Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2164493	12/29/2021
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 initial survey was performed on 12/29/2021. The findings were reviewed with the laboratory supervisor and technical consultant at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. 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 proficiency testing program released proficiency testing results to HHS and the State Agency. Findings include: (1) Prior to the onsite survey (08/30/2021), the surveyor printed the laboratory's proficiency testing scores for review from the CMS Casper database. The scores included on the Casper Report 0096D, did not report for the 2020 and 2021 proficiency testing events. It appeared the laboratory did not participate in proficiency testing; (2) On 12/29/2021 at 10:25 am, the technical consultant stated to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 Analyzer beginning 02/14 /2020. (3) The surveyor asked the technical consultant if the laboratory participated in proficiency testing during 2020 and 2021. On 12/29/2021 at 10:55 am, the technical consultant stated that all available proficiency testing events had been performed in 2020 and 2021; (4) The surveyor then reviewed the proficiency 2020 Hematology Comparative Evaluation First, Second, and Third events and the 2021 Hematology Comparative Evaluation First and Second events. On all five events the providers CLIA No stated, "Not on file"; (5) The technical consultant stated on 12/29/2021 at 03:

	06 pm, the laboratory had not authorized release of proficiency testing scores for the 2020 and 2021.
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 policy, and interview with the technical consultant, the laboratory failed to have a written technical consultant competency policy based on the position responsibilities as listed in Subpart M for one of one technical consultant. Findings include: (1) On 12/29/2021, the surveyor reviewed the competency assessment policy. It did not include guidance for assessing the competency of the technical consultant; (2) The surveyor then reviewed personnel records for competency assessments performed during 2020, and 2021. There was no evidence of competencies performed for the technical consultant based on their job responsibilities; (3) The surveyor asked the technical consultant if a written policy to evaluate the technical consultant based on job responsibilities was available. The technical consultant stated on 12/29/2021 at 03:26 pm a policy had not been written and the above competencies had not been performed.
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 instructions, and interview with the laboratory supervisor and technical consultant, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for nine of nine months. Findings include: (1) On 12/29/2021 at 10:20 am, the technical consultant stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer; (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were as follows: (a) Clean SRV Tray (3) The surveyor then reviewed maintenance records for nine months (January 2021 through September 2021). There was no evidence the weekly maintenance had been performed: (a) Between 01/31/2021 through 09/01/2021. (4) The surveyor reviewed the records with the technical consultant and laboratory supervisor. Both stated on 12/29/2021 at 02:07 pm, the weekly maintenance had been performed but had not documented as required.
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 records and interview with laboratory supervisor and technical consultant, the laboratory failed to make appropriate reference ranges available for two of two patient reports. Findings include: (1) On 12/29/2021 at 10:25 am, the technical consultant stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 analyzer; (2) The surveyor reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 12/28/2021 at 08:06 pm; the second report was for an adult male patient with the testing performed on 11/23/2021 at 02:51 pm. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit which were: (a) RBC - 4.2 - 5.40 10^6/l (b) Hemoglobin - 12.0 - 15.1 g/dL (c) Hematocrit - 36.0 - 44.0 % (3) The surveyor reviewed the findings with laboratory supervisor and the technical consultant. Both stated on 12/29/2021 at 11:05 am the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor and technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's

	degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor and technical consultant, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for one of five competency evaluations performed. Findings include: (1) On 12/29/2021, the surveyor reviewed records for five persons performing moderate complexity testing in 2020 and 2021. The records showed the evaluation for one of five persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #1 - The 08/12/2020 evaluation had been performed by the laboratory supervisor (this person had earned a master's degree in clinical laboratory science but did not have at least 1 year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible). (2) The surveyor explained to the laboratory supervisor and technical consultant that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a masters degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 1 year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory supervisor and technical stated to the surveyor on 12/29/2021 at 11:39 am, the evaluation had been performed by an individual who did not meet the years of experience of a technical consultant.