

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2107105	(X3) Date Survey Completed 07/16/2024
Name of Provider or Supplier Indigo Dermatology Llc	Street Address, City, State 675 S Babcock St, Melbourne, 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 11, 2024 to July 16, 2024. Indigo Dermatology LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual, previous surveyor notes, peer review records, and interview, the laboratory failed to have a policy and verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin stain (peer review) at least twice annually for Testing Personnel A in 2022 and Testing Personnel A and B in 2023. Findings: Review of the procedure manual revealed the laboratory was missing a procedure on peer review. On 07/11/2024 at 11:35 AM, the Mohs Technician stated he did not know where the policy on peer review was located. Review of the survey notes from the survey on 05/16/2022, showed peer review was performed in April 2022 for Testing Personnel B. Peer review records for 2022 were not available for review. Review of the QC and QA records received on 07/16/2024 at 2:57 PM revealed peer review records for 2022 were not included. Review of the Quality Control / Peer Review listed eight cases on page one and four cases on page two. The first five cases on page one were peer review for Testing Personnel A and the last three cases were peer review for Testing Personnel B. The dates of the cases on page one, in order were 12/20/2023, 12/18/2023, 12/18/2023, 02/06/2024, 01/09/2024, 01/03/2024, 12/12/2023, and 12/12/2023. The first three cases on page two were peer review for Testing Personnel B and the last case was peer review for Testing Personnel A. The dates of the cases on page two, in order were 12/14/2023, 12/12/2023, 02/12/2024, and 02/06/2024. Review of the Quality Control / Peer Review</p>

showed there was no date listed as to when the peer review was performed. There were no other peer review records. On 07/11/2024 at 11:24 AM, the Mohs Technician stated he did not know when the peer review was sent out for review.