Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2144421	09/13/2023
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 09/13/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant 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 and interview with the technical consultant, the laboratory failed to ensure the reportable range had been utilized for two of four analytes reviewed. Findings include: (1) On 09/13/2023 at 09:25 am, the technical consultant stated the laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter DxH 520 hematology analyzer beginning 05/15/2023; (2) A review of performance specification records identified the reportable ranges had been demonstrated by the laboratory as follows: (a) Hemoglobin: 0.00 - 19.31 g/dL (b) Platelet: 0.1 - 1846.6 (x10^3 cells/ L) (3) A review of the manual titled, "Manufacturer's Instructions for Use - DxH 520 Published Version: v2" in Chapter 1, section 1-23 titled "System Overview Performance" defined the reportable range as follows: (a) Hemoglobin: 0.20 - 25.0 g/dL (b) Platelet: 7.0-2000 (x10^3 cells/ L) (4) Interview with the technical consultant on 09/13/2023 at 02:18 pm, confirmed the laboratory was using the manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, laboratory maintenance records, and interview with the technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures during the review period of 06/01/2023 through 08/31/2023. Findings include: (1) On 09/13/2023 at 09:25 am, the technical consultant stated CBC (Complete Blood Count) testing was performed using the Beckman Coulter DxH 520 hematology analyzer beginning 05/15/2023; (2) A review of the manual titled, "Manufacturer's Instructions for Use - DxH 520 Published Version: v2" Chapter 12, section 12-1 stated the following required maintenance procedures: (a) "Performing a bleach cycle every 1000 cycles or monthly, whichever comes first"; (b) "Cleaning the WBC bath filter monthly". (3) A review of maintenance logs from 06/01/2023 through 08/31/2023 identified no documentation monthly maintenance had been performed as follows: (a) Bleach Cycle (i) Not documented as performed until 07/05/2023 (ii) Not documented as performed after 07/14/2023 (b) Cleaning WBC Bath Filter (i) Not documented as performed until 08/15/2023 (4) The records were reviewed with the technical consultant who stated on 09/13/2023 at 11:57 am, monthly maintenance had not been documented as performed as shown above.
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 the technical consultant, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for two of two function checks performed during the review period of January 2022 through the current date. Finding include: (1) On 09/13/2023 at 09:30 am, the technical consultant stated the following: (a) Urine sediment examinations were performed; (b) The specimens were processed in the Cardinal Health Benchtop 6V centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes; (2) A review of the centrifuge function check policy titled, "Function Check Procedure" stated the following: (a) "To ensure the centrifuge is functioning properly in an acceptable standardized manner, its speed and timer is be checked annually"; (b) " Acceptable Speed Cardinal Health Benchtop 6V - 1500 rpm +/-100". (3) A review of centrifuge function check records during 2022 through the

	current date identified the centrifuge speed had not been checked at the speed urines were processed for two of two checks performed as follows: (a) 06/28/2022 - The speed had been checked at 1705 rpm; (b) 06/23/2023 - the speed had been checked at 1705 rpm. (4) The records were reviewed with the technical consultant who stated on 09/13/2023 at 02:10 pm, the laboratory had not followed their policy.
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, the laboratory failed to verify the stated value of control materials before they were put into use for nine of nine lot numbers used during the review period of 06/01/2023 through the current date. Findings include: (1) On 09/13/2023 at 09:25 am, the technical consultant stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter DxH 520 hematology analyzer beginning 05/15/2023; (b) Three levels of QC (quality control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of records for nine control lot numbers identified no evidence the provided ranges were verified before the lot numbers were put into use for nine of nine lot numbers as follows: (a) Low control lot #352314811, Normal control lot #362314812, and High control lot #372314813 used from 06/01/2023 through 06/30/2023; (b) Low control lot #352314911, Normal control lot #362314912, and High control lot #372314913 used from 07/03/2023 through 07/31/2023; (c) Low control lot #352315011, Normal control lot #362315012, and High control lot #372315013 put into use on 08/01/2023 and currently in use. (3) The findings were reviewed with the technical consultant who stated on 09/13/2023 at 11:57 am the manufacturer's ranges had not been verified before the above lot numbers had been put into use.