Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1059972	05/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Aqua Dermatology Of Georgia, Pc	2045 Highway 34 East, Newnan, GA	

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 offsite revisit survey was conducted on June 23, 2021, for previous deficiencies cited on May 19, 2021. All deficiencies have been corrected. The facility is in compliance with all regulations surveyed.
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 during the lab tour and interview with the Moh's Histotechnologist, the laboratory failed to ensure reagents and solutions were not used after their expiration date as required. Findings include: 1. Observation during the laboratory tour on May 19, 2021 at approximately 10:30 AM, observation revealed the following reagents expired: Platinum line staining bottles: Yellow stain, Lot no. 79245 Exp. Date 10/20, Yellow stain: Lot no. 8824 Exp. date: 08/18, Green: Lot no. 75316 Exp. Date: 12/18, Green: Lot no. 2624 Exp. Date: 09/15, Red: Lot no. 83342 Exp. Date: 02/21, Blue: Lot no. 82135 Exp. Date: 03/21. 2. Observation during the Provider Performed Microscopy (PPM) lab tour revealed the following reagent expired: KOH(potassium hydroxide) Lot no. 8161-00 Exp. Date: March 2020. 3. Observation during the PPM lab tour revealed the following reagent expired: Chlorazol Black E, Lot no. 8094 Exp. Date: 04/2020. 4. Interview with the Moh's Histotechnologist in the private surgical waiting room on May 19, 2021 at approximately 10:40 AM, confirmed the reagents listed above were expired during the laboratory tours.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Provider Performed Microscopy (PPM) control log review and interview with the Moh's Histotechologist, the laboratory failed to document QC for qualitative laboratory testing as required. Findings include: 1. Laboratory quality control log review revealed the lack of KOH (potassium hydroxide) QC documentation for 2020 and 2021 thus far. 2. Interview with the Moh's Histotechnologist on May 19, 2021 at approximately 11:30 AM in the private surgical waiting room, confirmed the laboratory failed to document QC for KOH for 2020 and 2021 thus far .
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Provider Performed Microscopy (PPM) competency documents and interview with the Moh's Histotechnologist, the Laboratory Director(LD) failed to perform annual competencies on Testing Personnel (TP) as required. The Findings include: 1. Review of the CMS 209 form revealed 11 TP for moderate complexity testing (PPM). Review of the TP competency documents revealed the LD performed competencies on TP#3 (CMS 209) and TP#5 (CMS 209) in 2019. No other competencies were documented on the remaining 9 PPM TP in 2019. 2. Interview with the Moh's Histotechnologist on May 20, 2021 at approximately 11:15 AM, in the private surgical waiting room, confirmed the LD failed to perform annual competencies on 9 out of the 11 TP's for 2019.