Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1018117	04/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Urology Associates Of Florida, Pa	1986 35th Ave, Vero Beach, 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
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to receive an overall testing score of at least 80% in 2 (2nd events for 2017 & 2018) out of 6 (1st, 2nd & 3rd events for 2017 and 2018) testing events reviewed. Findings: Review of American Proficiency Institute (API) proficiency testing results showed that the laboratory received an overall score of 58% in bacteriology for the 2nd testing event in 2017, and an overall score of 73% in bacteriology for the 2nd testing event in 2018. During an interview on 4/4/19 at 11:10 AM, the General Supervisor B acknowledged the failure.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview and record review, the laboratory failed to perform a sterility check on the Uricult urine culture paddles, and failed to check and document each

	batch of urine culture paddles for its ability to support growth and select or inhibit specific organisms, or have an Individualized Quality Control Plan (IQCP) from April 4, 2017 to April 4, 2019. Findings: Review of the quality control records revealed no documentation showing that the laboratory performed a sterility check or that the laboratory had checked the Uricult urine culture paddles for its ability to support growth and select or inhibit specific organisms. Review of the laboratory's procedure manual showed that the laboratory failed to have an IQCP. During an interview on 4 /04/19 at 2:19 PM, the General Supervisor B stated that they didn't perform sterility check on the Uricult urine culture paddles, and they did not have an IQCP.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document and maintain records number of hours spent examining cytology slides during each 24 hour period. Findings: Review of the laboratory's cytology logs showed that the laboratory failed to have records showing the amount to time spent examining cytology slides during each 24 hour period from 4/04/17 through 4/04/19. During an interview on 4/04/19 at 3:20 PM, the General Supervisor B acknowledged that the pathologist did not record the amount to time spent examining cytology slides.