Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2169717	05/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Oceans Dermatology Llc	10151 Enterprise Center Blvd Suite 204, Boynton 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	An announced recertification survey was conducted on 5/22/24 at Oceans Dermatology, a clinical laboratory in Boynton Beach, Florida. Oceans Dermatology was found not in compliance with Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document the room temperature and humidity of the laboratory for 1 of 4 days reviewed in September 2023, and failed to ensure the cryostat temperature was documented for 1 of 4 days reviewed in September 2023. Findings include: Record review of the document titled "Mohs Accession Log" showed 6 cases of Mohs were tested on 9/14 /23 by Testing Person A and 2 cases were tested on 9/14/23 by Testing Person B. Review of the document titled "Mohs Laboratory Quality Control" showed no documentation of Laboratory Temperature, Laboratory Humidity, or Cryostat Temperature for 9/14/23. During the interview with Testing Person C on 5/22/24 at 12: 45pm, it was confirmed the documentation was missing for room temperature, humidity, and cryostat temperature on 9/14/23.

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to maintain daily quality control (QC) slide documentation for Mohs testing for 1 out of 4 testing days reviewed in September 2023. Findings include: Record review of the document titled "Mohs Accession Log" showed 6 cases of Mohs were tested on 9/14/23 by Testing Person A and 2 cases were tested on 9/14/23 by Testing Person B. Review of the document titled "Quality Control Staining" showed QC documentation on 9/7/23, 9/21 /23, and 9/28/23. There was no QC documentation for 9/14/23. The facility policy for quality control states "A daily QC slide is done using the first case of the day; the doctor will look for the normal reaction of the stain on the tissue and indicate it on the Daily QC slide log." During the interview with Testing Person C on 5/22/24 at 12: 45pm, it was confirmed the QC documentation for 9/14/23 was missing.