Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1030727	(X3) Date Survey Completed 06/10/2025
Name of Provider or Supplier Aqua Dermatology Of Florida Pa	**Street Address, City, State** 13361 Saddle Rd Suite 103, Fort Myers, 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 Aqua Dermatology of Florida PA dba Riverchase Dermatology on 06/10/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 record review and interview, the laboratory failed to document corrective actions taken when Water Bath #3 temperatures were outside of the established operating parameters for April, May, June, July, and August of 2024. Findings include: 1. The Water Bath established parameters for temperature was listed as 40-45 degrees Celsius (C) on the Microtome and Water Bath QC (Quality Control) forms. 2. The Water Bath #3 temperature was documented as 39 C on 4/12/24, 4/16/24, 4/30/24, 5/2/24, 5/3/24, 5/8/24, 5/9/24, 5/10/24, 5/15/24, 5/20/24, 5/21/24, 5/22/24, 6/10/24, 6/13/24, 6/17, 6/18/24, 6/20/24, 6/21/24, 6/24/24, 6/27/24, 6/28/24, 8/1/24, 8/2/24, 8/6/24, 8/7/24, 8/9/24, 8/13/24, 8/14/24, 8/15/24, 8/16/24, 8/19/24, 8/20/24, 8/22/24, 8/23/24, 8/26/24, and 8/29/24. 3. The Water Bath #3 temperature was documented as 38 C on 4/18/24, 4/19/24, 4/22/24, 4/23/24, 4/25/24, 4/26/24, 4/29/24,

	5/1/24, 6/25/24, 7/1/24, 7/2/24, 7/3/24, 7/5/24, 7/8/24, 7/9/24, 7/10/24, 7/11/24, 7/12/24, 7/15/24, 7/16/24, 7/17/24, 7/18/24, 7/25/24, 7/29/24, 7/30/24, 7/31/24, and 8/5/24. 4. The Laboratory Manager/Testing Person #A confirmed on 6/10/25 at 3:00 p.m., the Water Bath #3 listed temperatures of 38 C and 39 C were not within the established operating parameters and there was no documentation of corrective actions taken for the days the Water Bath #3 temperatures were outside of the established operating parameters for April, May, June, July, and August of 2024. .