Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1021746	12/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Aqua Dermatology Of Florida Pa	600 Village Sq Crossing Ste 201, Palm Beach Gardens, 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 on November 4, 2025 to December 5, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6108 493.1441 Condition: Technical Supervisor Responsibilities
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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, record review and interview, the laboratory failed to monitor and document temperature and humidity of the room where the immunohistochemical (IHC) slides were stained, failed to record the humidity of the main laboratory, failed to use a certified thermometer to record the refrigerator and freezer temperature, and failed to have a procedure defining criteria for temperature and humidity of the room and temperature refrigerator and freezer from 02/29/2024 to 11/04/2025. Findings: A 1. During a tour of the laboratory on 11/04/2025 at 10:40 PM, the following equipment was seen in the IHC room: two Roche Benchmark Ultra Plus stainers, a Leica ST5020 Multistainer, and a Leica CV5030 Robotic Cover Slipper. 2. Review of the operation manual for the Roche Benchmark Ultra Plus stainers listed the

	environmental requirements for the room temperature as 68 degree - 90 degrees Fahrenheit (F), 20 to 32 degrees Celsius (C) and humidity range of 10% to 90%. 3. Review of the operations manual for the Leica ST5020 listed the operating temperature for the room temperature as 15 to 40 degrees C and relative humidity range of 10% to 80%. 4. Review of the operations manual for the Leica CV5030 Robotic Cover Slipper listed the operational temperature for the cover slipper as 15 to 35 degrees C and relative humidity range of 20% to 80%. 5. Review of the temperature logs revealed there were no temperature logs for the IHC room. 6. During an interview on 11/04/2025 at 12:55 PM, the Laboratory Supervisor stated they were not taking the temperature or humidity of the IHC room. B 1. During a tour of the laboratory on 11/04/2025 at 10:40 PM, the following equipment was seen in the main laboratory: Leica EG1160 Paraffin Embedding Center, Leica RM2125 Rotary Microtome, Boekel Tissue Flotation Bath, Sakura Tissue-Tek SCA Cover Slipper, Leica Peloris II Rapid Tissue Processor, and Leica IP C Automated printing system for tissue cassettes. 2. Review of the operations manual for the Leica EG1160 Paraffin Embedding Center listed the operational temperature as 18 to 35 degrees C. 3. Review of the operations manual for the Leica RM2125 Rotary Microtome listed the operational temperature as 10 to 40 degrees C. 4. Review of the operations manual for the Boekel Tissue Flotation Bath listed the operational temperature as 20 to 30 degrees C and maximum relative humidity range of 80%. 5. Review of the operations manual for the Sakura Tissue-Tek SCA Cover Slipper listed the operational temperature as 10 to 30 degrees C and a relative humidity of 30% to 70%. 6. Review of the operations manual for the Leica Peloris II Rapid Tissue Processor listed the operational temperature as 5 to 35 degrees C and relative humidity as 10% to 80%. 7. Review of the operations manual for the Leica IP C Automated printing system for tissue cassettes listed the operational temperature as 15 to 30 degrees C and relative humidity at 20% to 80%. 8. Review of the Daily Temperature Chart for the main laboratory showed the humidity for the room was not recorded. 9. During an interview on 11/04/2025 at 1:00 PM, the Laboratory Supervisor stated they had not recorded the humidity of the main laboratory. C 1. An observation of the thermometer on 11/04 /2025 at 1:35 PM, revealed the thermometer used to record the refrigerator and freezer temperature did not have a sticker stating the thermometer was certified. 