Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2145906	03/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Classen Urgent Care Moore	1015 Sw 4th Street, Moore, 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 03/02/2021. 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.
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. Findings include: (1) The surveyor reveiwed 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 2019 and 2020. Although competencies had been performed for the technical consultant, based on their job responsibilities on 02/21/2019 and 06/01/2020, there was no policy to detail the responsibilities and define the frequency of the competencies; (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 to the surveyor on 03/02/2021 at 10:00 am, a policy had not been written.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to have a method to verify the accuracy of COVID-19 Antibody testing at least twice annually. Findings include: (1) On 03/02/2021 at 10:30 am, the technical consultant stated the following to the surveyor: (a) The laboratory began performing COVID-19 Antibody testing using the Hangzhou Biotest Biotech Rightsign test kit and plasma samples on 08/28/2020; (b) The test kit was temporarily discontinued on 10/11/2020, put back into use on 12/03/2020, and was currently being used in the laboratory. (2) The surveyor reviewed proficiency testing records for 2020 and the enrollment for 2021. The laboratory had not enrolled and participated in a proficiency testing program for COVID-19 Antibody testing for this test method; (3) Since the laboratory was not enrolled in proficiency testing (participation in a proficiency testing program is not required for COVID-19 Antibody testing; it is not a regulated test), the surveyor asked the technical consultant to explain if the laboratory had a method in place to verify the testing for accuracy and if the testing had been verified for accuracy since they began the testing. The technical consultant stated to the surveyor on 03/02/2021 at 11:45 am the laboratory did not have a method in place to verify the testing for accuracy and the testing had not been verified for accuracy to date.
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 the technical consultant, the laboratory failed to ensure an analyzer and materials were stored as required by the manufacturer for 2 of 14 months. Findings include: (1) On 03/02/2021 at 10:00 am, the technical consultant stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XN-330 analyzer; (b) The laboratory used three levels of Sysmex XN-L Check 10 quality control (QC) materials to perform QC each day of patient testing. (2) The surveyor reviewed the manufacturer's environmental requirements for the analyzer and the storage requirements for the QC material: (a) The operator's manual for the analyzer in Chapter 5, Section 5.1 required a room temperature of 15-25 degrees Centigrade (C) and a humidity of 20-80%; (b) The package insert for the QC materials required storage at 2-8 degrees C. (3) The surveyor reviewed laboratory temperature and humidity records for 14 months (January 2020 through February 2021) and identified that temperatures and humidity had not been documented during 2 of 14 months as follows: (a) September 2020 - 2 of 30 days (i) 09/25 - The humidity, room, and refrigerator temperatures had not been documented; (ii) 09/26 - The humidity, room, and refrigerator temperatures had not been documented. (b) October 2020 - 8 of 31 days (i) 10/01 - The humidity, room, and refrigerator temperatures had not been

	documented; (ii) 10/03 - The humidity, room, and refrigerator temperatures had not been documented; (iii) 10/14 - The humidity, room, and refrigerator temperatures had not been documented; (iv) 10/17 - The humidity and room temperature had not been documented; (v) 10/18 - The humidity and room temperature had not been documented; (vi) 10/19 - The humidity and room temperature had not been documented; (vii) 10/21 - The humidity, room, and refrigerator temperatures had not been documented; (viii) 10/27 - The humidity, room, and refrigerator temperatures had not been documented. (4) The surveyor reviewed the records with the technical consultant who stated to the surveyor on 03/02/2021 at 1:30 pm, the humidity, room temperature, and refrigerator temperatures had not been documented on the above days.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director/designee failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 2 of 6 events. Findings include: (1) The surveyor reviewed 2019 and 2020 proficiency testing events, and identified for 2 of 6 events, the attestation statements had been signed approximately 1-2 months after the samples had been tested (not within a timeframe for the director/designee to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Third 2019 Hematology Event - The sample testing had been completed on 11/16/2019, and the attestation statement had not been signed by the laboratory director/designee until 02/07/2020 (the graded evaluation had been received on 12/18/2020); (b) Third 2020 Hematology Event - The sample testing had been completed on 11/19/2020, and the attestation statement had not been signed by the laboratory director/designee 12/25 /2020 (the graded evaluation had been received on 12/16/2020). (2) The surveyor reviewed the findings with the technical consultant, who stated on 03/02/2021 at 11: 00 am the attestations above had been signed approximately 1-2 months after the proficiency samples had been tested. The surveyor explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.