

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2093798	(X3) Date Survey Completed 10/13/2022
Name of Provider or Supplier Aqua Dermatology Of Florida Pa	Street Address, City, State 216 Ponte Vedra Parke Dr, Ponte Vedra Beach, 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	At the time of the announced, onsite recertification survey, Scott D Warren Md Pa was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document the room temperature and humidity of the laboratory for 2 of 12 days reviewed in August 2022, and failed to ensure the cryostat temperature was documented for 2 of 12 days reviewed in August 2022. Findings include: 1. Review of the "Laboratory Ambient Room Temperature and Relative Humidity" log for August 2022 showed the room temperature and humidity was not documented on 8/9/22 and 8/10/22. Review of the "Mohs Frozen Section Specimen Log" showed patient testing was performed on 8/2/22, 8/3/22, 8/5/22, 8/9/22, 8/10/22, 8/12/22, 8/16/22, 8/17/22, 8/18/22, 8/23/22, 8/24/22, and 8/31/22. During an interview on 10/13/22 at 10:30am with the Histotechnologist, it was confirmed that the temperatures were not documented. 2. Review of the "Cryostat Temperature Log" for August 2022 showed the cryostat temperature was not documented for 8/9/22 and 8/10/22. Review of the "Mohs Frozen Section Specimen Log" showed 16 patients were tested on 8/9/22 and 8 patients were tested on 8/10/22. During an interview on 10/13/22 at 10:30am with the</p>

Histotechnologist, it was confirmed that the temperature of the cryostat was not documented.