Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2149326	07/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Blue Ocean Dermatology Llc	1840 Greenwich Ave, Winter Park, 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 July 15, 2020. Blue Ocean Dermatology clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory procedure manual failed to establish a comprehensive procedure to access the competency of 2 (B, C) out of 3 (A, B,C) testing personnel. Findings: Review of the procedure manual that was signed and dated by the Laboratory Director on 5/1/20 showed that the procedure titled "Quality Assurance Manual" section titled "Personnel Assessment" did not indicate how often competency assessments would be performed, and how competency assessment for testing personnel B and C were to be documented. No other procedure on competency assessment was available. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 7/14/20, the laboratory had an estimated annual test volume of 240 test per year. During an interview on 7/15/20 at 10:24 AM, the Chief Financial Officer acknowledged that the procedure did not include how often competency assessment were to be performed or how competency assessment were documented.
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 observation, record review and interview, the laboratory procedure manual failed to note the laboratory used 95% reagent grade alcohol and failed to include the instructions for making the 95% reagent grade alcohol in their H&E (Hematoxylin and Eosin) stain. Findings: During a tour of the laboratory on 7/15/20 at 9:30 AM, there was only 100% reagent grade alcohol in the cabinet containing flammable liquids. Review of the procedure titled "Quick H&E" that was signed and dated by the Laboratory Director on 5/1/20 failed to note that the laboratory used 95% reagent grade alcohol. The procedure also failed to include instructions for making the 95% reagent grade alcohol. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 7/14/20, the laboratory had an estimated annual test volume of 240 test per year. During an interview on 7/15/20 at 10:20 AM, the Chief Financial Officer stated that was no mention that the laboratory used 95% alcohol, there were not any instructions for making it, and that the Mohs Tech told her they used 95% alcohol in their H&E stain.