Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2089970	10/15/2019
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 10/15/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director/technical consultant #2 and technical consultant #1 at the conclusion of the survey.
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, observation, and interview with technical consultant #1, the laboratory failed to demonstrate the performance specification of reportable range for a new analyzer. Findings include: (1) At the beginning of the survey, the surveyor observed the laboratory and identified two i-STAT 1 analyzers (SN (Serial Number) #373250 and SN #400564). Technical consultant #1 stated the i-STAT 1 analyzer, SN #400564 was put into use on 06/28/18 and both analyzers were used to perform the following patient testing: (a) BNP (Brain Natriuretic Peptide) with the BNP test cartridge (b) PT/INR (Prothrombin Time/International Normalized Ratio) using the PT /INR cartridge (c) Troponin I using the cTnI cartridge (2) The surveyor reviewed the implementation records for the i-STAT 1 analyzer, SN #400564. There was no documentation the laboratory had demonstrated the reportable range for each test cartridge type prior to putting the analyzer into use for patient testing; (3) The surveyor reviewed the findings with technical consultant #1 who stated to the

	surveyor the laboratory failed to demonstrate the reportable range for each cartridge type.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with technical consultant #1, the laboratory failed to take corrective action necessary to ensure the reporting of accurate and reliable patient test results. Findings include: (1) At the beginning of the survey, technical consultant #1 stated to the surveyor: (a) Hemogram testing (i.e., WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, MCV (Mean Corpuscular Volume), MCHC (Mean Corpuscular Hemoglobin Concentration), RDW (Red Cell Distribution Width), MPV (Mean Platelet Volume) and Platelet Count) was performed using the Cell Dyn Emerald analyzer; (b) Three levels (Low, Normal, and High) of Cell Dyn 18 Plus QC (Quality Control) materials were tested each 8 hours of patient testing; (c) To clarify the laboratory's QC policy, the surveyor contacted technical consultant #1 following the survey on 12/18/19. Technical consultant #1 stated to the surveyor the laboratory reported patient results if 2 of the 3 QC levels were within the acceptable limits. (2) The surveyor reviewed the laboratory's written "Evaluation of Quality Control on Cell Dyn Instrumentation Procedure," which included the following instructions: (a) Reject run: (i) If more than one control is outside of the established acceptable +/- 2SD (Standard Deviation) limits; (ii) Any control is more than 3SD from the mean; (iii) Any one control or combination of controls is outside the acceptable +/- 2SD limits but within +/- 3SD from the mean on two consecutive runs (b) If run is rejected: (i) Verify control is in date and there is no sign of contamination or spoilage (ii) Rerun control and if results are within acceptable limits, patient testing may be performed (iii) Use a fresh bottle of control and test. If results are within acceptable limits, patient testing may be performed (iv) Replace reagents. Retest control. If QC results are still unacceptable, contact the supervisor and send samples to main hospital for testing until problem is resolved (v) Document all actions taken on QC review and maintenance logs (3) The surveyor reviewed QC records (i.e. QC report, Levey Jennings graphs, assay sheets, and QC Review Log) from 10/01/18 through the day of the survey. The surveyor identified for 1 (Lot #9098, High) of the 15 lot numbers of QC materials used during the review period, the laboratory failed to follow its written policy when QC results were outside the acceptable 2SD (449 - 477) but within 3SD (478 - 506) on two consecutive runs, or greater than 3SD from the mean for the analyte Platelet. In addition, there was no evidence corrective action had been taken. The findings follow: (a) 06/11/19: (i) 07:55 AM: The result of 494 exceeded 2SD but was within 3SD (ii) 03:15 PM: The result of 544 exceeded 3SD (iii) 05:20 PM: The result of 544 exceeded 3SD (iv) 05:21 PM: The result of 488 exceeded 2SD but was within 3SD (v) 05:23 PM: The result of 485 exceeded 2SD but was within 3SD (vi) 05:25 PM: The result of 498 exceed 2SD but was within 3SD (vii) 05:26 PM: The result of 484

	exceeded 2SD but was within 3SD (b) 06/12/19: (i) 08:21 AM: The result of 501 exceeded 2SD but was within 3SD (ii) 08:25 AM: The result of 486 exceeded 2SD but was within 3SD (iii) 01:04 PM: The result of 496 exceeded 2SD but was within 3SD (iv) 01:05 PM: The result of 511 exceeded 3SD (v) 01:07 PM: The result of 502 exceeded 2SD but was within 3SD (vi) 01:08 PM: The result of 487 exceeded 2SD but was within 3SD (vii) 01:09 PM: The result of 479 exceeded 2SD but was within 3SD (4) The surveyor reviewed the findings and the written policy again. Since the laboratory's Platelet results for the high QC level were greater than 3SD, or between 2SD to 3SD on 14 consecutive runs, the surveyor determined the laboratory failed to follow their policy for taking corrective actions to ensure accurate and reliable patient test results were reported; (5) The surveyor reviewed the findings with technical consultant #1 who stated to the surveyor the laboratory failed to ensure corrective action, as listed in the policy was taken for QC results that were outside 3SD and when any one control was outside the acceptable limits but within 2SD to 3SD on two consecutive runs.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the technical consultant failed to evaluate testing personnel to assure they were competent in performing test procedures and able to report test results accurately and proficiently. Findings include: (1) At the beginning of the survey, technical consultant #1 stated to the surveyor the laboratory performed vaginal wet prep examinations; (2) The surveyor reviewed the Laboratory Personnel Report (Form CMS-209) completed by the laboratory prior to the survey. The form listed 3 testing persons who would perform vaginal wet prep examinations: (a) Technical consultant #1 (b) Laboratory director/technical consultant #2 (c) Testing person #4 (3) The surveyor reviewed the 2018 and 2019 competency evaluations. There was no evidence 2 of the 3 testing persons listed above had been evaluated during the review period for testing performance and ability to report test results accurately and proficiently for vaginal wet prep examinations: (a) Technical consultant #1: (i) Annual competency performed 03/23/18 did not include an evaluation of vaginal wet prep examination performance; (ii) Annual competency performed 03/20/19 did not include an evaluation of Vaginal wet prep examination performance. (b) Laboratory director/technical consultant #2: (i) The annual competency performed on 09/06/19 did not include an evaluation of vaginal wet prep examination performance. (4) The surveyor reviewed the findings with technical consultant #1 and the laboratory director/technical consultant #1 who stated to the surveyor there was no documentation the persons listed above had been evaluated for testing performance of vaginal wet prep examinations.
D6054	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 annually, after the first year.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the technical consultant failed to ensure evaluations were performed for all testing persons performing moderate complexity testing at least annually. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for 7 persons who were trained and had performed testing or would perform testing during 2018 and to date in 2019: (a) Technical consultant #1 (b) Laboratory director/technical consultant #2 (c) Testing person #1 (d) Testing person #2 (e) Testing person #3 (f) Testing person #4 (g) Testing person #5 (2) There was no evidence annual evaluations had been performed for 1 of the 7 testing persons (testing person #5) after 08/16/16. The surveyor asked technical consultant #1 if testing person #5 currently performed testing at the laboratory. Technical consultant #1 stated testing person #5 would perform testing if the lab was short staffed and that testing person #5 had performed patient testing on 04/06/19; (3) The surveyor asked technical consultant #1 if there were competency evaluations available from 2017, 2018, and to date in 2019 for testing person #5. Technical consultant #1 stated to the surveyor annual competencies had not been performed at this laboratory for testing person #5 during that time period.