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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>39D0876172              | <b>(X3) Date Survey Completed</b><br>09/19/2019 |
| <b>Name of Provider or Supplier</b><br>Urology Associates Of Kingston  | <b>Street Address, City, State</b><br>672 South River Street, Suite 111, Plains, PA |   |
| 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>  |
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| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>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:<br/>Based on review of testing personnel competency assessment records, review of the competency assessment policy and interview with testing personnel (TP) #1, the laboratory failed to have a complete competency assessment policy and evaluate the competency of 2 of 3 clinical consultants (CC) from 2017 to the day of survey. Findings Include: 1. On the day of survey, 09/19/2019, the laboratory could not provide a complete competency assessment policy for the CC's from of 2017 to the date of survey. 2. The laboratory could not provide competency assessments performed on 2 of 3 CC in 2017, 2018 and 2019. 3. The TP#1 confirmed the finding above on 09/19/2019 around 9:30 am.</p> |
| <b>D5403</b>              | <p><b>PROCEDURE MANUAL</b><br/>CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in</p>   |

493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedures and interview with the testing personnel (TP) #1, the laboratory failed to have a complete procedure manual required for urine sediment microscopic examination from 2017 to the date of survey. Findings Include: 1. On the day of survey, 09/19/2019, review of the laboratory's procedure manual revealed, the laboratory's urine sediment microscopic examination policy did not include the following from 10/02/2017 to 09/19/2019: - Control procedures. - Reportable ranges for test results. - Pertinent literature references. 2. TP #1 confirmed the findings above on 09/19/2019 around 10:00 am.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of laboratory procedures and interview with Testing Personnel (TP) #1, the laboratory failed to have procedure manuals in use signed by the current laboratory director (LD) in 2018 to the date of survey. Findings include: 1. On the day of survey, 09/19/2019, review of the urine sediment microscopic examination procedure revealed, the current LD did not sign the manual in use from 1/18/2018 to 09/19/2019. 2. TP #1 confirmed the findings above on 09/19/2019 around 10:15 am. \*\*\* Repeat Deficiency \*\*\*

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of microscope maintenance records and interview with Testing Personnel (TP) #1, the laboratory failed to perform maintenance on 2 of 2 microscopes used examine urine microscopic examinations in 2018. Findings include: 1. On the day of survey, 09/19/2019, review of microscope maintenance records revealed, 2 of 2 microscopes (Amscope B660B and Mckesson Lumeon Series) used for urine microscopic examinations were due for maintenance in October of 2018. 2.

Maintenance on 2 of 2 microscopes were not performed until 03/04/2019. 3. TP#1 confirmed the findings above on 09/19/2019 around 9:50 am. \*\*\* Repeat Deficiency \*\*\*

**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 the review of patient test reports and interview with testing personnel (TP) #1, the laboratory failed to include reference ranges on patient test reports for urine sediment microscopic examination perform from 2017 to the date of survey. Findings Include: 1. On the day of survey, 09/19/2019, a review of some test reports (2 of 2) revealed, patient test reports did not include reference ranges for urine sediment microscopic examination performed from 10/03/2017 to 09/19/2019. 2. TP #1 confirmed the finding above on 09/19/2019 around 11:00 am.