

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472947	(X3) Date Survey Completed 10/10/2023
Name of Provider or Supplier Urology Center Of Southern Oklahoma, Pc	Street Address, City, State 1119 Walnut Dr, Ste 2, Ardmore, 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 10/09/2023 through 10/10/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the office manager, general supervisor, and testing person #2 during an exit conference performed at the conclusion of the survey.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>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 director failed to assess the competency of the technical consultant based on the position responsibilities as listed in subpart M. 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 August 2021 through the current date identified competencies, based on job responsibilities, had not been performed for the technical consultant listed on the CMS-209; (3) The findings were reviewed with the technical consultant who stated on 10/09/2023 at 12:23 am there was no policy and competencies were not performed for the technical consultant during the review period of October 2021 to the current date.</p>
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 general supervisor and testing person #2, the laboratory failed to ensure the humidity was monitored as required in the Urinalysis Testing Room for nine of nine months reviewed and the Molecular UTI (Urinary Tract Infection) Testing Room for five of five months reviewed. Findings include: URINALYSIS TESTING ROOM (1) On 10/09/2023 at 10:15 am, testing person #2 stated the laboratory performed urinalysis testing on Siemens Clinitek Advantus analyzer using the Multistix PRO 10LS reagent strips; (2) A review of the Operator's Guide for the test system identified the manufacturer required the analyzer be operated at a relative humidity of 20-80%, non-condensing; and actively controlled; (3) A review of temperature records identified no documentation that humidity had been monitored for the above test system between 01/01/2023 to 09/30/2023; (4) The records were reviewed with testing person #2 who stated on 10/03/2023 at 02:33 pm, the laboratory humidity had not been monitored as required by the manufacturer. MOLECULAR UTI TESTING ROOM (1) On 10/09/2023 at 10:35 am, the general supervisor stated the laboratory performed UTI pathogen identification and antibiotic resistance marker testing using the Kingfisher Duo Prime and Applied Biosystems QuantStudio 7 Pro Real-Time PCR Systems; (2) A review of the manufacturer's instructions identified the following: (a) KingFisher Duo Prime Technical Manual Rev. 1.0, Cat. No. N16621 under the section "Operating Conditions" stated "To make sure that condensation does not occurs, the humidity is low (relative humidity is between 10% and 80%); (b) QuantStudio 7 Pro Real-Time PCR System User Guide - Appendix A Instrument Specifications and Layout under the section "Environmental Requirements" identified the manufacturer required the test system be operated at a humidity of 15%-80% (noncondensing). (3) A review of Room Climate Log from the Molecular UTI testing room between 05/01/2023 through 09/30/2023 identified no documentation that humidity had been monitored; (4) The records were reviewed with the general supervisor who stated on 10/03/2023 at 2:33 pm, the laboratory humidity had not been monitored as required by the manufacturer. 48517 Based on a review of records, observation, and interview with the general supervisor, the laboratory failed to ensure materials were stored as required for three of three months reviewed in 2023. Findings include: (1) On 10/09/2023 at 02:00 pm, observation of the contents of the laboratory freezer identified the following materials: (a) One box of Applied Biosystems MagMax viral/pathogen ultra mag mix, lot #2301032 - the storage requirement as stated on the box was -15 to -25 degrees C (Centigrade). (2) A review of temperature records for three months (May 2023 through July 2023) identified the laboratory documented temperatures using a min (minimum) and max (maximum) thermometer. Three temperatures were documented each day which included the current temperature reading, the coldest reading, and the warmest reading. Documented temperatures were beyond the storage requirement for the materials three of three months as follows: (a) May 2023 - For 24 days, 20 of 72 temperatures were documented as warmer than -15 degrees C and 13 of 72 temperatures were documented as colder than -25 degrees C; (b) June 2023 - For 14 days, 14 of 42 temperatures were documented as warmer than -15 degrees C and 8

of 42 temperatures were documented as colder than -25 degrees C; (c) July 2023 - For 22 days, 22 of 66 temperatures were documented as warmer than -15 degrees C and 6 of 66 temperatures were documented as colder than -25 degrees C. (3) The records were reviewed with the general supervisor, who stated on 10/09/2023 at 02:00 pm, the materials were not being 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 testing person #2, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the urinalysis laboratory on 10/09/2023 at 11:00 am, identified the following expired collection tubes that appeared to be available for use: (a) 400 Vacuette K2EDTA tubes - lot # B220533T with an expiration date of 08/31/2023. (2) Interview with testing person #2 10/09/2023 at 11:00 am confirmed the Vacuette K2EDTA tubes were available for use.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of records, policies and procedures, and interview with the general supervisor, the laboratory failed to have a function check protocol that ensured the Globe centrifuge was functioning properly for one of one function check performed during the review period of April 2023 through the current date. Findings include: (1) On 10/09/2023 at 10:35 am, the general supervisor stated the following: (a) The laboratory began performing UTI pathogen identification and antibiotic resistance marker testing using the Applied Biosystems QuantStudio 7 Pro Real-Time PCR Systems in April 2023; (b) Sample preparation included centrifuging specimens in the Globe Centrifuge at a speed of 140 rpm (revolutions per minute) for four minutes; (2) A review of the policy titled, "Equipment Description and Maintenance" did not specify the laboratory's method for ensuring the speed and timer will be checked for accuracy and stated the centrifuge "will be maintained every six months"; (3) A review of the centrifuge function check records from April 2023 through the current date identified the following for one of one check performed: (a) 10/02/2023 - The speed had been checked at 139 and 141 rpm. There was no documentation the timer had been checked. (4) The records were reviewed with the general supervisor who

stated on 10/10/2023 at 10:55 am, the centrifuge timer had not been checked for accuracy.

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 record and interview with testing person #2 and office manager, the laboratory failed to ensure a patient test report included the name and address of the laboratory location where the testing was performed for one of one report reviewed. Findings include: (1) On 10/09/2023 at 10:15 am, testing person #2 stated the laboratory performed urinalysis testing on Siemens Clinitek Advantus analyzer using the Multistix PRO 10LS reagent strips; (2) A review of one patient report for the above testing identified the report did not include the name and address of the laboratory location; (3) The report was reviewed with testing person #2 and office manager who stated on 10/09/2023 at 02:10 pm, the laboratory name and address had not been included in the patient test reports.

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 a patient report and interview with testing person #2 and office manager, the laboratory failed to provide normal reference intervals for one of one Urinalysis report reviewed. Findings include: (1) On 10/09/2023 at 10:15 am, testing person #2 stated the laboratory performed urinalysis testing on Siemen Clinitek Advantus analyzer using the Multistix PRO 10LS reagent strips; (2) A review of one patient report for the above testing identified the report did not include normal reference ranges; (3) The report was reviewed with testing person #2 and office manager who stated on 10/09/2023 at 02:15 pm, the patient report did not include normal reference ranges.