Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2089970	03/01/2018
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 findings were reviewed with technical consultant #1 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 technical consultant #1, the laboratory failed to ensure a proficiency testing attestation statement had been signed by the analyst. Findings include: (1) During the survey, surveyor #1 reviewed 2016 and 2017 proficiency testing records. The following was identified for 1 of 6 Chemistry proficiency testing events: (a) First 2016 Chemistry Group 2 Event - The attestation statement had not been signed and dated by the analyst. (2) Surveyor #1 reviewed the records with technical consultant #1, who stated the attestation statement had not been signed and dated by the analyst.
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, manufacturer's instructions, and interview with technical consultant #1, the laboratory failed to retain quality control records for at least 2 years. Findings include: (1) At the beginning of the survey, technical consultant #1 stated to the surveyors CBC (Complete Blood Count) testing was performed using the Cell-Dyn Emerald; (2) Later during the survey, surveyor #2 reviewed quality control records (lot #7240) with the following identified: (a) October 2017 records were not available (3) The surveyors ask technical consultant #1 if the quality control records for October 2017 could be located; (4) Technical consultant #1 stated the October 2017 quality control records for CBC testing could not be located. The surveys could not determine if the quality control records for the above month had been monitored and evaluated.
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 technical consultant #1, the laboratory failed to evaluate proficiency testing results that had not been evaluated by the proficiency testing program. Findings include: (1) During the survey, surveyor #1 reviewed 2016 and 2017 proficiency testing records. The review indicated the laboratory did not address results that were not evaluated by the proficiency testing program for 2 of 6 Hematology events as follows: (a) Third 2016 Event (i) Urobilinogen - 1 of 1 result had not been evaluated by the proficiency testing program. Under "Expected Result" it stated, "See Data Summary." There was no evidence the laboratory reviewed the data summary to evaluate their result. (b) Second 2017 Event (i) Urobilinogen - 1 of 1 result had not been evaluated by the proficiency testing program. Under "Expected Result" it stated, "See Data Summary." There was no evidence the laboratory reviewed the data summary to evaluate their result. (2) Surveyor #1 reviewed the records with technical consultant #1, who stated the laboratory had not evaluated the results that were not graded by the proficiency testing program.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)

	Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written procedure, and interview with technical consultant #1, the laboratory failed to ensure control procedures monitored the accuracy and precision of the analytic process. Findings include: (1) At the beginning of the survey, technical consultant #1 stated to the surveyors: (a) CBC (Complete Blood Count) testing was performed on the Abbott Cell-Dyn Emerald analyzer; (b) Three levels (Low, Normal and High) of Abbott Cell-Dyn 18 Plus Control quality control (QC) materials were performed each day of patient testing. (2) Later during the survey, surveyor #2 reviewed the following: (a) The laboratory's written quality control procedure which stated,"Follow Procedure to establish acceptable +/- 2SD ranges". Technical consultant #1 explained to the surveyors each new lot of QC materials were tested 20 times to establish a mean and 2 SD (standard deviations) range; (b) Package insert, which stated "The MEAN RANGE does not represent standard deviations (SD)". (3) The surveyors reviewed the records for 3 lot numbers of quality control materials used from 12/16/17 to date. It was identified that, although the laboratory had established their own means and ranges for each lot number, they did not utilized their calculated averages as their means and limits of acceptability. Examples were as follows: (a) Low control (lot #L7324), normal control (lot #N7324) and high control (lot #H7324) put into use 12 /16/17 to date; (i) RBC (red blood cell) (aa) Low control (i) The laboratory established a mean of 2.23, but the mean of 2.22 had been used to evaluate quality control results; (ii) The laboratory established a lower limit of 2.14, but the lower limit of 2.09 had been used to evaluate quality control results; (iii) The laboratory established an upper limit of acceptability was 2.32, but the upper limit of 2.37 had been used to evaluate quality control results. (ii) Platelet (aa) Normal control (i) The laboratory established mean was 215, but the mean 207 had been used to evaluate quality control results; (ii) The laboratory established lower limit of acceptability was 195, the lower limit of 172 had been used to evaluate quality control results; (iii) MCHC (mean corpuscular hemoglobin concentration) (aa) High control (i) The laboratory established mean was 32.1, but the mean 32.4 had been used to evaluate quality control results; (3) The surveyors reviewed the findings with technical consultant #1 who stated the laboratory did not follow the laboratory's quality control policy to ensure control procedures monitored the accuracy and precision for CBC testing.
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 a patient test report and interview with technical consultant #1, the laboratory failed to ensure patient test reports included the name and address of the laboratory location. Findings include: (1) On the second day of the survey, the surveyors reviewed a patient test report as follows: (a) PT/INR (Prothombin Time /International Normalized Ratio) testing was performed with the results reported on 03 /01/2018. (2) The surveyors identified that the name of the laboratory on the reports was "OL SO Memorial Urgent", which did not match the name on the Clia certificate. The name on the Clia certificate was "Saint Francis Lab-South Memorial". In addition, the report did not include the address of the laboratory location; (3) The surveyors reviewed the reports with technical consultant #1, who stated the name on the report did not match the name on the Clia certificate, and the laboratory address was not included on the report.