Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1016973	05/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Aqua Dermatology Of Georgia , Pc	835 Cogburn Avenue, Marietta, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) Validation survey was completed on May 23, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on log sheet document review, policy and procedure manual (SOP) review , and staff interviews, the laboratory failed to enroll in an approved proficiency testing (PT) program for Mycology (KOH) or Histopathology. Findings include: 1. Review of Mycology log sheet documents revealed no evidence of PT being performed. 2. Review of Histopathology log sheet documents revealed no evidence of PT being performed. 3. Review of the SOP revealed no procedure for PT. 4. Interview with the histotechnologist coordinator and staff #4 (CMS 209) on 5/23/19 in the histotechnologist office at approximately 2:15 PM confirmed PT was not performed for Mycology or Histopathology.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on maintenance document review and staff interview, the laboratory failed to perform and document maintenance as defined by the manufacturer on the SCS BOND IHC. Findings include: 1. Review of BOND maintenance documents revealed monthly maintenance was not performed/documented: January 2018 - June 2018; August 2018- December 2018; or January 2019 - February 2019. 2. Interview with the histotechnologist coordinator on 5/23/19 at 2:35 PM in the histotechnologist office, confirmed the aforementioned monthly maintenance was not performed/documented.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on log sheet document review, policy and procedure manual (SOP) review , and staff interviews, the laboratory director (LD) failed to ensure the lab enrolled in an approved proficiency testing (PT) program for Mycology (KOH) or Histopathology. Findings include: 1. Review of Mycology log sheet documents revealed no evidence of PT being performed. 2. Review of Histopathology log sheet documents revealed no evidence of PT being performed. 3. Review of the SOP revealed no procedure for PT. 4. Interview with the histotechnologist coordinator and staff #4 (CMS 209) on 5/23/19 in the histotechnologist office at approximately 2:15 PM confirmed PT was not performed for Mycology or Histopathology.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of testing personnel(TP) competency documents and staff interview , the technical supervisor (LD) failed to perform annual competency on all testing personnel. Findings include: 1. Review of TP competency documents revealed no documentation of competency being performed for 12 of 12 TP (CMS 209) for the year 2018. 2. Interview with the histotechnologist coordinator on 5/23/19 at 2:35 PM in the histotechnologist office, confirmed the competencies were not done in 2018.