

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0222574	<b>(X3) Date Survey Completed</b>  03/20/2019
<b>Name of Provider or Supplier</b>  The Urology Group	<b>Street Address, City, State</b>  1860 Town Center Drive - Suite 150, Reston, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of fourteen laboratory policies and procedures in THE UROLOGY GROUP CYTOLOGY MANUAL and interview it was determined that the laboratory failed to have two laboratory procedures. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's narrative descriptive nomenclature for reporting test results. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the Laboratory Director/Technical Supervisor entered and reported test results into the laboratory information system (LIS). 3. During an</p>

interview via a phone call on March 20, 2019 at 10:25 AM, the Laboratory Director /Technical Supervisor confirmed these findings.

**D9999**

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