Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0296866	09/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Aqua Dermatology Of Florida Pa	1122 Druid Rd E, Clearwater, 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	An announced CLIA recertification survey was conducted at Riverchase Dermatology on 09/09/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 record review and interview with the Laboratory Supervisor, the laboratory failed to maintain documents for maintenance of equipment used in the histopathology laboratory that performs hematoxylin and eosin slide stains for two out of two years (2017-2019). Findings included: Record review of the "Frozen Section Procedure" reviewed by the Laboratory Director on 01/03/18 revealed the Quality Control (QC) section noted "Clean cryostat out each day of use from tissue fragments and at least monthly defrost and decontaminate 100% alcohol. Log decontamination onto QC Log." Record review of the "Mohs Technologist Job Description" revealed responsibilities included "Completion and recording of all necessary Quality Control for Mohs specimens." Record review of the "Mohs Lab Equipment Monitoring /Preventative Maintenance Quality Control" logs showed the equipment maintenance for the cryostat or the microscope was to be indicated by marking a "D - Daily", 'W-Weekly", "M-Monthly", "A-Annually", and "B-Biannually". Daily, Weekly, Monthly,

	Annually, and Bi-Annually equipment maintenance for cryostat and microscope were described on the log. Record review of the "Mohs Lab Equipment Monitoring /Preventative Maintenance Quality Control" logs for two out of two years (2017-2019) revealed the equipment maintenance for the cryostat and microscope had not been documented for 15 months (04/2018-07/2019) out of 24 months (09/2017 - 08 /2019). In addition, the log was documented incorrectly (with a check mark) for 5 months (11/2017, 01/2018-03/2018, and 08/2019) out of 24 months (09 /2017-08 /2019). In 01/2019, only cryostat monthly equipment maintenance was documented . In 12/2017, cryostat equipment maintenance was documented incorrectly and microscope maintenance was not documented., and for 09/2017 and 10/2017 daily equipment maintenance was documented correctly but monthly maintenance was not documented on the log. Record review of the "Bi-Annual Laboratory Self Inspection Checklist" showed that the self inspection was performed twice annually (12/2017, 06 /2018, 12/2018, 6/2019) by the Laboratory Supervisor and the checklist included "Equipment Monitoring/Preventative Maintenance Quality Control". This checklist item was checked off. On 09/09/19 at 11:15 am, the Laboratory Supervisor confirmed documentation was not performed or documentation was incorrect. The Laboratory Supervisor also stated that the laboratory's quality assurance did not catch the documentation issue.