Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1021746	02/08/2024
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	Recertification survey was conducted from 1/23/2024 to 2/8/2024. Naples Center for Dermatology & Cosmetic Surgery clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories. The following Condition is not met: D6168 Testing Personnel
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, the laboratory failed to have 7 tissue marking dyes and hemoxylin II in use that were not expired for Histology. Findings included: On 1/23/2024 at 3:50 PM, tissues inking station revealed the following for tissue marking dyes: 1. black dye expired 11/1/2022 2. orange dye expired 10/2/2021 3. blue dye expired 11/18/2022. 4. green dye expired 11/18/2022. 5. yellow dye expired 8/2020. 6. red dye expired 12/23/2021. 7. black dye expired 7/31 /2022 On 1/23/2024 at 3:59 PM, the Hematoxylin II cartridge rack in the refrigerator was noted with an expiration date of 1/17/2024. Review of Expired reagent Policy signed by laboratory director read, "in order to comply with Cap regulation ANP 21366, our laboratory will not and does not use expired reagents of any kind." Review of Dermatology Report revealed the following: a. patient #1 was tested on 12/13/2023 for Periodic Acid Shiff (PAS). b. patient #2 was tested on 10/13/2022 for Acid Fast

	Bacillus (AFB), Gram stain, and PAS. c. patient #3 was tested on 1/18/2024 for PAS, AFB and Gram stain. On 1/23/24 at 4:41 PM, the Testing Personnel confirmed 7 tissue marking dyes and hemoxylin II were expired.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's 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 failed to perform 2 out of 11 Testing Personnels' annual competencies for 2022 and 2023, (Testing Personnel E and F). Findings Included: Laboratory Personnel Report revealed the following: Employee E was Testing Personnel E. Employee F was Testing Personnel F. Review of 11 Competency Assessments revealed no documentation of annual competency assessments performed for 2 Testing Personnel, E and F in 2022 and 2023. Review of Quality Assurance read, " New testing personnel will receive initial competency before testing is performed, they will receive another competency assessment 6 months after, in order to get everyone on the same page on competency schedule an additional competency will be performed in June or December, whichever date falls first so all competency assessments will eventually be done in June or December." On 1/23/24 at 4:41 PM, Testing Personnel and Lab Office Manager confirmed annual competency assessments were not performed for Testing Personnel E and F in 2022 and 2023.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review, and interview, the laboratory failed to have a qualified testing personnel performing high complexity grossing in Histopathology. (Refer to D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60

semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on record review, and interview, the laboratory failed to have a qualified testing personnel performing high complexity grossing in Histopathology. Findings included: Review of Laboratory Personnel Report revealed Employee J was Testing Personnel J. Review of Performance Review revealed Testing Personnel J had completed grossing performance review on 4/1/22 and 4/3/2023 with the Laboratory Director's signatures. Review of College Transcripts revealed Testing Personnel J had Associate in Arts degree with one chemistry course for 3 units. Testing Personnel J was not

	qualified to perform high complexity grossing due to not having 6 semester hours of chemistry. On 1/23/2024 at 4:42 PM, Clinical lab Operations Manager and Lab Office Supervisor confirmed Testing Personnel J was unqualified to perform high complexity grossing for histopathology.