Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2198281	10/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology Sc Dba Dermatology	6545 N Wickham Rd Ste F101, Melbourne, 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	An initial certification survey was conducted on October 12, 2022. Forefront Dermatology SC Dba Dermatology and Plastic Surgery, a Forefront Practice clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's procedure manual failed to include instructions for labeling the Mohs surgical specimen from 03/10/2022 to 10/12/2022. Findings: Review of the procedure titled, "Mohs Specimen Handling Procedure

	and Mapping Procedure" noted the "Tissue is brought to the lab by the Mohs surgeon." The procedure did not include instructions on how the patients specimen was to be labeled. On 10/12/2022 at 11:45 AM, the Laboratory Director acknowledged the procedure did not include instructions for labeling the patient's sample.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide documentation that showed the Laboratory Director approved, signed and dated the procedure manual prior to the first day of testing on 03/10/2022. Findings: Review of the procedure manual showed there was no documentation that showed the Laboratory Director had approved, signed or dated the procedure manual. On 10/12/2022 at 12:07 PM, the Mohs Technician stated she was unable to locate the Laboratory Director's signature page.