Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2164493	12/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Oklahoma On Demand Urgent Care	11426 N 134th E Ave, Owasso, 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 12/06/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant and the laboratory supervisor during an exit conference performed at the conclusion of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical consultant, the laboratory failed to have a written policy to assess the competency of the technical consultant, based on the position responsibilities as listed in Subpart M, for one of one person. Findings include: (1) A review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the technical consultant, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of January 2022 through the current date identified competencies, based on job responsibilities, had not been performed for one of one person listed as the technical consultant; (3) The findings were reviewed with the technical consultant who stated on 12/06/2023 at 03:05 pm a policy had not been written and competencies had not been performed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the

	laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the technical consultant and laboratory supervisor, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for six of 12 lot numbers used during the review period of 01/04/2023 through the current date. Findings include: (1) On 12/06/2023 at 11:18 am, the laboratory supervisor stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 hematology analyzer; (b) Three levels of EIGHTCHECK-3WP X-TRA 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 the policy titled, "XP-300 Procedure" under section E. "Starting a New Lot of Controls" stated the following: (a) "Parallel test new controls by analyzing the three levels of control a minimum of twice a day for 5 days prior to expiration of the previous lot. After a minimum of 10 data points are accumulated and values are running within assay ranges, the lot may be placed into production. The new lot will be validated prior to the current lot expiration." (3) A review of records for 12 control lot numbers used from 01/04/2023 through the current date identified the laboratory did not follow their policy for verifying new QC lot numbers as follows: (a) Lot #30810710, 30810711, and 30810712 used from 04/02/2023 through 06/27/2023 - Tested two days prior to expiration date of the previous lot number; (b) Lot #32490710, 32490711, and 32490712 put into use on 09/27/2023 through the current date - Tested three days prior to expiration date of the previous lot. (4) The findings were reviewed with the technical consultant and laboratory supervisor. Both stated on 12/06/2023 at 12:38 pm, the laboratory did not follow their written policy.
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 observation, a review of records, and interview with the technical consultant and the laboratory supervisor, the laboratory failed to ensure laboratory supplies were stored as required by the manufacturer for five of five months reviewed in 2023. Findings include: (1) On 12/06/2023 at 11:15 am, observation of the laboratory identified the following materials: (a) One package of BD Vacutainer PST Gel and Lithium Heparin blood collection tubes, lot #3194811 - the storage requirement as stated on the package was 4 to 25 degrees C (Centigrade); (2) A review of temperature records between January 2023 through May 2023 identified documented temperatures warmer than 25 degrees C for five of five months as follows: (a) January

	2023, five of 31 temperatures were documented as warmer than 25 degrees C (b) February 2023, three of 28 temperatures were documented as warmer than 25 degrees C (c) March 2023, ten of 31 temperatures were documented as warmer than 25 degrees C (d) April 2023, five of 30 temperatures were documented as warmer than 25 degrees C (e) May 2023, four of 31 temperatures were documented as warmer than 25 degrees C (3) The records were reviewed with the technical consultant and the laboratory supervisor on 12/06/2023 at 4:01 pm, who stated that the blood collection tubes had not been stored as required by the manufacturer.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory supervisor, the laboratory failed to ensure expired material was not available for use. Findings include: (1) On 12 /06/2023 at 11:15 am, the laboratory supervisor stated CBC (Complete Blood Count) testing was performed using the Sysmex XP 300 hematology analyzer; (2) Observation of the laboratory on 12/06/2023 at 11:18 am identified the following supplies that appeared to be available for use: (a) Six tubes of BD Vacutainer PST Gel and Lithium Heparin 83 Units, lot #2259105 with an expiration date of 09/30/2023 (3) Interview with the laboratory supervisor on 12/06/2023 at 1:22 pm confirmed the expired materials were available for use.
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 records, manufacturer's instruction manual, and interview with the technical consultant and laboratory supervisor, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Sysmex XP-300 hematology analyzer during the review period of January 2023 through November 2023. Findings include: (1) On 12/06/2023 at 11:15 am, the laboratory supervisor stated CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 hematology analyzer; (2) A review of the "Sysmex XP-300 Maintenance Checklist" on section 14.8 Appendix of the manufacturer's instructions manual required the following maintenance procedures: (a) Weekly "Clean SRV tray" (b) Every 3 months "Clean SRV" (3) A review of maintenance logs from January 2023 through November 2023 identified maintenance had not been documented as performed for the following: (a) Weekly: i. Between 03/23/2023 and 04/03/2023 ii. Between 04/17/2023 and 05/04/2023 iii. Between 07/21/2023 and 08/01/2023 iv. Between 09/22/2023 and 10/02/2023 v. Between 10/23/2023 and 11/06/2023 (c)

	Every 3 months: i. After 04/14/2023 (4) The records were reviewed with the technical consultant and laboratory supervisor who stated on 12/06/2023 at 3:45 pm, maintenance procedures had not been documented as performed as stated above.
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 technical consultant and laboratory supervisor, the laboratory failed to ensure patient test reports included the name of the laboratory location for one of one patient CBC (Complete Blood Count) report reviewed. Findings Include: (1) On 12/06/2023 at 01:30 pm, the technical consultant and laboratory supervisor stated CBC testing was performed using the Sysmex XP-300 analyzer; (2) A review of one patient report with testing performed on 09/18/2023 identified the report did not include the name of the laboratory. The name on the report stated "Main Office" and the name of the laboratory (as stated on the Clia certificate was "Oklahoma On Demand Urgent Care"); (3) The report was reviewed with the technical consultant and laboratory supervisor. Both stated on 12/06 /2023 at 04:00 pm, the laboratory name was not included on the patient report.