

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0666021	<b>(X3) Date Survey Completed</b>  02/21/2024
<b>Name of Provider or Supplier</b>  Urological Associates, Pc	<b>Street Address, City, State</b>  3319 Spring Street, Davenport, IA	
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>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on lack of proficiency testing records, review of the Laboratory Test List &amp; Annual Volume form and confirmed by laboratory personnel identifier #3 (refer to Laboratory Personnel Report) at approximately 9:45 am on 02/14/2024, the laboratory failed to enroll in an approved proficiency testing program for antimicrobial susceptibility testing. The findings include: 1. The laboratory performs antimicrobial susceptibility testing on urine cultures using the Pathnostics molecular test system. 2. At the time of the survey, the laboratory did not enroll in proficiency testing for antimicrobial susceptibility testing on urine cultures.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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>

This STANDARD is not met as evidenced by:  
 Based on review of training and competency assessments and interview with laboratory personnel #3 (refer to the Laboratory Personnel Report) at approximately 9:45 am on 2/14/24, the laboratory failed to follow written policies documenting laboratory personnel competency for one out of seven testing personnel in 2023 and 2024. The findings include: 1. Laboratory Personnel identifier #3 had a competency assessment performed on 8/9/2023 and 2/14/2024. 2. The laboratory director performed and signed off as the evaluator on both competencies. The competencies stated the evaluator performed: \*GX-7 Spec Plate ABR Assay: direct observation of routine best performance; monitoring the recording & reporting review worksheets, QC, PM, maintenance records; direct observation of performance instrument maintenance, Assessment of test performance (PT/blind sample); and Assessment of problem solving skills. \*GX-017 Integra Viaflo: direct observation of routine best performance; monitoring the recording & reporting review worksheets, QC, PM, maintenance records; direct observation of performance instrument maintenance, Assessment of test performance (PT/blind sample); and Assessment of problem solving skills. \*GX8 CHROMagar ESBL Assay: direct observation of routine best performance; monitoring the recording & reporting review worksheets, QC, PM, maintenance records; direct observation of performance instrument maintenance, Assessment of test performance (PT/blind sample); and Assessment of problem solving skills. 3. Interview with testing personnel identifier #3, revealed that the laboratory director did not visit the laboratory in 2023 or 2024 to perform the direct observations as part of the competency assessment. 4. Additionally, testing personnel identifier #3 also performed semen analysis testing using the SQA vision analyzer. The laboratory did not document competency for this test system in 2023 and 2024.

**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 lack of a centrifuge function check procedure, review of centrifuge records, and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 2/14/2024, the laboratory failed to define the frequency for performing centrifuge speed and time checks. In addition, the laboratory failed to perform centrifuge speed and timer checks on one out of three centrifuges in 2022 and three out of three centrifuges in 2023. The findings include: 1. The blood centrifuge, serial number 211013G4302 had speed and timer checks performed on 10/4/2021. 2. The urine centrifuge, serial number 21021036 had speed and timer checks performed on 1/7/2022. 3. The urine centrifuge, serial number 21729 has speed and timer checks performed on 9/2/2022. 4. The laboratory did not have a policy that defined the frequency for performing centrifuge speed and timer checks. 5. The laboratory did not perform routine speed and timer checks on the above centrifuges.

**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:

A. Based on observations during the survey, review of patient test reports and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 9:40 am on 2/14/2023, the laboratory failed to have the correct name and address of the testing facility for two out of two patient test reports that had urine culture identification and antimicrobial sensitivity testing performed in November 2023. The findings include: 1. Patient identifiers A & B both had urine culture identification and antimicrobial sensitivity testing performed in November 2023. 2. Laboratory personnel identifier #3 stated that the laboratory performed urine culture identification at the Urological Associates PC, Moline, Illinois (14D0909901). Urological Associates, PC, Davenport, Iowa (16D0666021) performed the urine antimicrobial sensitivity testing. 3. Observation made during the survey confirmed the laboratory did not have equipment available to perform urine culture identifications, they only had equipment for performing urine antimicrobial sensitivity testing. 3. The test reports for patient identifiers A and B did not differentiate which laboratory performed which testing. The reports indicated that Urological Associates PC, Moline, Illinois (14D0909901) performed both tests. B. Based on review of patient test reports and confirmed by laboratory personnel identifiers #1, #4 and #5 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 2/14/2024, the laboratory failed to have the correct name and address of the testing facility for three out of three patients that had histology and cytology testing performed from 11/1/2023 - 2/14/2024. The findings include: 1. Patient identifier C had a biopsy performed in November 2023 which included gross interpretation of the specimen and slides stained and interpreted. 2. Patient identifier D had a biopsy performed in February 2024 which included gross interpretation of the specimen and slides stained and interpreted. 3. Patient identifier E had non-gynecological testing performed in February 2024 on a urine specimen which include gross interpretation and slides stained and interpreted. 4. Laboratory personnel #1, #3 and #4 all confirmed that the gross examination of the specimens and processing of the slides took place at Urological Associates PC, Davenport, IA (16D0666021). The laboratory then sent the stained slides to Cross Medical Laboratories, Iowa City, Iowa (16D0386471) where the slides were read and interpreted. 5. The test report for patient identifiers C, D and E did not differentiate which laboratory performed which testing. The reports indicated that Urological Associates PC, Davenport, Iowa (16D0666021) performed all of the testing.