

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2107014	(X3) Date Survey Completed 03/18/2019
Name of Provider or Supplier Aqua Dermatology Of Georgia, Pc	Street Address, City, State 1357 Hembree Road, Suite 250, Roswell, 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) recertification survey was completed on March 18, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance records and an interview with the laboratory coordinator, the Technical Supervisor (TS) who is also the laboratory director failed to review maintenance records in 2017, 2018 and 2019. Findings include: 1. Review of maintenance logs including: the Avantik QS12 Cryostat, Humidity, room temperature, eye wash, monthly Quality Assurance(QA) logs revealed logs were not reviewed and signed on a monthly basis by (TS) who is also the laboratory director. 2. An interview with the laboratory coordinator on March 18, 2019 at approximately 11:50 am in the review room confirmed maintenance logs were not reviewed and signed by the (TS) who is also the laboratory director.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated</p>

to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) documents and interview with the laboratory coordinator , the Technical Supervisor(TS) who is also the laboratory director failed to perform or sign off on annual competencies on all testing personnel in 2017 and 2018. Findings include: 1. Review of testing personnel documents revealed the technical Supervisor failed to sign off or perform annual competencies on TP #7, #8 and #9 (CMS 209 form). 2. An interview with the laboratory coordinator at approximately 11:59 AM on March 18, 2019 in the review room confirmed the (TS) did not sign off or perform annual competencies for the aforementioned testing personnel.