

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2149326	<b>(X3) Date Survey Completed</b>  09/07/2022
<b>Name of Provider or Supplier</b>  Blue Ocean Dermatology Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on September 7, 2022. Blue Ocean Dermatology LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of the reagent log, and interview, the laboratory failed to ensure the reagents used in their Hematoxylin and Eosin Staining (H&amp;E) were not expired prior to patient testing from 09/30/2021 to 09/07/2022. Findings: Observations made during a tour of the laboratory on 09/07/2022 at 10:00 AM, revealed opened bottles of 100% Reagent Alcohol, Scott's Tap Water Substitute, Hematoxylin, and Eosin that were expired. The 100% Reagent Alcohol (lot number 1933106) expired on 6/25/2022 and was opened on 07/16/2020. There were no other lot numbers of the 100% Reagent Alcohol in the laboratory. The Scott's Tap Water Substitute (lot number 2106413) expired on 03/10/2022 and had no open date recorded on the bottle or on the reagent log. There were no other lot numbers of the Scott's Tap Water Substitute in the laboratory. On 09/07/2022 at 10:02 AM, the Chief Financial Officer stated she could only assume the reagents were used and acknowledged no other lot numbers of the 100% Reagent Alcohol and Scott's Tap Water Substitute were in the laboratory. The Hematoxylin (lot number 94043) expired on 09/2021 and was opened on 10/08/2020. The laboratory also had two other bottles of Hematoxylin that were used and were not expired. Hematoxylin Solution Gills No. 3 (lot number SLCH6472) expired on 03/01/2023 was opened on 03/10/2022 and Hematoxylin Gill III (lot number 2034516) expired on 12/17/2022 and had no open</p>

date recorded on the bottle or on the reagent log. The Eosin (lot number 111246) expired on 06/30/2022 and was opened according to the reagent log on 01/25/2020. The laboratory also had one other bottle of Eosin that was used and was not expired. Eosin (lot number 121683) expired on 11/30/2022 had no open date recorded on the bottle or on the reagent log. On 09/07/2022 at 10:02, the Chief Financial Officer stated she could only assume the reagents were used.