

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1021746	(X3) Date Survey Completed 09/08/2021
Name of Provider or Supplier Aqua Dermatology Of Florida Pa	Street Address, City, State 600 Village Sq Crossing Ste 201, Palm Beach Gardens, 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 9/8/21 at Waters Edge Dermatology LLC, a clinical laboratory in Palm Beach Gardens, Florida. Waters Edge Dermatology LLC is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the standard level deficiencies:
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on Wisconsin State Laboratory of Hygiene (WSLH) proficiency record review and interview with the General Supervisor, the laboratory failed to have documentation of signed attestations for the mycology subspecialty for dermatophyte testing medium (DTM) proficiency testing for two out of two years reviewed (2019-2021). The findings included: Review of WSLH DTM proficiency testing records for two out of two years (2019 - 2021) revealed the laboratory had 4 proficiency testing events (3rd Event 2019, 3rd Event 2020, and 1st and 2nd Event 2021) that the attestation statements were not signed and were missing 2 proficiency testing events</p>

(1st and 2nd Event 2021) attestation statements. Interview on 9/08/21 at 12:05 p.m., the General Supervisor stated he did not know that the Laboratory Director and Testing Personnel had to sign the WLSH DTM proficiency testing attestation statements.