

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0649765	(X3) Date Survey Completed 08/25/2023
Name of Provider or Supplier Oral Pathology Consultants	Street Address, City, State 650 West Baltimore Street 7 North, Baltimore, MD	
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 review of the standard operating procedure manual (SOPM), review of laboratory records, and interview with the laboratory director (LD), the laboratory's SOPM failed to include instructions for ordering additional histopathology stains and slide recuts and instructions for creating and maintaining amended and addended test reports. Findings: 1. The laboratory evaluated oral pathology slides that were processed at a different laboratory (Lab B). 2. When a pathologist ordered additional histopathology stains or slide recuts for evaluation of patient results, a form titled "Additional Orders Worksheet" was filled out and submitted to Lab B. The SOPM did</p>

not include instructions for completing, sending, and maintaining the "Additional Orders Worksheet". 3. The LD stated that the laboratory would addend patient test reports when molecular results were received from an outside laboratory. The SOPM did not include instructions for how to create and maintain addended or amended patient test reports. 4. During the survey on 08/25/2023 at 1:10 PM, the LD confirmed that the SOPM did not include instructions for completing, sending, and maintaining the "Additional Orders Worksheet" and for creating and maintaining addended and amended test reports.