

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0908819	(X3) Date Survey Completed 05/01/2018
Name of Provider or Supplier New Jersey Urology	Street Address, City, State 1500 Pleasant Valley Way, Suite 306, West Orange, 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 Qualigen Fast Pack analyzer from 5/18/16 to the date of the survey. The findings include: 1.The PM stated that QC new lot verification "will be performed two times before putting the new batch into use". 2. All QC new lot verification was being performed once for each batch before putting into use. 3. The OM confirmed on 5/1/18 at 10:30 am that the laboratory did not follow the PM.</p>