

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2122379	(X3) Date Survey Completed 05/04/2021
Name of Provider or Supplier Cleveland Urology Associates - Antenucci	Street Address, City, State 10500 Antenucci Blvd, Suite 101, Garfield Heights, OH	
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
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 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 record review and an interview with the Practice Manager, the laboratory failed to include in the their policies and procedures the histopathology and cytology requirements for specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system</p>

becomes inoperable. 4315 out of 4315 histopathology patients and 350 out of 350 cytology patients tested from 04/14/2019 through 05/11/21021 potential to be affected by this deficient practice. Findings Include: 1. A virtual review of the laboratory's CMS-116 form, approved by the lab director via signature and date on 01/20/2021 found 4315 patients tested in the subspecialty of histopathology and 350 patients tested in the subspecialty of cytology. 2. A virtual review of the laboratory's policies and procedures failed to find policies and/or procedures for the histopathology and cytology tests. 3. A phone interview with the Practice Manager, on 05/11/2010, confirmed that the laboratory had policies and procedures for histopathology and cytology tests, but were unable to locate them; thus, the laboratory failed to produce policies and procedures for histopathology and cytology at the time of inspection.