

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0110154	(X3) Date Survey Completed 10/23/2024
Name of Provider or Supplier Urology Group, Pa	Street Address, City, State 4 Godwin Avenue, Midland Park, 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), lack of Quality control verification (QVC) records and interview with the General Supervisor (GS), the laboratory failed to follow the PM for "New Quality Control (QC) Lot Verification Procedures"" from 8/12/21 to 10/23/24. The finding includes: 1. The PM stated: a) "Run sample of new delivery QC lot and document the results" b) " Run the new lot for three times on three separate days prior to instituting the new lot" c) "Document the results for each analytes low medium and high. Compare the results to the value in the insert" 2. There was no documented evidence that the aforementioned procedures were performed. 3. The GS confirmed on 10/23/24 at 12:00 pm the laboratory did not follow the PM.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other</p>

materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM), and interview with the General Supervisor (GS) the laboratory failed to have a Quality Control (QC) procedure for Manual Urine Microscopic (MUM) tests from 10/1/22 to 10/23/24. The findings include: 1. There was no procedure for performing QC for MUM tests on each day of patient testing. 2. The GS confirmed on 10/23/24 at 11:25 am that the PM did not have QC procedure for MUM tests.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on the lack of Quality Control (QC) records and interview with the General Supervisor (GS) the laboratory failed to perform and document QC for Manual Urine Microscopic (MUM) tests on each day of patient testing from 10/1/22 to 10/23/24. The finding includes: 1. There was no documented evidence laboratory personnel performed and documented QC for MUM tests on each day of patient testing. 2. The GS confirmed on 10/23/24 at 1:30 pm the laboratory did not perform and document QC for MUM tests.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the General Supervisor (GS), the Laboratory Director (LD)

failed to ensure that the QC program was maintained for laboratory services provided from 8/12/21 to 10/23/24. The findings include: 1. The PM states "Total PSA, Free PSA, Testosterone are run once every 24 hours" a) The PM did not specify how QC shifts and trends are monitored. b) The PM did not specify criteria for acceptable QC. c) The PM did not specify what corrective action to follow when QC fails. 2) The GS confirmed on 10/23/24 at 11:30 am the LD did not ensure the QC plan was maintained. .