Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0474552	02/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab - Warren Clinic Springer	6160 South Yale Avenue, Tulsa, 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 02/22/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and technical consultant at the conclusion of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the technical consultant, the laboratory failed to follow their policy for performing clinical consultant competencies based on the position responsibilities as listed in Subpart M for one of one clinical consultant. Findings include: (1) A review of the competency assessment policy and interview with the technical consultant on 02/22/2023 at 01:05 pm identified that competencies for the clinical consultant, based on the position responsibilities were required to be performed annually; (2) A review of personnel records for competency assessments performed during 2021 and to date in 2023 identified no evidence of competencies performed after 01/22/2021; (3) The findings were reviewed with the technical consultant who stated on 02/22/2023 at 01:20 pm the competencies had not been documented as performed.
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 procedure manuals and interview with the technical consultant, the laboratory failed to ensure two of two procedure manuals had been approved, signed, and dated by the laboratory director. Findings include: (1) A review of two procedure manuals identified no evidence they had been signed and dated as approved by the laboratory director. Examples of policies and procedures contained in the manuals were: (a) One manual titled, "Procedures" contained procedures such as: (i) "Routine urinalysis Procedure and Guidelines" (ii) "Wet Prep Procedure" (iii) "Mono Test Serum" (b) A second manual titled, "Procedures" contained policies and procedures such as: (i) "Critical Result Reporting" (ii) "Quality Assurance Program" (iii) "iSTAT General Procedure" (2) The manuals were reviewed with the technical consultant who stated on 02/22/2023 at 01:25 pm, the two procedure manuals had not been signed and dated as approved by the laboratory director.
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 technical consultant and testing person #5, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for one of three instruments reviewed from January 2022 through the current date. Findings include: (1) On 02/22/2023 at 10:05 am, the technical consultant stated the Hardy Diagnostics Quick Slide Hemapro slide stainer was used to stain patient blood smears to perform manual differentials; (2) A review of the Hemapro "Users Operation Manual" on page 22 under the title, "Tubing Kit Replacement" stated, "The orange pump tubes and the clear lines with color coded cannulas must be replaced every six (6) months to ensure the Hemapro is operating under normal operating conditions"; (3) A review of records from 01/01/2022 through the current date identified no documentation to prove the tubing kit replacement procedure had been performed before or after 07/29/2022; (4) The records were reviewed with the technical consultant and testing person #5. Both stated on 02/22/2023 at at 02:40 pm the maintenance procedure had not been performed as stated 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 and interview with the technical consultant, the laboratory failed to ensure one of one IQCP (Individualized Quality Control Plan) included the required components; and failed to perform quality control as stated in the IQCP for four of four cartridge types. Findings include: REQUIRED COMPONENTS OF IQCP (1) On 02/22/2023 at 11:00 am, the technical consultant stated the following were performed using three iSTAT 1 handheld analyzers (serial numbers 410170, 304488, and 347704); (a) BUN, Ionized Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, and Sodium testing using the Chem 8+ cartridge; (b) Troponin I testing using the cTnI cartridge; (c) BNP (B-type Natriuretic Peptide) testing using the BNP cartridge; (d) PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge (only performed on Serial Numbers 304488 and 347704). (e) An IQCP had been developed for the test systems. (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 technical consultant who stated on 02/22/2023 at 03:45 pm, a QA plan had not been included in the IQCP. QUALITY CONTROL (1) A review of the QCP (Quality Control Plan) for the above IQCP identified the QCP (Quality Control Plan) required QC (quality control) testing be performed on a monthly basis; (2) A review of QC records for the testing performed from January 2022 through December 2022 identified no documentation to prove QC testing had been performed as stated in the QCP for four of four cartridge types as follows: (a) Chem 8+ (i) Serial Number 410170 - QC not documented as performed: (aa) Between 07/19/2022 and 09/16/2022 (bb) After 11/24/2022 (ii) Serial Number 304488 - QC not documented as performed: (aa) Between 05/28/2022 and 07/13/2022 (bb) Between 07/19/2022 and 09/16/2022 (iii) Serial Number 347704 - QC not documented as performed: (aa) Between 05/28/2022 and 07/13/2022 (bb) Between 07/19/2022 and 09/16/2022 (b) Troponin I (i) Serial Number 410170 - QC not documented as performed: (aa) Between 07/19/2022 and 09/19/2022 (bb) After 11/30/2022 (ii) Serial Number 304488 - QC not documented as performed: (aa) Between 05/20/2022 and 07/19/2022 (bb) Between 07/19/2022 and 09/19/2022 (cc) After 11/30/2022 (iii) Serial Number 347704 - QC not documented as performed: (aa) Between 05/20/2022 and 07/19/2022 (bb) Between 07/19/2022 and 09/19/2022 (cc) After 11/30/2022 (c) BNP (i) Serial Number 410170 - QC not documented as performed: (aa) Between 07/23/2022 and 09/25/2022 (bb) Between 09/25/2022 and 11/01/2022 (ii) Serial Number 304488 - QC not documented as performed: (aa) Between 07/23/2022 and 09/25/2022 (bb) Between 09/25/2022 and 11/01/2022 (iii) Serial Number 347704 - QC not documented as performed: (aa) Between 07/23/2022 and 09/25/2022 (bb) Between 09/25/2022 and 11/01/2022 (c) PT/INR (i) Serial Number 304488 - QC not documented as performed: (aa) Between 07/07/2022 and 09/05/2022 (ii) Serial Number 347704 - QC not documented as performed: (aa) Between 07/07/2022 and 09/05/2022 (3) The records were reviewed with the technical consultant who stated on 02/22/2023 at 04:15 pm, QC had not been documented as performed as shown above.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for

	acceptability. This STANDARD is not met as evidenced by: Based on a review of patient reports and interview with the laboratory director and technical consultant, the laboratory failed to ensure patient test reports included the address of the laboratory location where the test was performed for three of three patient reports. Findings include: (1) On 02/22/2023 at 10:05 am, the technical consultant stated the following were performed: (a) CBC (Complete Blood Count) testing using the Cell Cyn Ruby analyzer; (b) Urinalysis testing using the Clinitek Advantus analyzer; (c) PT/INR (Prothrombin Time/International Normalized Ratio) testing using the iSTAT 1 analyzer and the PT/INR cartridge. (2) A review of patient reports identified the address of the laboratory location where the test was performed was not included for three of three reports: (a) CBC testing reported on 02/22/2023 at 03:23 pm; (b) Urinalysis testing reported on 02/22/2023 at 02:39 pm; (c) PT/INR testing reported on 02/11/2023 at 04:20 pm. (3) The reports were discussed with the laboratory director and technical consultant. Both stated on 02/22/2023 at 05:50 pm, the reports did not include the address of the laboratory where the testing had been performed.