

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0104449	(X3) Date Survey Completed 04/26/2018
Name of Provider or Supplier New Jersey Urology	Street Address, City, State 659 Kearny Ave, Kearny, 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
D5401	<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 surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Office Manger (OM), the laboratory failed to follow the QC new lot verification procedure to ensure QC was within the acceptable ranges before it was put into use for analytes performed on the Qiagen Fast Pack analyzer from 2/11/16 to the date of the survey. The findings include: 1. The laboratory did not verify QC lots as follows: a. Lot 16050001 and 1605002 - expiration date 6/21/17 b. Lot 1606030 - expiration date 9/9/17 c. Lot 1704036 - expiration date 10/15/18 2. The OM confirmed on 4/26/18 at 1:20 pm that the laboratory did not follow the PM.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:
 Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the laboratory did not document corrective action taken when Endocrinology controls were out of range in 2017 and 2018. The findings include: 1. There was no documented evidence of Corrective Action (CA) taken when Endocrinology controls were out of range as follows: a. Prostate Specific Antigen (PSA) High Control (2107) - 1/16, 2/20, 4/10, 5/1, 5/24, 5/30, 9/11 and 12/11 b. PSA Low Control (2017) - 11/27 c. Testosterone (TES) High Control (2018) - 4/24 d. TES Low Control (2017) - 7/10, 11/1, 11/27 - (2018) - 1/16/, 4/24 2. TES Low and High QC were out of range on April 24, 2018. 3. Approximately 4- 5 patient samples were run per day. 4. The OM confirmed on 4/26/18 at 1:00 pm that corrective action was not taken on out of range controls.

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 surveyor review of the Final Report (FR) and interview with the Office Manager (OM), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from 2/11/16 to the date of survey. The OM confirmed on 4/26/18 at 1:30 pm that the TRD was not on the FR.