Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0879546	06/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Urology Associates Enterprises, Llc	595 Shrewsbury Ave, Shrewsbury, NJ	

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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM) the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for Prostate-Specific Antigen (PSA) performed on the Qualigen Fast Pack analyzer from 11/15/18 to the date of survey. The OM confirmed on 6/1/21 at 10:20 am that the laboratory did not verify QC materials for PSA performed on Qualigen Fast Pack analyzer. Note: This is a repeat deficiency
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure all PT results obtained from the American Proficiency Institute (API) for Prostate-Specific Antigen (PSA) tests were reviewed and evaluated by the appropriate staff for the 2nd event in 2019. The finding includes: 1. The laboratory participated in a Chemistry 2nd Event in 2019 but there was no evidence of evaluation of PT results. 2. The OM confirmed on 6/1/21 at 10:30 am that all PT results were not evaluated.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure that the QC program is maintained for laboratory services provided from 11/15/18 to the date of the survey. The findings include: 1. The LD did not review Prostate- Specific Antigen QC. 2.The OM confirmed on 6/1/21 at 10:35 am the LD did not ensure the QC program is maintained.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of Personnel Files (PF) and interview with the Office Manager (OM), the Laboratory Director failed to have education documented for three out of four TP from 11/15/2018 to the date of the survey. The OM confirmed on 6/1/21 at 10:00 am that all education records were not available.