

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D2145906	<b>(X3) Date Survey Completed</b> 01/16/2019
<b>Name of Provider or Supplier</b> Classen Urgent Care Moore	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The initial certification survey was performed on 01/16/19. The laboratory was found out of compliance with the following CLIA regulations: 493.801: D2000: Conditon: Enrollment and Testing of Samples 493.1403: D6000: Condition: Laboratory Director, Moderate Complexity The findings were reviewed with the technical consultant at the conclusion of the survey by phone.
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, and interview with the technical consultant and testing person #2, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: ROOM TEMPERATURE (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory began patient testing on 07/30/18 and performed the following waived testing: (a) Influenza A &amp; B testing using the BD Veritor reader and test kit; (b) Chemistry testing (e.g., Albumin, Sodium, Potassium, Uric Acid, etc.) using the Piccolo Xpress Chemistry analyzer; (c) Fingerstick Glucose testing using the HemoCue 201; (d) Macroscopic urinalysis testing using the Consult 10SG urine reagent dipsticks with the dipstick reader. (2) The surveyor then reviewed laboratory temperature records but there was no documentation the laboratory temperature had been monitored from 07/30/18 through 12/07/18. The surveyor asked the technical consultant if additional temperature records were available. Testing person #2 stated to the surveyor, the laboratory temperature had not been monitored until 12/07/18 when the temperature/humidity meter was received; (3) The surveyor then reviewed the manufacturers' temperature requirements for the testing and identified the following: (a) BD Veritor</p>

reader and Influenza A & B test kit: The manufacturer required a storage and operating temperature between 15-30 degrees C (Centigrade); (b) Piccolo Xpress Chemistry analyzer: The manufacturer required a storage and operating temperature between 15-32 degrees C; (c) HemoCue 201: The manufacturer required a storage and operating temperature between 18-30 degrees C; (d) McKesson Consult Diagnostics 10SG urine reagent dipsticks: The manufacturer required a testing temperature between 15-30 degrees C. (4) The surveyor reviewed the manufacturers' temperature requirements with the technical consultant and explained the only requirement for performing waived testing is to follow the manufacturer's instructions. In order to prove the manufacturers' temperature requirement is met, the laboratory temperature must be monitored and documented on a regular (i.e. daily) basis; (5) The technical consultant stated to the surveyor the laboratory failed to ensure the manufacturers' temperature requirements for the testing listed above had been met. HUMIDITY (1) The surveyor reviewed the manufacturers' humidity requirement for the waived testing performed by the laboratory and identified the following: (a) Piccolo Xpress Chemistry analyzer: The manufacturer required a storage and operating humidity between 8-80%; (b) HemoCue 201: The manufacturer required a storage and operating humidity of less than 90%; (c) McKesson Consult Diagnostics dipstick reader: The manufacturer required a storage and operating humidity of less than 85%. (2) The surveyor reviewed the humidity records but there was no documentation the laboratory humidity had been monitored from 07/30/18 through 12/07/18. The surveyor asked the technical consultant if additional records were available. Testing person #2 stated to the surveyor, the laboratory humidity had not been monitored until 12/07/18 when the temperature/humidity meter was received; (3) The surveyor reviewed the manufacturers' requirements with the technical consultant and explained the only requirement for performing waived testing is to follow the manufacturer's instructions. In order to prove the manufacturers' humidity requirement is met, the humidity must be monitored and documented on a regular (i.e. daily) basis; (4) The technical consultant stated to the surveyor the laboratory failed to ensure the manufacturers' humidity requirements for the testing listed above had been met.

**D2000**

**ENROLLMENT AND TESTING OF SAMPLES**  
 CFR(s): 493.801

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

This CONDITION is not met as evidenced by:  
 Based on a review of records and interview with the technical consultant, the laboratory failed to enroll in an HHS approved proficiency testing program for the testing performed by the laboratory. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory began CBC (Complete Blood Count) testing (i.e., WBC-White Blood Count, RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet count, etc.) using the Sysmex XN-330 analyzer on 07/30/18; (2) The surveyor asked the technical consultant for proficiency testing records. The technical consultant stated to the surveyor the laboratory had not

