Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2089970	04/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab-South Memorial	10506 S Memorial Dr, 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 04/15/2022. The findings were reviewed with the technical consultant 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 the technical consultant, the laboratory failed to retain records for at least two years for two of nine months. Findings include: (1) On 04/15/2022 at 10:30 am, the technical consultant stated the following: (a) Routine CBC (Complete Blood Count) was performed on the Abbott 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) A review of the Levy Jenning records between May 2020 through January 2021 showed the following: (a) Quality Control records between 11/13/2020 and 01/01/2021 were not available. (3) The records were reviewed with the technical consultant, The technical consultant stated on 04/15/2022 at 03:40 pm records between 11/13/2020 and 01/01/2021 for CBC testing could not be located. Therefore, there was no evidence the records for the above months had been monitored and evaluated for shifts and trends for two of nine months.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the

	laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, written procedures, and interview with the technical consultant, the laboratory failed to follow competency assessment procedures for one of eight testing persons. Findings include: (1) On 04/15/2022 at 10:30 am, the technical consultant stated the following: (a) Routine CBC (Complete Blood Count) was performed on the Abbott Emerald analyzer; (b) Chemistry testing was performed using the CG8+ cartridge on the Abbott iSTAT analyzer; (c) PT/INR (Prothrombin Time/International Normalized Ratio) testing was performed using the PT/INR cartridge on the Abbott iSTAT analyzer; (d) Serum pregnancy testing was performed using the Beckman Icon 25 kit; (e) Mononucleosis testing was performed using the Remel Colorslide II kit. (2) A review of the laboratory's written procedure manual under the section titled, "EMPLOYEE ASSESSMENT FOR COMPETENCY" stated: (a) "1. Competency evaluation is ongoing with review of results. However, competency will formally be addressed at semiannual and annually from initial training date.". (3) A review of the personnel records revealed the following: (a) Testing person #2 (i) The initial training evaluation had been documented as performed on 05/15/2020; (ii) The semiannual evaluation had been documented as performed on 11/13/2020; (iii) The annual evaluation had been documented as performed on 11/03/2021 (18 months after the initial training). (4) The findings were reviewed with the technical consultant. The technical consultant stated on 04/15/2022 at 12:10 pm, the competency assessment procedure had not been followed as indicated above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure an analyzer was stored as required by the manufacturer for two of two months. Findings include: (1) On 04/15/2022 at 10: 30 am, the technical consultant stated the following: (a) Routine CBC (Complete Blood Count) was performed on the Abbott Emerald analyzer;(2) A review of the manufacturer's environmental requirements for the analyzer required the relative humidity be maintained within a range of 20-80%; (3) A review of the laboratory humidity records from January 2022 through February 2022 revealed the humidity readings were less than 20% for two of two months as follows: (a) January 2022 - 13 of 31 humidity readings were documented as less than 20% (days 2,3,5,6,7,19,21,22,23,25,26,29,30); (b) February 2022 - 10 of 28 humidity readings was documented as less than 20% (days 3,4,5,12,13,18,23,24,25,26). (4) The records

	were reviewed with the technical consultant who stated on 04/15/2022 at 02:20 pm the laboratory humidity had been maintained below 20% as indicated above.