

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2019760	<b>(X3) Date Survey Completed</b>  01/07/2025
<b>Name of Provider or Supplier</b>  Aqua Dermatology Of Florida, Pa	<b>Street Address, City, State</b>  261 9th St S, Naples, 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 January 07, 2025. AQUA DERMATOLOGY OF FLORIDA PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin &amp; Eosin (H&amp;E) stain for six testing dates from 01/01/2024 to 06/30/2024. Findings included: 1- Review of the Form CMS-209, Laboratory Personnel Report (CLIA); signed by the laboratory director on 01/02/2025 revealed that the laboratory had one Testing Person (TP#1) performing High Complexity testing. 2-The laboratory used the "RCD Laboratory-Daily QC Worksheet" to record the acceptability of the H&amp;E stain. Review of the QC form showed that for the following testing dates 04/03/2024, 04/17/2024, 05/08/2024, 05/15/2024, 05/16/2024 and 06/12/2024, the Initials recorded for those days did not match with the Initials of TP#1. 4-Review of patient Log for the days of reference revealed that 13 patients were tested. 5-During an interview on 01/07/2025 at 12:00 PM the Office Consultant confirmed that the TP#1 failed to document the acceptability of the Daily QC slide for H&amp;E Stain for the days listed above.</p>