Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2169717	06/10/2026
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 CLIA recertification survey was conducted at Oceans Dermatology LLC on June 10, 2026. The laboratory was surveyed under 42 CFR, Part 493, CLIA requirements. Standard deficiencies cited are as follows:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, interview, and review of the laboratory procedure manual, and safety data sheets (SDS), the laboratory failed to ensure protection from chemical hazards used in their Hematoxylin and Eosin (H&E) stain from 5/22/24 to 6/10/26. Findings Included: 1. During a tour of the laboratory on 6/10/26 at 12:13 PM, there was no fume hood over the automated stainer and there were no respirators observed. 2. Review of the procedure titled, Hematoxylin and Eosin Automatic Stainer (signed and dated by the Laboratory Director on 1/08/26) revealed, the laboratory used the following chemicals in their H&E stain: 100% Reagent Alcohol, Hematoxylin, Eosin, Formalin Substitute, and Tap Water. 3. Review of the Safety Data Sheet (SDS)'s for the Mercedes Scientific 100% Reagent Alcohol, Mercedes Scientific Hematoxylin Stain Solution, Gill III, and Mercedes Scientific Eosin Y Solution, 1% w/v (weight per volume) in Alcohol, noted, "if exposure limits are exceeded or irritation is experienced, NIOSH/MSHA Approved respiratory protection should be worn." 4. Review of the SDS's for the Mercedes Scientific 100% Reagent Alcohol and Mercedes Scientific Eosin Y Solution, 1% w/v (weight per volume) in Alcohol, noted, "Do not breathe dust/fume/gas/mist/vapors/spray," and "Wear protective gloves /protective clothing/eye protection/face protection." 5. Review of the SDS's for the

	Mercedes Scientific Hematoxylin Stain Solution noted, "Ensure adequate ventilation, especially in confined areas." 6. Review of the SDS's for the Mercedes Scientific 100% Reagent Alcohol, Mercedes Scientific Hematoxylin Stain Solution, Gill III, and Mercedes Scientific Eosin Y Solution, 1% w/v (weight per volume) in Alcohol showed each had the symbol for respiratory tract irritant. 7. On 6/10/26 at 3:00 PM, the Consultant acknowledged there was no fume hood over the stainer and the laboratory was not performing any chemical monitoring. Word Key NIOSH - National Institute for Occupational Safety and Health MSHA - Mine Safety and Health Administration
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on interview, and record review, the laboratory failed to verify the accuracy of the Mart-1 (Melanocytic Marker) Immunohistochemical (IHC) stains at least twice annually for 2024 and 2025. Findings Included: 1. Review of the test menu attached to the Clinical Laboratory Improvement Amendments Application for Certification (signed by the Laboratory Director on 6/10/26) revealed, the laboratory read out the H&E stain and the MART-1 IHC stain. 2. Review of the Quality Assurance Proficiency Testing form revealed, peer review was performed on Testing Personnel A (Laboratory Director) and on Testing Personnel B on 6/06/24, 12/26/24, 6/05/25, and 12/08/25. 3. Review of the Quality Assurance Proficiency Testing form and review of the Melanoma Quality Control Slides log revealed only one peer review case was performed on Testing Personnel B on 6/05/25 that had a Mart-1 stained slide. 4. Review of the Quality Assurance Proficiency Testing form revealed, there was no documentation of the review of the Mart-1 stain listed on the form. 5. On 6/10 /26 at 1:20 PM, the Consultant acknowledged only one case from 2024 and 2025 had a Mart-1 stained slide.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on interview, and record review, the laboratory failed to document the acceptability of the Mart-1 (Melanocytic Marker) Immunohistochemical (IHC) stain positive and negative quality control slide for 19 of 19 days (1/09/25, 1/16/25, 1/23 /25, 2/06/025, 2/13/25, 2/27/25, 3/06/25, 3/13/25, 3/20/25, 4/03/25, 5/15/25, 6/05/25, 6 /19/25, 7/10/25, 7/17/25, 7/23/25, 8/07/25, 8/14/25, 9/18/25); and failed to document the acceptability of the Mart-1 IHC stain negative quality control slide for 5 of 5 days, (10/23/25, 11/06/25, 11/20/25, 12/11/25, 12/18/25). Findings Included: 1. Review of the Melanoma Quality Control Slides log for 2025 noted, check if the positive and

	negative control slides are ok. 2. Review of the Melanoma Quality Control Slides log for 2025 revealed the laboratory failed to document the acceptability of the Mart-1 (Melanocytic Marker) Immunohistochemical stain positive and negative quality control slide for the following dates: 1/09/25, 1/16/25, 1/23/25, 2/06/25, 2/13/25, 2/27 /25, 3/06/25, 3/13/25, 3/20/25, 4/03/25, 5/15/25, 6/05/25, 6/19/25, 7/10/25, 7/17/25, 7 /23/25, 8/07/25, 8/14/25, and 9/18/25. 3. Review of the Melanoma Quality Control Slides log for 2025 revealed, the laboratory failed to document the acceptability of the Mart-1 (Melanocytic Marker) Immunohistochemical stain negative quality control slide for the following dates: 10/23/25, 11/06/25, 11/20/25, 12/11/25, and 12/18/25. 4. On 6/10/26 at 2:36 PM, the Consultant acknowledged the stain quality was not documented.