Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2119403	04/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Aqua Dermatology Of Florida Pa	2150 49th St North, Saint Petersburg, 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
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review, procedure manual review, and interview with Laboratory Manager, the laboratory failed to document quality assurance activities for two out of two years (2016-2018). Findings included: During record review it was found that documentation was missing for quality assurance. The procedure manual stated that there would be quarterly meetings. During an interview on 04/09/18 at 10:30 AM, the laboratory manager confirmed there was no documentation for quality assurance and that the procedure manual should be amended regarding quarterly meetings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, procedure manual review, and interview with Laboratory

	Manager, the laboratory failed to document quality assurance activities for two out of two years (2016-2018). Findings included: During record review it was found that documentation was missing for quality assurance. The procedure manual stated that there would be quarterly meetings. During an interview on 04/09/18 at 10:30 AM, the laboratory manager confirmed there was no documentation for quality assurance and that the procedure manual should be amended regarding quarterly meetings.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review, procedure manual review, and interview with Laboratory Manager, the laboratory failed to document quality assurance activities for two out of two years (2016-2018). Findings included: During record review it was found that documentation was missing for quality assurance. The procedure manual stated that there would be quarterly meetings. During an interview on 04/09/18 at 10:30 AM, the laboratory manager confirmed there was no documentation for quality assurance and that the procedure manual should be amended regarding quarterly meetings.