2. Review of the quality control logs showed there was no documentation showing the thermometer was calibrated. 3. During an interview on 11/04/2025 at 1:40 PM, the Laboratory Supervisor stated he did not know if the thermometer was certified and acknowledged it did not have a sticker on it. D 1. Review of the procedure manual showed there was no procedure defining criteria for the temperature and humidity of the rooms, and temperatures of the refrigerator and freezer. 2. During an interview on 11/04/2025 at 4: 20 PM, the Laboratory Supervisor acknowledged he could not find a procedure defining criteria for the temperature and humidity of the rooms, and temperatures of the refrigerator and freezer.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by:

	Based on observation, review of procedure manual, and interview, the laboratory failed to properly label the quality control (QC) slides used for Immunohistochemical (IHC) stains from Sysmex from 02/09/2024 to 11/04/2025. Findings included: 1. Review of the test menu for the laboratory showed the laboratory performed the following IHC stains: Actin (Muscle Specific IHC stain), Adipophillin (sebaceous neoplasms IHC stain), Androgen Receptor (tumor cell marker IHC stain), BCL-2 (B-cell lymphoma 2 IHC stain), BCL-6 (lymphoma IHC stain), Ber-EP4 (Epithelial Antigen IHC stain), CD1A (Cluster of Differentiation 1A gastrointestinal epithelium and cytoplasmic hepatocytes IHC stain), CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), CD4 (Cluster of Differentiation 4 T cell Lymphocytic IHC stain), CD5 (Cluster of Differentiation 5 T cell Lymphocytic IHC stain), CD7 (Cluster of Differentiation 7 T cell Lymphocytic IHC stain), CD8 (Cluster of Differentiation 8 T cell Lymphocytic IHC stain), CD10 (Cluster of Differentiation 10 dendritic cell Cell Surface Enzyme IHC stain), CD20 (Cluster of Differentiation 20 B cell Lymphocytic IHC stain), CD30 (Cluster of Differentiation 30 Transmembrane Cytokine Receptor), CD31 (Cluster of Differentiation 31 platelet endothelial cell adhesion molecule-1 IHC stain), CD34 (Cluster of Differentiation 34 progenitor cells IHC stain), CD45 (Cluster of Differentiation 45 leukocyte IHC stain), CD56 (Cluster of Differentiation 56 neuroedrocrine marker, NK cells IHC stain), CD63 (Cluster of Differentiation 56 melanoma IHC stain), CD68 (Cluster of Differentiation 68 Monocytes and Tissue Macrophages IHC stain), CD117 (Cluster of Differentiation 117, stem cell IHC stain), Chromogranin (Neuroendocrine cell IHC Marker), CK 5/6 (Cytokeratin 5/6 IHC stain), CK7 (Cytokeratin 7 Protein IHC stain), CK-CAM 5.2 (epithelial tumor IHC stain), CK-PAN (Epithelial IHC stain), CK20 (Cytokeratin 20 IHC stain), Desmin (Smooth Muscle Tumor IHC stain), EMA (Epithelial Membrane Antigen IHC stain), ERG (Endothelium; TMPRSS2-ERG IHC stain), Factor XIIIa (Factor XIIIa protein IHC stain), HHV-8 (Herpes Virus Type 8 IHC stain), HMB45 (Anti-Human Melanosome IHC stain), HMW - (high molecular weight IHC stain), HPV (Human Papilloma Virus IHC stain), HSV 1 & 2(Herpes Simplex Virus Type 1 &2 IHC stain), Ki-67 (Nuclear Non-histone Protein IHC stain), Melan-A (Melanocytic Marker IHC stain), MiTF (Microphthalamia Transcription Factor IHC stain), MLH-1 (Mutl Homolog 1 Colorectal Cancer IHC stain), MOC-31 (Epithelial IHC Stain), MPO (Myeloperoxidase IHC stain) MSH2 (Melanocyte Stimulation Hormone 2 Tumor Suppressor Gene IHC stain), MSH6 (Melanocyte Stimulation Hormone 6 Colorectal Cancer and Endometrial Cancer IHC stain), NSE (Neuron Specific Enolase IHC Stain), Neurofilament (neoplastic cells IHC stain), P53 (tumor suppressor protein), P63 (Myoepithelial and Basal cells IHC stain), PMS-2 (Postmeiotic Segregation Increase 2 IHC stain), Podoplanin (lymphatic channel endothelium IHC stain), PRAME (Melanoma IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), SOX-10 (Melanoma IHC stain), Synaptophysin Neuroendocrine cell IHC Marker), Treponema Pallidum (Syphilis IHC stain), TTlF-1 (Epithelial cells IHC stain), Tyrosinase (Melanocyte IHC stain), Vimentin (Mesenchymal Cells IHC stain), and VZV (Varicella Zoster Virus IHC stain). 