

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0702190	<b>(X3) Date Survey Completed</b>  12/21/2022
<b>Name of Provider or Supplier</b>  Urology Assocs Of North Central Oh Inc	<b>Street Address, City, State</b>  675 Bally Row, Mansfield, OH	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review, direct observation and an interview with the Office Manager, the laboratory failed to have a written procedure manual for post-vasectomy sperm presence or absence testing in the speciality of hematology. All 120 patients tested in the speciality of hematology in the years of 2021 and 2022 had the potential to be affected by this deficient practice. Findings include: 1. Review of the Form CMS-116 found the speciality of hematology marked as testing performed with no volume listed. 2. Review of the laboratory's manual failed to find evidence of hematology testing performed. 3. During a tour of the laboratory, the surveyor observed a microscope present on 12/21/2022 at 12:06 PM. The surveyor asked the Office Manager how the microscope was used. 4. An interview with the Office Manager, on 12/21/2022 at 12:26 PM, confirmed that six post-vasectomy sperm presence or absence tests were performed per month via the microscope by the Laboratory Director, which totaled 120 patients for the years of 2022 and 2021. 5. An interview with the Office Manager on 12/21/2022 at 12:27 PM, confirmed that the laboratory failed to have a written procedure manual for post-vasectomy sperm presence or absence testing.</p>
<b>D5479</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)</p>

(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Office Manager, the laboratory failed to follow the manufacturer's specifications for using microbiological media when reporting patient results in the subspecialty of bacteriology. This deficient practice had the potential to affect 43 out of 1930 patient results in the year of 2022. Findings include: 1. Review of the manufacturer's specifications for blood agar plates (BAP) and MacConkey agar plates (Mac) found the following statements for each. BAP: "...3. Incubate aerobically, or in 5-10% CO<sub>2</sub>, for 18-24 hours at 33-37 degrees C [Celsius]..." Mac: "...3. Incubate in ambient air at 33-37 degrees C for 18-24 hours..." 2. Review of the incubator temperature logs found BAP and Mac agar plates incubated at the following temperatures on the following dates in 2022: 08/11/2022 38 degrees C 07/07/2022 38 degrees C 06/30/2022 39 degrees C 06/21/2022 39 degrees C 04/21/2022 39 degrees C 02/22/2022 32 degrees C 3. Review of the urine culture patient log found 43 patients resulted when the incubator was out of range: 08/11/2022 10 patients reported 07/07/2022 9 patients reported 06/30/2022 12 patients reported 06/21/2022 8 patients reported 04/21/2022 3 patients reported 02/22/2022 1 patient reported 4. An interview with the Office Manager, on 12/21/2022 at 12:24 PM, confirmed that the laboratory failed to follow manufacturer's specifications for BAP and Mac plates when reporting 43 out of 1930 patient results in the year of 2022.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Office Manager, the Laboratory failed to ensure policies and procedures were established and followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure they are competent and are able to maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This deficient practice affected one out of 4 Testing Personnel (TP) in the subspecialties of general chemistry and bacteriology from 11/19/2022 to 12/21/22. Findings include: 1. Review of the laboratory's "Policy and Procedures for Evaluation of Lab Personnel's Performance and Competency" failed to find mention of initial training. 2. Review of the laboratory's documentation failed to find evidence of initial training prior to patient testing for TP #1. 3. The surveyor requested

documentation for initial training for TP #1, hired 11/19/2022. 4. An interview with the Office Manager, on 12/21/22 at 12:22 PM, confirmed that documentation of initial training for TP #1 was not present at the time of the inspection and could not be produced.