

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1016973	(X3) Date Survey Completed 01/25/2022
Name of Provider or Supplier Aqua Dermatology Of Georgia , Pc	Street Address, City, State 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) recertification survey was completed on January 25, 2022. 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:
D5006	<p>MYCOLOGY CFR(s): 493.1203</p> <p>If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on Proficiency Testing (PT) and staff interview, the laboratory failed to perform Proficiency Testing (PT) for the speciality of Mycology (KOH). Findings include: 1. Review of Mycology log sheet documents revealed that PT was not performed in 2020. 2. During an interview with the Histotechnologist Coordinator, on January 25, 2022, at approximately 1:45 PM, in an office outside of the laboratory #2, confirmed PT was not performed for the specialty of Mycology in 2020.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to calibrate the</p>

Olympus BX41 microscope per the procedure manual. Findings include: 1. Observation during the lab tour revealed the last calibration on the Olympus BX41 microscope was in February 2018. 2. Observation during the lab tour revealed there was no calibration on the Lumeon microscope used for KOH readings. 3. During an interview with the Histotechnologist Coordinator on January 25, 2022, in an office outside of Laboratory #2, confirmed the microscope was not calibrated since February 2018.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the laboratory records, procedure manual (SOP), and staff interview, the laboratory director failed to ensure that the quality assessment(QA) programs are established and maintained to identify failures in quality. Findings include: 1. Review of the SOP revealed the lack of a written Quality Assessment (QA). 2. No QA documents were available to review on KOH preparation slides for 2020 at the time of survey. 3. During the interview with the Histotechnologist Coordinator on January 25, 2022, in an office outside of the #2 laboratory, confirmed the missing QA for 2020.