

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0925695	(X3) Date Survey Completed 02/06/2023
Name of Provider or Supplier Flor Mayoral Md Pa	Street Address, City, State 6705 Red Rd Ste 314, Coral Gables, FL	
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
D0000	A recertification survey conducted on 02/06/2023 found the FLOR MAYORAL MD PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 observation, record review and interview, the laboratory procedure manual failed to include the instructions for making the Toluidine Blue (T-Blue) Solution for their Toluidine Blue Stain (TBS) and the TBS procedure. Findings include: -During the tour of the laboratory on 02/06/2023 at 11:30 AM, the surveyor found in the</p>

flammable cabinet that there was one 25-gram flask of Toluidine Blue and one gallon container with approximately 100 milliliters of a blue solution labelled with a sign that said "T-Blue Prep 1/19/2023 and Exp 7/19/23". -Record review revealed that the laboratory started doing TBS on 07/19/2022 and stained 17 cases using the TBS. - Review of the procedure manual revealed that the procedure failed to include the preparation of the T-Blue Solution and the procedure for the TBS stain. During an interview on 02/06/2023 at 12:00 PM, the laboratory manager confirmed that the procedure manual failed to include the procedure for T-Blue Solution preparation and TBS.