

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2108627	(X3) Date Survey Completed 04/25/2018
Name of Provider or Supplier James E Rotolo Md	Street Address, City, State 1696 Rt 88 West, Brick, 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 Biannual Assessment (BA) procedure, Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed follow the BA procedure for the Calendar year 2016 and 2017. The finding includes: 1. PM stated to perform BA twice a year with five random cases for Histopathology, Cytology and Fluorescence in situ hybridization (FISH). 2. There was no evidence that BA was performed 3. The OM confirmed on 4/25/18 at 10:30 am that the BA procedure was not followed.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials</p>

having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

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 failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for analytes performed on the Qualigen FastPack analyzer from 10/25/16 to the date of survey. The OM confirmed on 4/25/18 at 1:00 pm that the laboratory did not verify QC materials for analytes performed on Qualigen FastPack analyzer

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with Office Manager (OM), the laboratory failed to take corrective action when one out of two levels of controls were out of range for Prostate Specific Antigen (PSA) test performed on Qualigen FastPack analyzer from December 2017 through April 2018. The findings include: 1. Fastpack Control C2 Lot number 1801022-1 was out of range on 4/13/18 and no corrective action was taken. 2. Three patient samples were run and reported. 3. The OM confirmed on 4/25/18 at 11:00 am that no corrective action was taken for out of range QC on 4/25/18.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on the surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to establish a written policy for new QC lot verification used for Prostate Specific Antigen (PSA) tests performed on the Qualigen Fast Pack System from May 2016 to the date of the survey. The OM confirmed on 4/25/18 at 1:30 PM the laboratory did not establish written policies for new QC lot verification. This deficiency was previously cited.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

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 Testing Personnel failed to maintain quality control records. The findings include. 1. The laboratory failed to retain the FastPack System Control Range Cards. 2. Control Ranges for all previous used QC lots where not documented. 3. There was no in use date on QC material. 4. The OM confirmed on 4/25/18 at 11:50 am that the laboratory did maintain QC records.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

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 Director failed to ensure that the laboratory maintained a QC program from August 10/25/16 to the date of the survey. The findings include; 1. There was no documented evidence of QC review for shifts and/or trends on for the Qualigen FastPack analyzer. 2. The OM confirmed on 4/25/18 at 10:30 am the laboratory did not review monthly quality control records.