

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D2144421	<b>(X3) Date Survey Completed</b> 07/29/2019
<b>Name of Provider or Supplier</b> Saint Francis Lab-Sand Springs Urgent Care	<b>Street Address, City, State</b> 102 S Main St, Sand Springs, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial survey was performed on 07/29/19 The findings were reviewed with technical consultant #2 and the laboratory technical services manager during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with technical consultant #2, the laboratory failed to have a written technical consultant and clinical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed personnel records for competency assessments performed during 2018 and 2019. There was no evidence competencies had been performed for the technical consultants and clinical consultant, based on their job responsibilities; (2) Surveyor #2 asked technical consultant #2 if a written policy to evaluate the technical consultant and clinical consultant based on job responsibilities was available. Technical consultant #2 stated a policy to evaluate the technical consultant and clinical consultant based on job responsibilities had not been written; and competencies had not been performed.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> 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,</p>

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.

This STANDARD is not met as evidenced by:

Based on a review of records, policy and procedure manual, and interview with technical consultant #2, the laboratory failed to ensure the procedure manual included reportable ranges that had been verified during the validation for the iSTAT 1 analyzer. Findings include: (1) At the beginning of the survey, technical consultant #2 stated to the surveyors the laboratory began using the iSTAT 1 analyzer (serial number 399311) and the CTNL (Troponin I) cartridge to perform Troponin I testing on 03/08/18; (2) Surveyor #2 reviewed validation records for the analyzer/cartridge combination, and identified the reportable range had been demonstrated as follows: (a) Troponin I - 0.34 - 26.17 (4) Surveyor #2 then reviewed the procedure manual and identified the laboratory had defined reportable ranges that were wider than the verified ranges: (a) Troponin I- 0 - 50 (5) Surveyor #2 reviewed the findings with technical consultant #2, who agreed the procedure manual did not include the reportable ranges for the above analyte that had been verified during the validation.

**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 technical consultant #2, the laboratory failed to ensure analyzers and blood collection tubes were stored as required by the manufacturer. Findings include: (1) During the survey, technical consultant #2 stated the following were stored at room temperature in the laboratory: (a) Abbott iSTAT analyzer (serial #399311) - used to perform PT /INR (Prothrombin Time/International Normalized Ratio) testing and Troponin I testing; (b) Abbott Cell-Dyn Emerald analyzer used to perform Hemogram testing; (c) BD Vacutainer K2 EDTA tubes (20 tubes Lot#9004574) were used for Hemogram

testing; (d) BD Vacutainer Buffered Sodium Citrate tubes (25 tubes Lot#9036654) were used for PT/INR testing; (e) BD Vacutainer Lithium Heparin tubes (3 tubes Lot#8345618) were used for Troponin I testing. (2) Later during the survey, surveyor #2 reviewed the manufacturer's environmental requirements for the analyzer and blood collection tubes. The manufacturer's required a room temperature as follows: (a) Abbott iSTAT- range of 16-30 degrees C (Celsius) (b) Abbott Cell-Dyn Emerald - 18-32 degrees C (b) BD Vacutainer blood collection tubes - range of 4-25 degrees C (3) Surveyor #2 asked technical consultant #2 for room temperature records from January 2018 through December 2018. Technical consultant #2 stated to surveyor #2 the room temperature had not been monitored.

**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, written procedure, and interview with technical consultant #2, the laboratory failed to demonstrate the performance specifications for new test methods; Findings include: **MONONUCLEOSIS TESTING** (1) At the beginning of the survey, technical consultant #2 stated to surveyor #2 the laboratory began using the Remel Color Slide II Mononucleosis kit to perform patient testing on Mononucleosis 03/08/18; (2) Surveyor #2 requested documentation from technical consultant #2 to substantiate the performance specifications (i.e., accuracy) had been demonstrated for the test kit before it had been put into use; (3) Technical consultant #2 stated to the surveyor, the performance specifications had not been demonstrated for the test kit. **PROTHROMBIN TIME/INTERNATIONAL NORMALIZED RATIO TESTING** (1) During the survey, technical consultant #2 stated the laboratory began performing PT/INR (Prothrombin Time/International Normalized Ratio) testing using the iSTAT 1 analyzer (serial number 399311) on 03/29/18; (2) Surveyor #2 reviewed the validation records for the analyzer. There was no documentation the reportable range had been demonstrated; (3) Surveyor #2 asked technical consultant #2 if the reportable range had been demonstrated. Technical consultant #2 stated to surveyor #2 the laboratory had not demonstrated the reportable range.

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
 Based on a review of records, policies and procedures and interview with technical consultant #2, the laboratory failed to define a function check protocol to ensure the centrifuge was functioning properly. Findings include: (1) At the beginning of the survey, technical consultant #2 stated to surveyor #2 urine sedimentation testing was performed in the laboratory. The specimens were processed in the Cardinal Health centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes; (2) Surveyor #2 reviewed the policy and procedure manual and could not locate a function check protocol that defined how often function checks (speed and timer checks) were to be performed on the centrifuge, including limits of acceptability; (3) Surveyor #2 asked technical consultant #2 if the laboratory had a function check protocol for the centrifuge. The technical consultant #2 stated to surveyor #2 the laboratory did not have a policy to check the speed and timer of the centrifuge.

**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 technical consultant #2, the laboratory failed to perform quality control as stated in the IQCP. Findings include: (1) At the beginning of the survey, technical consultant #2 stated the following to surveyor #2: (a) PT/INR (Prothrombin Time/International Normalized Ratio), BNP (Brain Natriuretic Peptide) and Troponin I testing were performed using the iSTAT 1 analyzer (serial number 399311); (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system and external QC (quality control) was performed each 30 days and with new lot numbers of cartridges. (2) Later during the survey, technical consultant stated to the surveyors the laboratory began performing PT/INR, BNP and Troponin I testing using the Abbott iSTAT1 analyzer on 03/29/18. (3) Surveyor #2 reviewed the IQCP (dated as effective on 03/29/18) and identified the QCP required positive and negative external QC (quality control) materials be performed once each month (i.e., approximately every 30 days) and with new lot numbers of test kits; (3) Surveyor #2 then reviewed the supporting documentation for the QCP and identified the following: (a) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (b) Positive and negative QC had been tested for 14 days (not at least 30 days). (4) Surveyor #2 reviewed the records with technical consultant #2 who stated QC had not been tested for at least 30 days.

**D5807**

**TEST REPORT**  
 CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on a review of a patient report and interview with technical consultant #2, the laboratory failed to provide therapeutic reference intervals for INR test results.

Findings include: (1) During the survey, the surveyor reviewed a patient INR (International Normalized Ratio) report for a patient who had testing performed on 05/14/18. It did not include a therapeutic range (range for treatment of venous thrombosis, treatment of pulmonary embolism, prevention of systemic embolism, etc); (2) The report was reviewed with technical consultant #2 who stated that INR reports did not include a therapeutic range.