

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2142152	(X3) Date Survey Completed 03/09/2022
Name of Provider or Supplier Advanced Dermatology And Cosmetic Surgery	Street Address, City, State 11474 Sw Village Parkway, Port Saint Lucie, 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 March 9, 2022. Advanced Dermatology and Cosmetic Surgery clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical 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 record review and interview, the laboratory's procedure manual failed to include instructions for labeling the Mohs surgical specimen from 02/02/2022 to 03/09/2022. Findings: Review of the laboratory's procedure manual showed the manual was last signed and dated by the Laboratory Director on 02/02/2022. Review of the</p>

procedure titled, "Mohs Quality Assurance Manual" noted the "Specimen is placed in a petri dish." The procedure did not include instructions for labeling the petri dish with a computer generated label with the patient's name, date of birth, date of service and account number. On 03/09/2022 at 11:20 AM, the Regional Manager stated the procedure did not include instructions for labeling the petri dish containing the patient's sample.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to provide all required information for the Mohs surgical reports for five of five sampled patients, (#1, #2, #3, #4, #5). Findings: The laboratory provided a copy of the patients' visit notes for the Mohs surgical procedures to patients if requested. Review of visit notes showed the name of the laboratory was missing from the report. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 03/09/2021, the laboratory's annual estimated histopathology test volume was 200 tests. On 03/09/2022 at 11:43 AM, the Medical Assistant stated they gave a copy of the visit notes to patients if they requested it. On 03/09/2022 at 11:46 AM, the Regional Manager stated the laboratory's name was not on the reports.