Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1009746	09/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Leavitt Medical Associates Of Florida Inc D/B/A	5060 Commercial Way, Spring Hill, 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 was conducted on September 13, 2023. Leavitt Medical Associates of Florida Inc. d/b/a Advanced Dermatology and Cosmetic Surgery clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the quality control (QC) records, peer review records and interview, the laboratory failed to have documentation to verify accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain at least twice annually for 2022. The findings include: Review of the Daily Quality Control Slide log showed the Laboratory Director evaluated the H&E stain quality for 12 of 12 months (January to December) for Mohs surgical cases performed in 2022. Review of the Mohs Proficiency form for the Laboratory Director dated 12/13/2023 showed the form was signed and dated by the Laboratory Director only. Mohs Proficiency form showed no indication the slides were review by another doctor. No other Mohs Proficiency forms were available for review for the Laboratory Director for 2022. On 09/13/2023 at 4:08 AM, the Area Administrative Manager stated the forms were not completed and they did not know where any other Mohs proficiency for 2022 was located.
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 review of the procedure manual and interview, the laboratory's procedure manual failed to include instructions for labeling the Mohs surgical specimen from 12 /07/2022 to 09/13/2023. The findings include: A review of the Revision History for the laboratory procedure titled "Mohs Quality Assurance Manual" showed the last Content Revision was signed and approved by Laboratory Director on 12/07/2022. Review of the procedure titled, "Mohs Quality Assurance Manual" noted, "The specimen arrives in the lab contained in a petri dish with the map." On 09/13/2023 at 4:11 PM, the Area Administrative Manager acknowledged there were no instructions on labeling the specimen placed in the petri dish.