

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2033686	(X3) Date Survey Completed 08/17/2023
Name of Provider or Supplier Classen Urgent Care Clinic	Street Address, City, State 2818 Classen Blvd, Norman, 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 08/17/2023. 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.
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on interview with the technical consultant, the laboratory failed to provide written instructions to clients from Classen Family Medicine, for CBC testing performed on the Sysmex XN 330 analyzer. Findings include: (1) On 08/17/2023 at 10:50 am, the technical consultant stated the following: (a) CBC testing was performed using the Sysmex XN-330 analyzer; (b) Specimens were transported to the laboratory for STAT analysis from Classen Family Medical Clinic. (2) Interview with the technical consultant 08/17/2023 at 10:25 am confirmed the laboratory did not provide written instructions (i.e., client service manual) to the client to explain the laboratory's specimen handling policies.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p>

(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 and interview with the technical consultant (TC), the laboratory failed to ensure three of three Vacutainer brand tubes were stored as required by the manufacturer, in a room denoted as the nursing supply room. Findings include: (1) Observation of the nursing supply room and interview with the TC on 08/17/2023 at 09:50 am, identified the following: (a) 11 BD Vacutainer SST tubes, lot # 3041180, storage temperature of 4-25 degrees Celsius; (b) Eight BD Vacutainer LiHep tubes, lot # 216068, storage temperature of 4-25 degrees Celsius; (c) Six BD Vacutainer K2, EDTA tubes, lot # 2347067, storage temperature of 4-25 degrees Celsius. (2) Interview with the technical consultant on 08/17/2023 at 09:50 am confirmed the laboratory was not monitoring the temperature of the nursing supply room.

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 technical consultant, the laboratory failed to ensure expired Wright's stain was not available for use. Findings include: (1) Observation of the laboratory on 08/17/2023 at 09:50 am, identified the following expired reagents, used for manual differential staining, that appeared to be available for use: (a) One bottle of MCC Wright's Dip Stat stain - lot #2424-02 with an expiration date of 01/31/2023; (b) One bottle of MCC Wright's Dip Stat stain - lot #1369-01 with an expiration date of 03/31/2022; (2) Interview with the technical consultant on 08/17/2023 at 09:50 a.m. confirmed the MCC Wright's Dip Stat stain was available for use.