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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>31D0115021   | <b>(X3) Date Survey Completed</b><br>03/01/2018 |
| <b>Name of Provider or Supplier</b><br>New Jersey Urologic Institute   | <b>Street Address, City, State</b><br>10 Industrial Way E, Eatontown, NJ |   |
| 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 surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on four out of four testing personnel in 2017. The finding includes: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done. 2. The TP #1 listed on CMS form 209 confirmed on 3/1/18 at 1:00 pm that CA was not performed correctly.</p>   |
| <b>D5477</b>              | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check QC on each batch of Urine</p> |

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|                     | <p>Culture Media (UC) from July 2017 to the date of the survey. The findings include: 1. The laboratory did not check UC for: a. Ability to support growth. b. Ability to select or inhibit specific organisms 2. The TP #1 listed on CMS form 209 confirmed on 3/1/18 at 1:30 pm that the laboratory did not perform the above mentioned QC checks.</p>  |
| <p><b>D5787</b></p> | <p><b>TEST RECORDS</b><br/>CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by:<br/>Based on lack of an Accession Log (AL) and interview with the Testing Personnel (TP), the laboratory failed to maintain an Accession Log (AL) for Urinalysis and Urine Microscopic tests from July 2017 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 3/1/18 at 2:10 pm that the laboratory did not maintain an AL for laboratory tests.</p>  |
| <p><b>D5805</b></p> | <p><b>TEST REPORT</b><br/>CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of the Test Report (TR) and interview with the Testing Personnel (TP), the laboratory failed to have all the required information on the TR from July 2017 to the date of survey. The findings include: 1. UC did not have an interpretation of colony count. 2. The name of the laboratory performing the test was not on the TR if the test was performed off site. 3. The TP #1 listed on CMS form 209 confirmed on 3/1/18 at 2:35 pm that the TR did not have all the required information.</p> |
| <p><b>D5891</b></p> | <p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b><br/>CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by:</p>  |

Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have a procedure to verify manually entered results into electronic medical records for accuracy from July 2017 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 3/1/18 at 1:10 pm that the laboratory did not have the procedure mentioned above.