

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2066492	(X3) Date Survey Completed 07/07/2021
Name of Provider or Supplier Saint Francis Lab - Sf Cancer Center	Street Address, City, State 11212 E 48th Street, 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 07/07/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory services technical manager and the lead technologist at the conclusion of the survey.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>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).</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the lead technologist and laboratory services technical manager, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for 1 of 6 Hematology events reviewed. Findings include: (1) On 07/07/2021, the surveyor reviewed proficiency testing records for the second and third events in 2019; the first, second, and third events in 2020; and the first event in 2021. The following was identified for 1 of 6 Hematology events: (a) Third 2020 Hematology Event for Blood Cell Identification - 1 of 5 results (BCI-11) had not been graded by the proficiency testing program - Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the participant summary report to evaluate their result. (2) The surveyor reviewed the records with the lead technologist and laboratory services technical manager. Both stated on 07/07/2021 at 11:15 am, the laboratory had not evaluated the result that were not graded by the proficiency testing program.</p>

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, observation, and interview with the lead technologist and laboratory services manager, the laboratory failed to ensure materials were stored as required for 1 of 1 month. Findings include: (1) On 07/07/2021 at 13:10 pm, the surveyor observed the contents of the laboratory freezer. The following calibration verification materials were being stored in the freezer, with the manufacturer's storage requirements: (a) Validate Calibration Verification /Linearity GC4 Test kit, lot #14AK269200 - Used to perform calibration verification procedures for Direct Bilirubin and Total Bilirubin testing. The storage requirement was -10 to -25 degrees C (Centigrade); (b) Validate Calibration Verification/Linearity Test kit, lot #13AQ262200 - Used to perform calibration verification procedures for ALT (Alanine Aminotransferase), Alkaline Phosphatase, Amylase AST (Aspartate Aminotransferase), CK (Creatine Kinase), GGT (Gamma-Glutamyl Transferase), and LD (Lactate Dehydrogenase) testing. The storage requirement was -10 to -25 degrees C . (2) The surveyor reviewed temperature records from 06/01/2021 through 06/30/2021. The documented temperatures were colder than -25 C (the coldest temperature allowed for the materials) during 1 of 1 month as follows: (a) June 2021 - 30 of 30 documented temperatures were colder than -25 degrees C. The documented temperatures ranged from -28.5 to -33.7 degrees C. (3) The surveyor reviewed the records with lead technologist and laboratory services manager. Both stated on 07/07/2021 at 04:0901:30 pm, the freezer temperatures were unacceptable as shown 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 lead technologist and laboratory services technical manager, the laboratory failed to ensure two levels of quality control were performed as stated in the QCP portion of the IQCP for 14 of 15 days reviewed. Findings include: (1) On 07/07/2021 at 09:10 am, the lead technologist stated the following to the surveyor: (a) The laboratory used two iSTAT 1 analyzers

(serial numbers 374934 and 374527) to perform Ionized Calcium testing using the Chem 8+ Cartridge; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as effective on 01/01/2016) and identified the QCP (Quality Control Plan) required two levels of external QC (Quality Control) materials be performed monthly and with new lot numbers or shipments of test cartridges; (3) The surveyor then reviewed QC records for testing performed from 06/23/2020 through 06/07/2021 and identified for 14 of 15 days, instead of performing two levels of QC material (level 1 and level 3) on each analyzer monthly, the laboratory had tested one level of QC material on each analyzer (level 1 tested on serial number 374934 and level 3 tested on serial number 374527) monthly; (4) The surveyor reviewed the records with the lead technologist and laboratory services manager and asked if there was additional documentation to prove that two levels of QC material were being tested on each analyzer monthly. The lead technologist and laboratory services manager stated to the surveyor on 07/07/2021 at 12:00 pm, two levels of QC had not been tested on each analyzer monthly.

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 records and interview with the lead technologist and laboratory services technical manager, the laboratory failed to ensure patient test reports included the address of the laboratory location where the testing was performed. Findings include: (1) On 07/07/2021 at 09:05 am, the lead technologist stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Abbott Ruby analyzer; (b) CMP* testing was performed using the Abbott ci4100 analyzer. (2) The surveyor reviewed patient CBC and CMP reports (CBC testing performed on 07/07/2021 at 12:53 pm and CMP testing performed on 07/07/2020 at 11:43 am. The reports did not include the address of the laboratory location; (3) The surveyor reviewed the reports with the the lead technologist and laboratory services technical manager. Both stated on 07/07/2021 at 01:40 pm, the reports did not include the address of the laboratory location. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein