Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2144421	08/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Saint Francis Lab-Sand Springs Urgent Care	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 08/20/2021. The findings were reviewed with the laboratory director and technical consultant during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1403; D6000: Laboratory Director
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to following the manufacturer's instructions for specimen transport and storage for 1 of 10 patient specimens. Findings include: (1) On 08/20/2021 at 10:55 am, the laboratory director stated the following to the surveyor: (a) The laboratory performed COVID-19 testing using the following instrument (i) Abbott ID Now - qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal swabs. (2) The surveyor reviewed the manufacturer's product insert titled, "ID NOW COVID-19" which stated, "For best performance, direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance, it is highly recommended the nasal, throat or nasopharyngeal swab is placed in a clean, unused tube labeled with patient information, and capped tightly at room temperature (15-30C) for up to one (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than one (1) hour delay occurs, dispose of sample. A new sample must be collected for testing."; (3) The surveyor reviewed 10 test reports for patients tested on 08/19/20201 and identified the following: (a) Patient Report #3 - Specimen

	collection date and time (08/19/20201 at 11:35 am) and the result date and time (08/19 /2021 at 01:38 pm); (4) The surveyor was not able to determine if the results had been interpreted within the one (1) hour after collection since the time between the specimen collection date and time and the result date and time was was 2 hours and 3 minutes; (5) The surveyor reviewed the records with the laboratory director. The laboratory director stated on 08/20/2021 at 12:25 pm the laboratory could not prove the results had been interpreted within one (1) hour after collection as indicated above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director, the laboratory failed to follow the manufacturer's instructions for verifying automated differential flags for 6 of 6 patient reports. Findings include: (1) On 08/20/2021 at 10:55 am, the laboratory director stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Cell Dyn Emerald analyzer; (2) The surveyor reviewed the manufacturer's operator's manual for information regarding flagged results. The following was identified: (a) For L1, L2, and L3 flags the instructions stated, "Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count." (3) The surveyor asked the laboratory director if the laboratory had a written policy for addressing the flags. The laboratory director stated on 08/20/2021 at 03:35 pm it was the laboratory's policy to review a stained smear when automated differential flags were obtained; (4) The surveyor then reviewed patient records and identified that for 6 of 6 records reviewed, the laboratory had not verified the results when automated differential flags were obtained as follows: (a) L1 flag obtained on a patient sample tested on 05/30/2021 at 01:00 pm (b) L3 flag obtained on a patient sample tested on 06/09/2021 at 04:10 pm (c) L3 flag obtained on a patient sample tested on 06/18/2021 at 08:01 pm (d) L3 flag obtained on a patient sample tested on 06/20/2021 at 12:56 pm (e) L3 flag obtained on a patient sample tested on 07/11/2021 at 11:37 am (f) L2, L3 flags obtained on a patient sample tested on 07/28/2021 at 08:21 pm (5) The findings were reviewed with the laboratory director who stated on 08/20/2021 at 03:25 pm, the laboratory had performed a smear but not documented the findings.
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 and interview with the laboratory director, the laboratory failed to demonstrate the performance specifications for one of one new test method; and failed to ensure the demonstrated reportable ranges were utilized for one of one new test method Findings include: ASI COLOR MONO II TEST (1) On 08/20/2021 at 10:55 am, the laboratory director stated to the surveyor that qualitative mononucleosis testing was performed using the ASI Color Mono II test kit (a non-waived test kit) beginning 07/16/2021; (2) The surveyor asked the laboratory director if the performance specifications (accuracy, precision) had been demonstrated before the test kit had been put into use for patient testing. On 08/20/2021 at 02:10 pm the laboratory director stated the performance specifications had not been demonstrated before patient testing; (3) The following were examples of patient mononucleosis testing performed when the performance specifications had not been demonstrated prior to putting into use for patient testing: (a) Patient #1 - Testing performed on 07/16 /2021 (b) Patient #2 - Testing performed on 07/18/2021 (c) Patient #3 - Testing performed on 07/31/2021 (d) Patient #4 - Testing performed on 08/09/2021 iSTAT CHEM8+ CARTRIDGE (1) On 08/20/2021 at 10:45 am, the laboratory director stated to the surveyor the iSTAT 1 analyzer (serial number 399311), using the Chem 8+ cartridge (included the analytes Sodium, Potassium, Ionized Calcium, Total CO2, Creatinine, BUN, Chloride, and Glucose), was available for patient testing on 03/02 /2020; (2) The surveyor reviewed the performance specification records for the test system. The reportable ranges were verified as follows: (a) Sodium (i) The laboratory verified 103-173 mmol/L (ii) The manufacturer's reportable range was 100-180 mmol /L (b) Potassium (i) The laboratory verified 2.3-7.8 mmol/L (ii) The manufacturer's reportable range was 2.0-9.0 mmol/L (c) Ionized Calcium (i) The laboratory verified 0.34-2.34 mmol/L (ii) The manufacturer's reportable range was 0.25-2.50 mmol/L (d) Total CO2 (i) The laboratory verified 12-41 mmol/L (ii) The manufacturer's reportable range was 5-50 mmol/L (e) Creatinine (i) The laboratory verified 0.3-15.4 mg/dL (ii) The manufacturer's reportable range was 0.2-20.0 mg/dL (f) Chloride (i) The laboratory verified 62-123 mmol/L (ii) The manufacturer's reportable range was 65-140 mmol/L (g) Glucose (i) The laboratory verified 27-600 mg/dL (ii) The manufacturer's reportable range was 20-700 mg/dL (3) The surveyor reviewed the performance specification with the laboratory director and asked if there was documentation to prove the laboratory was utilizing the reportable ranges that had been demonstrated by the laboratory; (4) On 08/20/2021 at 02:35 pm, the laboratory director stated the laboratory was using the manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory.
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, written policies, and interview with the laboratory director the laboratory failed to follow written quality control policies for 1 of 22 months. Findings include: (1) On 08/20/2021 at 10:45 am, the laboratory director stated the following to the surveyor: (a) Troponin I testing was performed in the laboratory using the cTnl cartridge and the iSTAT1 analyzer (serial number 399311); (b) BNP (Brain Natriuretic Peptide) testing was performed in the laboratory using the BNP cartridge and iSTAT analyzer (serial number 399311); (c) PT/INR (Prothrombin Time/International Normalized Ratio) testing was performed in the laboratory using the PT/INR cartridge and the iSTAT analyzer (serial number 399311). (d) An IQCP (Individualized Quality Control Plan) had been developed for the above test systems. (2) The surveyor reviewed the IQCP that had been developed for the test system. The QCP (Quality Control Plan) portion of the IQCP required 2 levels of external quality control materials be tested once every 30 days; (3) The surveyor reviewed QC (quality control) records for 22 months (October 2019 through July 2021) and identified the laboratory failed to follow the written QCP of performing quality control testing every 30 days. Quality control testing had not been performed as follows: (a) Troponin I (i) Between 10/19/2019 and 12/15/2019 (b) BNP (i) Between 10/19/2019 and 12/05/2019 (c) PT/INR (i) Between 10/22/2019 and 12/05/2019 (4) The findings were reviewed with the laboratory director who stated on 08/20/2021 at 02:45 pm, the laboratory had not performed quality control testing as required by the QCP.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies, and interview with the laboratory director, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow the manufacturer's instructions for verifying automated differential flags for 6 of 6 patient reports. Refer to D5411; (b) The laboratory failed to demonstrate the performance specifications for one of one new test method; and failed to ensure the demonstrated reportable ranges were utilized for one of one new test method. Refer to D5421; (c) The laboratory failed to follow written quality control policies for 1 of 22 months. Refer to D5445.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by:

	Based on a review of records and interview with the laboratory director, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the performance specifications had been demonstrated for 1 of 1 new test methods. Refer to D5421.