participated in any proficiency testing events; (3) The surveyor then asked the technical consultant if the laboratory had enrolled in a proficiency testing program before performing patient testing. The technical consultant stated to the surveyor, the laboratory had not enrolled in a proficiency testing program until 11/21/18; (4) The surveyor reviewed the laboratory's proficiency testing enrollment form which stated the date ordered: 11/21/18. The surveyor explained to the technical consultant laboratories are required by CMS to enroll in an HHS approved proficiency testing program for each of the specialties and subspecialties for which it seeks certification; (5) The technical consultant stated to the surveyor the laboratory did not enroll in proficiency testing; (6) Examples of patients with CBC testing performed when the laboratory failed to enroll and participate in proficiency testing included the following: (a) Patient #1 - Testing performed on 08/01/18 (b) Patient #2 - Testing performed on 08/14/18 (c) Patient #3 - Testing performed on 08/22/18 (d) Patient #4 - Testing performed on 08/24/18 (e) Patient #5 - Testing performed on 09/01/18 (f) Patient #6 - Testing performed on 09/06/18 (g) Patient #7 - Testing performed on 09/11/18 (h) Patient #8 - Testing performed on 09/13/18 (i) Patient #9 - Testing performed on 09/24/18 (j) Patient #10 - Testing performed on 10/03/18 (k) Patient #11 - Testing performed on 10/09/18 (l) Patient #12 - Testing performed on 10/12/18 (m) Patient #13 - Testing performed on 10/28/18 (n) Patient #14 - Testing performed on 11/03/18 (o) Patient #15 - Testing performed on 11/10/18

**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 policies and procedures, and interview with the technical consultant, the laboratory failed to have written policy and procedure for assessing employee competency. Findings include: (1) During the survey, the surveyor reviewed the laboratory's written policies and procedures. A policy that explained how testing persons, the technical consultant, and clinical consultant were assessed for competency could not be located; (2) The surveyor asked the technical consultant if a competency policy for assessing the competency of testing persons, the technical consultant, and the clinical consultant was available for review. The technical consultant verified a written policy and procedure had not been written. NOTE: For non-waived testing, the regulations require initial training, a semiannual evaluation during the first year, and an annual evaluation thereafter for each testing person for ensuring competency. The policy/procedure for evaluating competency must include, but is not limited to: \*Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing \*Monitoring the recording and reporting of test results \*Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records \*Direct observation of performance of instrument maintenance and function checks \*Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples \*Assessment of problem solving skills NOTE: The interpretive guidelines at 493.1235, states "Competency Assessment Guidelines: Technical consultant, clinical consultant, technical supervisor, general supervisor - Documented competency assessment is required for the following named positions on the Form

209: technical consultant clinical consultant, technical supervisor, general supervisor. The laboratory must have policies and procedures to assess competency based on the position responsibilities listed in Subpart M and these assessments must performed at a frequency determined by the laboratory. If these people perform testing on patient specimens, they are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities (see 493.1413(b)(8)/493.1451(b)(8)).

**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 technical consultant, the laboratory failed to follow the manufacturer's instructions for quality control materials. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory began patient CBC (Complete Blood Count) testing on 07/30/18 using the Sysmex XN-330 analyzer. In addition, the technical consultant stated to the surveyor the laboratory analyzed three levels (low, normal, and high) of XN-L CHECK QC (Quality Control) materials each day of patient testing; (2) The surveyor reviewed the manufacturer's instructions (package insert) for the QC materials, which stated, "When changing control lot, it is recommended to run current and new controls in parallel at least 10 times over 5 days then autosest target" (mean). The surveyor then reviewed QC records from 08/01/18 through the date of the survey and identified 9 QC lot numbers had been utilized: (a) Low, Lot #81871401; Normal, Lot #81871402; and High, Lot #81871403 - Put into use on 07/30/18 and used through 10/05/18; (b) Low, Lot #82711401; Normal, Lot #82711402; and High, Lot #82711403 - Put into use on 10/06/18 and used through 12/20/18; (c) Low, Lot #83551401; Normal, Lot #83551402; and High, Lot #83551403 - Put into use on 12/20/18 and used through 01/16/19. (3) The records indicated for 6 of the 9 lot numbers listed above, the laboratory failed to follow the manufacturer's instructions to analyze the QC materials twice per day for 5 days: (a) Low, Lot #82711401; Normal, Lot #82711402; and High, Lot #82711403: Had been analyzed only 2 times; (b) Low, Lot #83551401; Normal, Lot #83551402; and High, Lot #83551403 - Put into use on 12/20/18: Had been analyzed only 2 times. (4) The surveyor reviewed the findings with the technical consultant who stated to the surveyor the laboratory did not follow the manufacturer's instructions for running the new QC lot numbers with the current QC lot numbers twice per day for 5 days.

