

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0945946	(X3) Date Survey Completed 07/05/2022
Name of Provider or Supplier Oral Pathology Diagnostic Service	Street Address, City, State 263 Farmington Ave, Farmington, CT	
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 staff interview, the laboratory failed to establish and follow a complete written policies and procedures for the handling and examination of oral biopsy specimens prior to patient testing in the subspecialty of oral pathology. Findings include: 1. Record review on 06/30/2022 of the laboratory protocols revealed lack of documentation of the following procedural steps: a. Specimen collection, labeling, processing, and transporting. b. Specimen acceptability and rejection. c. Control procedures to include H&E and special stains. d. Corrective action to be taken when control results fail to meet staining acceptability. e. The laboratory's protocol for</p>

microscopic examination, interpretation and entry of results including life threatening /panic outcomes. f. Actions to be taken if the microscope and/or lab information system becomes inoperable. 2. Staff interview on 06/30/2022 at 10:15 AM with the laboratory director confirmed the above findings. 3. The laboratory performs 4000 microscopic examinations in the subspecialty of oral pathology annually.