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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D0115021 | (X3) Date Survey Completed 07/19/2019 |
| Name of Provider or Supplier New Jersey Urologic Institute | Street Address, City, State 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. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D3031 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) Verification records and interview with the Testing Personnel (TP), the laboratory failed to retain all QC verification records from 3/1/18 to the date of survey. the Findings include: 1. Old and new lot numbers of the QC material being verified were not retained. 2. The work records of the QC material being verification were not retained. 3. The TP #9 on CMS form 209 confirmed on 7/16/19 at 1:40 pm the the QC verification records were not retained.</p> |
| D5477 | <p>CONTROL PROCEDURES 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: 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 3/1/18 to the date of the survey. The findings include: 1. The laboratory did not check UC for ability to select or inhibit specific organisms 2. The TP# 9 listed on CMS form 209 confirmed on 7/16/19 at 1:35 pm that the laboratory did not perform the above mentioned QC check.</p> |
| <p>D5787</p> | <p>TEST RECORDS 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: Based on review of the Accession Log (AL) and interview with the Testing Personnel (TP), the laboratory failed to maintain an AL for Urine Microscopic tests from 3/1/18 to the date of survey. The TP# 9 listed on CMS form 209 confirmed on 7/16/19 at 1:00 pm that the laboratory did not maintain an AL for Urine Microscopic tests.</p> |
| <p>D5791</p> | <p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure to verify new QC material used for tests performed on the Qualigen FastPack analyzer from 3/1/18 to the date of the survey. The TP #9 listed on CMS form 209 confirmed on 7/16/19 at 1:25 pm that the laboratory did not have a procedure to verify new QC.</p> |