2. Observation on 11/04/2025 at 2:50 PM, revealed the IHC QC slides were not labeled. 3. During an interview on 11/04 /2025 at 2:55 PM, the Laboratory Supervisor stated they labeled the boxes that each IHC control slides were in and did not label each individual slide.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document quality control information including the lot numbers, expiration dates, and open dates for all reagents used for the Hematoxylin and Eosin (H&E) stain from 02/09/2024 to 11/04/2025. Findings included: 1. Review of the policy titled Reagent Log Procedure noted, "A reagent log is kept in order to monitor the incoming, usage, outgoing and expiration dates of all reagents used in the histology laboratory." 2. Review of the laboratory's quality control records revealed there was no documentation of the reagents used in the H&E stain. 4. During an interview on 11/04/2025 at 3:25 PM, the Laboratory Supervisor acknowledge they did not have a reagent log for reagents used for the H&E stain.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Technical Supervisor (Laboratory Director) failed to perform the semi-annual (sixth month) competency evaluation on one (Testing Personnel J) of six (Testing Personnel H, J - N) Testing Personnel's semi-annual competency evaluation on the testing personnel who performed grossing for 2024 and 2025 (See D6127); and the Technical Supervisor (Laboratory Director) failed to perform five (Testing Personnel J - N) of six (Testing Personnel H, J - N) Testing Personnel's competencies on the Testing Personnel who performed grossing for 2024 and 2025. (See D6128)
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Supervisor (Laboratory Director) failed to perform the semi-annual (sixth month) competency evaluation on one (Testing Personnel J) of five (Testing Personnel H, J - M) Testing Personnel's semi-annual competency for those that performed grossing for 2024 and 2025. Findings Included: 1. Review of the competency evaluations revealed there were six Testing Personnel who performed grossing. 2. Review of Performance Evaluations revealed the evaluations were performed on 06/01/2024 and on 05/01/2024 for Testing Personnel J. 3. During an interview on 11/04/25 at 2:20 PM, the Laboratory Supervisor acknowledged the competency performed on 06/01/2024 was her initial competency and the sixth month competency evaluation was missing.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Supervisor (Laboratory Director) failed to perform four (Testing Personnel H, J - M) of five (Testing Personnel H, J - M) Testing Personnel's competencies that performed grossing for 2024 and 2025. Findings Included: 1. Review of the competency evaluations revealed there were five Testing Personnel who performed grossing. 2. Review of the Performance Evaluations revealed the evaluations were performed on 06/01/2024 for Testing Personnel J, on 04 /01/2024 for Testing Personnel K - M, on 05/01/2025 for Testing Personnel J, and on 04/01/2025 for Testing Personnel K - M. 3. Review of the Performance Evaluation forms, signed and dated by the Laboratory Supervisor, indicated the forms were "Prepared by and Interviewed by" the Laboratory Supervisor. 4. Review of the Histology Equipment and Procedures for Tech Competency form showed the Laboratory Supervisor evaluated the performance, dated, and initialed the competency form for Testing Personnel J - M. 5. Review of the transcripts for the Laboratory Supervisor revealed he had only 19 science credits of which only four credits were in chemistry. Review of the regulation revealed the Laboratory Supervisor did not meet the qualification to be Technical Supervisor 6. During an interview on 11/13/25 at 8: 27 AM, the Laboratory Supervisor acknowledge he performed and filled out the competency evaluations.