2024
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 initial survey was performed on 03/27/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the incoming technical consultant at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the incoming technical consultant, the laboratory failed to ensure a proficiency testing attestation statement had been signed by the laboratory director or designee for one of three Hematology/Coaguation events reviewed in 2023. Findings include: (1) A review of the first, second, and third 2023 Hematology/Coagulation proficiency testing records identified the following for one of three events: (a) Third 2023 Event - The attestation statement had not been signed by the laboratory director or designee. (2) The records were reviewed with the incoming technical consultant who stated on 03/27/2024 at 11:55 am, the attestation statement had not been signed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the incoming technical consultant, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of three Hematology events reviewed in 2023. Findings include: (1) A review of 2023 Hematology proficiency testing records identified the following for one of three events: (a) Third 2023 Event (i) Wet Prep - One of one result (VA-03) stated, "See Data Summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (2) The records were reviewed with the incoming technical consultant who stated on 03/27/2024 at 11:55 am, the laboratory had not evaluated the result that was not graded by the proficiency testing program.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of policy and procedure manual and interview with the incoming technical consultant and testing person #2, the laboratory failed to ensure the procedure manual had been approved and signed by the laboratory director. Findings include: (1) On 03/27/2024 at 09:05 am, the incoming technical consultant and testing person #2 stated the laboratory began performing CBC (Complete Blood Count) testing using the Beckman Coulter DxH 520 analyzer on 05/15/2023; (2) A review of the "General Procedures" manual identified no evidence it had been signed and dated as approved by the laboratory director; (3) The manual was reviewed with the incoming technical consultant who stated on 03/27/2024 at 01:06 pm, the policy and procedure manual had not been approved and signed by the laboratory director.
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 incoming technical consultant, the laboratory failed to demonstrate the performance specifications for two of eight new test methods. Findings include: (1) On 03/27/2024 at 01:00 pm, the incoming technical consultant stated the following test kits were put into use for patient testing in February 2023: (a) Medline hCG Combo Pregnancy Test Cassette using serum samples (b) Remel Colorslide II Mononucleosis test (2) A review of records for the test kits identified no evidence the performance specifications (accuracy, precision, etc, as applicable for the test systems) had been demonstrated; (3) Interview with the incoming technical consultant on 03/27/2024 at 01:10 pm confirmed the performance specifications, as applicable, had not been demonstrated prior to putting the test kits into use for patient testing. 47979 Based on a review of records and interview with the incoming technical consultant and testing person #2, the laboratory failed to utilize the demonstrated reportable ranges for one of one new test method. Findings include: (1) On 03/27/2024 at 09:00 am, the incoming technical consultant and testing person #2 stated the laboratory began performing Chloride, Glucose, and Potassium testing using the CHEM 8+ cartridge and two i-STAT1 analyzers (Serial Numbers 430179 and 430190) in January 2023; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Serial Number 430179: (i) Chloride - 60 - 126 mmol/L (ii) Glucose - 24 - 583 mg/dL (iii) Potassium - 2.3 - 7.9 mmol/L (b) Serial Number 430190: (i) Chloride - 60 - 126 mmol /L (ii) Glucose - 24 - 570 mg/dL (iii) Potassium - 2.3 - 7.9 mmol/L (3) Interview with the incoming technical consultant on 03/27/2024 at 03:33 pm confirmed the laboratory was using the following manufacturer's reportable ranges: (a) Chloride - 65 - 140 mmol/L (b) Glucose - 20 - 700 mg/dL (c) Potassium - 2.0 - 9.0 mmol/L
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 incoming technical consultant, the laboratory failed to ensure one of two IQCP's (Individualized Quality Control Plan) included the required components. Findings include: (1) On 03/27/2024 at 11:20 am, the incoming technical consultant stated the laboratory began using the iSTAT 1 analyzer to perform the following testing in February 2023 and an IQCP had been developed for the test system: (a) Glucose, BUN (Urea Nitrogen), Sodium, Potassium, Chloride, TCO2, Creatinine, and Ionized Calcium using the Chem 8+ cartridge; (b) PT /INR (Prothrombin Time/International Normalized Ratio) using the PT/INR cartridge; (c) BNP (B-Type Natriuretic Peptide) using the BNP cartridge; (d) Troponin I using the cTnI cartridge. (2) A review of the IQCP identified a QA (Quality Assessment) plan had not been included in the IQCP; (3) The records were reviewed with the incoming technical consultant who stated on 03/272024 at 04:15 pm, a QA plan had not been included in the IQCP.

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (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 incoming technical consultant, the laboratory failed to perform a negative and positive control material seven of 28 days of patient SARS-CoV-2, Influenza A, Influenza B, and RSV (Respiratory Syncytial Virus) testing during two of four months reviewed in 2023 and 2024. Findings include: (1) On 03/27/2024 at 01:40 pm, the incoming technical consultant stated the following: (a) The laboratory began performing RSV (Respiratory Syncytial Virus), Influenza A, Influenza B, and SARS CoV-2 testing using the Cepheid Gene Xpert DX analyzer on 10/23/2023; (b) An IQCP (Individualized Quality Control Program) had not been developed for the test system (the laboratory was in the process of developing an IQCP). (2) A review of QC (Quality Control) and patient testing records for testing performed in October 2023, November 2023, January 2024, and February 2024 identified negative and positive QC materials had not been documented as performed each day of patient testing for seven of 19 days. The specific days of patient testing were: (a) 10/23,24,26,30/2023 (b) 11/08,16,28/2023 (4) The records were reviewed with the incoming technical consultant who stated on 03/27/2024 at 03:50 pm, negative and positive QC materials had not been documented as performed as stated above.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the incoming technical consultant, the laboratory director failed to ensure that personnel performing moderate complexity testing had the appropriate training for three of five persons. Findings include: (1) On 03/27/2024 at 10:00 am, the incoming technical consultant stated the laboratory began performing patient testing in February 2023; (2) A review of personnel records identified the following for three of five testing persons performing testing when the laboratory became operational: (a) Testing Person #3 - There was no documentation of initial training. A semi annual competency evaluation had been documented as performed on 09/07/2023; (b) Testing Person #4 - There was no documentation of initial training. A semi annual competency evaluation had been

	documented as performed on 09/01/2023; (c) Testing Person #5 - There was no documentation of initial training. A semi annual competency evaluation had been documented as performed on 09/19/2023. (2) The records were reviewed with the incoming technical consultant who stated on 03/27/2024 at 10:35 am, there was no documentation to prove the testing persons had been initially trained to perform moderate complexity testing in this laboratory.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the incoming technical consultant, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of five testing persons performing testing from February 2023 through the current date. Findings include: (1) A review of personnel records for five persons performing moderate complexity testing identified the following for one of five persons: (a) Testing Person #2 - The initial training was completed on 05/24/2023. There was no evidence a semiannual evaluation had been performed (no competency performed to date). (2) The records were reviewed with the incoming technical consultant who stated on 03/27/2024 at 10:35 am, a semiannual competency evaluation had not been performed.