

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2154199	(X3) Date Survey Completed 11/20/2024
Name of Provider or Supplier Clearly Derm Llc	Street Address, City, State 950 Se 5th Avenue, Delray Beach, 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 November 20, 2024. Clearly Derm LLC 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 observation, interview and review of the procedure manual, the laboratory failed to have a step-by-step procedure for the preparation of 70% alcohol and 95% alcohol used in the Hematoxylin and Eosin (H&E) stain and the Periodic Acid Stain for biopsy specimens from 06/04/2024 to 11/20/2024. Findings: During a tour of the</p>

laboratory on 11/20/2024 at 9:20 AM, only 100% alcohol was observed in the flammable cabinet. Review of the procedure manual section titled Material and Reagents Used noted the laboratory used 70% and 95% Alcohol in the Tissue Tek Vacuum Infiltration Processor. Review of the procedure manual titled Procedure for Hematoxylin and Eosin Staining noted the laboratory used 95% Alcohol for staining slides. Review of the procedure titled Schiff's Periodic Acid Stain for Fungus noted the laboratory used 95% Alcohol for staining slides. Review of the procedure manuals signed by the Laboratory Director on 06/04/2024 showed there was no procedure with a step-by-step procedure for the preparation of 70% alcohol and 95% alcohol. On 11/20/2024 at 11:30 AM, the Histology Technician stated there were no instructions for the making alcohol dilutions.

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 interview and review of reference laboratory pathology reports, the pathology reports failed to report the address where the technical component for the biopsies were performed for 3 of 3 patients, (#2, #3, #4). Finding: Review of the pathology reports performed at a reference laboratory revealed the address of where the technical component for the biopsy was not listed. On 11/20/2024 at 1:00 PM, the Histology Technician acknowledged the pathology reports did not indicate the address of where the technical component was performed.