

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2089970	(X3) Date Survey Completed 02/07/2024
Name of Provider or Supplier Saint Francis Lab-South Memorial	Street Address, City, State 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 initial survey was performed on 02/07/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant and incoming technical consultant during an exit conference performed at the conclusion of the survey.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the hematology policy and procedure manual, and interview with the technical consultant and testing person #1, the laboratory failed to have a complete written procedure for one of one procedure reviewed. Findings include: (1)</p>

On 02/07/2024 at 11:30 am, the technical consultant and testing person #1 stated the following: (a) CBC (Complete Blood Count) testing was performed using the Beckman Coulter DxH 520 analyzer; (b) Three levels of QC (quality control) materials were tested daily; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of the procedure titled, "Complete Blood Counts (CBC, CBCM, Hemogram, Hgb, Hct, Platelet count, WBC count) - Beckman Coulter 500 Series" identified the procedure did not include the method to verify the stated values of new lot numbers of quality control materials before they were put into use; (3) The findings were reviewed with the technical consultant who stated on 02/07/2024 at 12:45 am, the CBC procedure had not included all of the required information.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the laboratory failed to perform calibration verification procedures at least once every six months for three of three iSTAT test systems during the review period of January 2023 through the current date. Findings include: (1) On 02/07/2024 at 03:00 pm, the laboratory director stated the following testing was performed using the iSTAT 1 analyzer (Serial Number 400564): (a) Sodium, Potassium, Chloride, CO₂, Ionized Calcium, Glucose, BUN, and Creatinine testing using the Chem 8+ cartridge; (b) BNP (B-Type Natriuretic Peptide testing using the BNP cartridge; (c) Troponin I testing using the cTnI cartridge. (2) A review of records from January 2023 through the current date identified no evidence calibration verification had been performed at least once every six months as follows: (a) Chem 8+ Cartridge - Not performed between 06/15/2023 and 02/06/2024 (b) BNP Cartridge - Not performed between 06/19/2023 and 02/06/2024 (c) Troponin I Cartridge - Not performed between 06/19/2023 and 02/06/2024. (3) The records were reviewed with the technical consultant who stated on 02/07/2024 at 03:50 pm, calibration verification procedures had not been performed every six months as shown above.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 and incoming technical consultant, the laboratory failed to perform a negative and positive control material 32 of 74 days of patient SARS-CoV-2, Influenza A, Influenza B, and RSV (Respiratory Syncytial Virus) testing reviewed from October through January 2024. Findings include: (1) On 02/07/2024 at 01:30 pm, the laboratory director stated the following: (a) The laboratory began performing SARS-CoV-2, Influenza A, Influenza B, and RSV testing using the Cepheid Gene Xpert DX analyzer on 10/23 /2023; (b) An IQCP (Individualized Quality Control Program) had not been developed for the test system and the laboratory was in the process of developing an IQCP). (2) A review of the test volume list completed for the survey identified the laboratory performed approximately 292 of each of the tests annually; (3) A review of QC (Quality Control) and patient testing records for testing performed from October through January 2024 identified negative and positive QC materials had not been documented as performed each day of patient testing for 32 of 74 days; (4) The records were reviewed with the technical consultant and incoming technical consultant who stated on 02/07/2024 at 02:15 pm, negative and positive QC materials had not been documented as performed as stated above.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 and testing person #1, the laboratory failed to verify the stated values of control materials before they were put into use for six of 18 lot numbers. Findings include: (1) On 02/07/2024 at 11:30 am, technical consultant and testing person #1 stated the following: (a) CBC (Complete Blood Count) testing was performed using the Beckman Coulter DxH 520 analyzer; (b) Three levels of QC (quality control) materials were tested daily; (c) The

manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of records identified no evidence the provided ranges were verified before the lot numbers were put into use for six of 18 lot numbers as follows: (a) Low control lot #352315011, Normal control lot #362315012, and High control lot #372315013 put into use on 08/07/2023; (b) Low control lot #352315211, Normal control lot #362315212, and High control lot #372315213 put into use on 09/06/2023. (3) The findings were reviewed with the technical consultant who stated on 02/07/2024 at 12:00 pm, the manufacturer's ranges had not been verified before the above lot numbers had been put into use.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant, the laboratory director failed to ensure the correct qualitative serum pregnancy methodology was reported for three of three proficiency testing events reviewed in 2023. Findings include: (1) On 02/07/2023 at 01:00 pm, the technical consultant stated the laboratory began using the Medline hCG Combo Pregnancy Test Cassette kit to perform qualitative serum pregnancy testing on 11/15/2022; (2) A review of 2023 Chemistry Core proficiency testing records identified the laboratory had selected the incorrect methodology of Beckman Coulter ICON hCG test kit for the first, second, and third events; (3) The records were reviewed with the technical consultant who stated on 02/07/2024 at 01:50 pm, the laboratory had reported the incorrect methodology for serum pregnancy testing for the three events in 2023.