

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0705623	(X3) Date Survey Completed 02/20/2023
Name of Provider or Supplier Aqua Dermatology Of Florida, Pa	Street Address, City, State 1111 Kane Concourse Ste 100, Bay Harbor Islands, 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	A recertification survey conducted on 2/16/2023 found the RIVERCHASE DERMATOLOGY clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to dispose of its biochemical and biohazardous waste, as required by the manufacturer's instructions. During an interview at around 2:30pm on February 16, 2023, when asked where she was disposing of the laboratory waste chemicals and reagents, the laboratory director answered by pointing to the hand sink drain. During the survey there was no observation of containers, marked as waste collection containers for the proper storage and disposal of waste chemicals and reagents. Even though a large amount of chemicals and reagents appeared to be in use. The laboratory consultant admitted during an interview at around 4:30pm on February 16, 2023 that she also did not find any laboratory waste containers, that she would prepare some, and agreed that a sink is an improper method for the disposal of chemical and biohazard waste. That the laboratory waste should be removed safely and securely, by the specialist biohazard waste removal service.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</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.

This STANDARD is not met as evidenced by:

Based on observation, and interview: The laboratory did not accurately document the laboratory daily room temperature, required to be 68 F to 75 F. The laboratory did not accurately document the laboratory humidity, required to be 40% to 75%. This is because during the survey, the thermometer and humidity measuring device was observed being located within an enclosed cupboard. Thus, due to its physical confines, the device could not reasonably be accurately measuring the laboratory daily room temperature or humidity. The laboratory director admitted during an interview at around 2:30pm on February 16, 2023 that the thermometer was located in an enclosed cupboard. The laboratory consultant admitted during an interview at around 4:30pm on February 16, 2023, that the enclosed cupboard was the improper place to take temperature and humidity measurements for the entire laboratory space. Due to the failure to accurately monitor and document the laboratory room temperature and humidity. There were one-hundred and twenty-one (n=121) patients per year, or approximately two hundred and forty two (n=242) patients over the past two years were potentially affected by this deficiency. Based on observation, record review, and interview, the cryostat used to provide Mohs treatments to patients, had a temperature that was warmer than its acceptable operating range. The acceptable operating range for the Leica CM 1850 cryostat was -20 C to -30 C, but it was used on the following dates / number of patients / with temperatures outside of the acceptable range as follows: January 4. 2023, 4 patients (-19 C) January 9. 2023, 5 patients (-19 C) January 23. 2023, 6 patients (-18 C) December 12, 2022, 8 patients (-19 C) September 19, 2022, 8 patients (-17 C) August 22, 2022, 2 patients (-17 C) August 8, 2022, 6 patients (-18 C) July 25, 22, 2022, 3 patients (-19 C) July 11, 22, 2022, 5 patients (-19 C) The laboratory consultant admitted during an interview at around 4:30pm on February 16, 2023, that the cryostat temperatures were warmer than they should have been for providing Moh's treatments to patients, because they were documented as being outside the required operating range. The laboratory consultant by email on February 20, 2023, admitted that there was a cooling issue with the cryostat which caused this deficiency. Due to the failure to adequately cool biopsies for Moh's surgeries, because the cryostat temperatures were outside of the acceptable operating range. There were forty-seven (n=47) patients over six months, between January 23, 2023, and July 11, 2022, who were potentially affected by this deficiency.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, two containers of flammable solutions were being incorrectly stored outside the required flammable safety cabinets. During the survey a spray container marked as 100% alcohol was observed being incorrectly stored in a wooden cupboard. Due to the risk of igniting a fire, the MSDS storage requirement for 100% alcohol is inside a flammable safety cabinet. Thus, this container of alcohol was observed being incorrectly stored outside a flammable safety cabinet. During the survey a container marked as 70% Isopropyl alcohol was observed being incorrectly stored in an open trolley. Due to the risk of igniting a fire, the MSDS storage requirement for 70% Isopropyl alcohol is inside a flammable safety cabinet. Thus, the container of alcohol was observed being incorrectly stored outside a flammable safety cabinet.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, a gallon container of reagent solution used for the bluing of Mohs patient biopsies; Platinum Line Scott's Tap Water Substitute, lot # 2032507, expired on December 2, 2021. At the time of survey, the laboratory was observed using a chemical reagent that had exceeded its expiration date, over a year ago, with no replacement unexpired reagent available. The laboratory consultant admitted during an interview at around 4:30pm on February 16, 2023 that the reagent had exceeded its expiration date, and that it had been in use until the survey. Due to the use of an expired reagent, which had exceeded its expiration date on December 2, 2021, to the present time. There were approximately one-hundred and twenty-one (n=121) over the past year, who were potentially affected by this deficiency.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview, the laboratory failed to have annual maintenance performed on the Leica CM 1850 cryostat, required by the manufacturer during the year 2021, and also failed to have annual maintenance performed on the Nikon Eclipse E200 microscope, during the year 2022. The cryostat and microscope annual preventative maintenance was not documented and incomplete during the past two years of this laboratory survey. The laboratory records showed

that maintenance on the cryostat was performed in November 2020. Annual preventative maintenance was due on November 2021, but was not performed. Likely due to the failure to maintain the cryostat, it was discovered as not being able to maintain temperatures within its normal operating range later in 2022 and 2023. The laboratory consultant admitted during an interview at around 4:30pm on February 16, 2023 and by email on February 20, 2023, that the required annual maintenance for the year 2021 had not be performed. Due to the failure to provide preventative annual maintenance, the cryostat temperature malfunctioned and forty-seven (n=47) patients were potentially affected by this deficiency.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, the laboratory failed to document any corrective actions for the out of range cryostat temperatures, in a corrective action log. The laboratory consultant admitted during an interview at around 4:30pm on February 16, 2023, and by an email on February 20, 2023, that the cooling system of the Leica CM 1850 cryostat was known to be malfunctioning and had eventually to be replaced on February 10, 2023 by a service engineer. However, the laboratory director continued to use the cryostat for the Mohs surgery of forty-seven (n=47) patients between January 23, 2023, and July 11, 2022, when its lowest available documented temperatures were -17 C to -19 C. Whereas, the acceptable cryostat cooling temperatures were to be within the range of 20 C to -30 C. Thus, during six months, the laboratory director documented the out of acceptable range temperatures for the testing of Moh's patients who were having skin cancer treatment. There was no evidence of a corrective action log, and no documentation of any corrective actions. The laboratory consultant admitted during an interview at around 4:30pm on February 16, 2023, that there was no corrective action log, and no documentation of correctives actions on the dates that the cryostat temperature was malfunctioning, while being used to provide Mohs surgeries to patients. Due to the failure to provide and document corrective actions, the cryostat temperature malfunction was not timely corrected, and forty-seven (n=47) patients were potentially affected by this deficiency.