**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 and testing person #2, the laboratory failed to ensure the manufacturer's environmental specifications were met. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (e.g. WBC (White Blood Count), RBC (Red Blood Count), Hematocrit, Hemoglobin, Platelet count, etc.) using the Sysmex XN-330 hematology analyzer. In addition, the technical consultant stated to the surveyor the laboratory began patient testing on 7/30/18; (2) The surveyor reviewed the manufacturer's environmental requirements. The manufacturer required a humidity between 20 and 80% and a temperature between 18-32 degrees Centigrade for optimal performance. The surveyor then reviewed the laboratory humidity /temperature records but could not find documentation which showed the humidity /temperature had been documented from 07/30/18 through 12/07/18. The surveyor asked the technical consultant if additional records were available. Testing person #2 stated the laboratory humidity/temperature had not been monitored until 12/07/18 when the humidity/temperature meter was received; (3) The surveyor reviewed the manufacturer's environmental requirements for the Sysmex XN-330 analyzer with the technical consultant. The technical consultant stated to the surveyor the laboratory failed to ensure the manufacturer's environmental specifications for the analyzer had been met during the time the humidity/temperature had not been documented.

**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, and interview with the technical consultant and testing person #2, 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 due to the following issues identified during the survey: (a) The laboratory failed to follow the manufacturer's instructions for quality control materials. Refer to D5411; (b) The laboratory failed to ensure the manufacturer's environmental specifications had been met. Refer to D5413.

**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, manufacturer's instructions, and interview with the technical consultant and testing person #2, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (2) The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the testing performed in the laboratory. Refer to D6015; (3) The laboratory director failed to ensure the laboratory established and maintained an effective quality assessment program to assure the quality of laboratory services. Refer to D6021; (4) The laboratory director failed to ensure individuals performing moderate complexity testing had the appropriate training. Refer to D6029.

**D6014**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(iii)

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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the technical consultant and testing person #2, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the laboratory followed the manufacturer's instructions. Refer to D5411; (2) The laboratory failed to ensure the manufacturer's environmental specifications had been met. Refer to D5413.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the testing performed in the laboratory. Findings included: (1) The laboratory director failed to ensure the laboratory enrolled in a proficiency testing program for CBC testing. Refer to D2000.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, written policy and procedure, and interview with the technical consultant, and testing person #2, the laboratory failed to ensure an effective quality assessment program had been established and maintained to assure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure the laboratory had an effective quality assessment program due to the issues identified during the survey. Refer to D5791.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the laboratory director failed to ensure individuals performing moderate complexity testing had the appropriate training. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor, the laboratory began CBC (Complete Blood Count) testing on 07/30/18 using the Sysmex XN-330 analyzer; (2) The surveyor then reviewed personnel records for the 9 testing persons who performed the moderate complexity CBC testing (testing persons rotated to an associated laboratory, dependent on staffing needs.) The surveyor identified for 7 of the 9 testing persons, the initial orientation/training forms were not specific for the laboratory (i.e., Classen Care Urgent Care-Moore) and did not include training which covered the operation, maintenance, reagents, control procedures, etc., for the Sysmex XN-330 analyzer, but for the Medonic M-Series analyzer. In addition the records indicated training was performed at the sister clinic (Classen Care Urgent Care-Norman) and was conducted prior to the date the laboratory (i.e., Classen Care Urgent Care-Moore) began patient testing. The findings follow: (a) For 7 of the 9 testing persons: (i) Testing person #1: The date of the initial training was 03/08/18; (ii) Testing person #2: The Sysmex Quiz was given on 03/06/18. The date of the initial training was 06/02/18; (iii) Testing person #3: The Sysmex Quiz was given on 03/06/18. The date of the initial training was 03/06/18; (iv) Testing person #4: The Sysmex Quiz was given on 03/06/18. The date of the initial training was 04/28/18; (v) Testing person #6: The Sysmex Quiz was given on 03/06/18. The date of the initial training

was 03/06/18; (vi) Testing person #7: The Sysmex Quiz was given on 03/07/18. The date of the initial training was 03/07/18; (vii) Testing person #8: The Sysmex Quiz was given on 03/06/18. The date of the initial training was 08/14/18. (b) For 1 of the 9 testing persons (Testing person #9), there was no documentation an initial training had been performed. (3) The surveyor reviewed the findings with the technical consultant who stated to the surveyor: (a) The initial training for the testing persons listed above was not specific for the testing performed at this laboratory; (b) There was no documentation to prove testing person #9 had been initially trained to perform moderate complexity testing.

**D6042**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:  
Based on a review of records, manufacturer's instructions, and interview with the technical consultant and testing person #2, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the laboratory followed the manufacturer's instructions. Refer to D5411; (2) The technical consultant failed to ensure the manufacturers' environmental specifications had been met. Refer to D5413.