Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D1018117	**(X3) Date Survey Completed** 07/12/2023
Name of Provider or Supplier Advanced Urology Associates Of Florida, Pa	**Street Address, City, State** 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**
D0000	A recertification survey was conducted from July 11, 2023 to July 12, 2023. Advanced Urology Associates of Florida clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observation, record of the procedure manual, and interview, the laboratory failed to ensure uni-directional sample preparation, reagent prep and amplification for PCR (Polymerase Chain Reaction) Urinary Tract Microbiata detection from 05/11 /2021 to 07/12/2023. Findings: The laboratory had two rooms, the sample processing room and the clean room, that were used for the processing and running of PCR Urinary Tract Microbiata detection. A tour of the sample processing room (dirty room) and the PCR room (clean room) on 07/12/2023 at 3:24 PM, revealed the centrifuge was in the clean room. Review of the procedure titled Isolation of DNA for Urinary Tract Microbiata Profiling Experiments using the MagMAX MVP Ultra Kit on the KingFisher Duo Purification System, noted 100 mL (microliters) of the patient's sample was added to the appropriate wells in row A of the processing plate, the wells were covered with a clear adhesive and centrifuged at 2250 x g (gravity) for 15 minutes. After centrifugation, the supernatant is removed, PBS (Phosphate Buffered Saline) and Enzyme Mix is added to each sample, and the processing plate is then brought to the clean room. On 7/12/23 at 3:24 PM, Testing Personnel C stated the samples were added to the processing plate, sealed, brought to the clean room to be centrifuged for 15 minutes, and brought back to the dirty room where PBS and Enzyme Mix were added to each sample.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of quality control documents and the i-Stat Chem8+ instructions, and interviews, the laboratory failed to provide documentation of the performance of the calibration on the Abbott i-Stat instrument at least once every 6 months for 184 patients from 9/1/2021 to 07/12/2023 (See 5439), and the laboratory failed to perform two levels of quality controls at least daily on days when patient specimens were tested on the Abbott i-Stat instrument for 184 patients from 9/1/2021 to 07/12/2023 (See D5447).
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of quality control documents and the i-Stat Chem8+ instructions, and interview, the laboratory failed to provide documentation of the performance of the calibration on the Abbott i-Stat instrument at least once every 6 months for 184 patients from 9/1/2021 to 07/12/2023. Findings: Review of a letter to i-Stat customers dated September 2021 noted the "i-Stat Chem8+ (blue) cartridge is now also U.S. FDA 510 (k) cleared for use with venous and arterial whole blood samples collected in non-anticoagulated syringes and blood collection tubes in non-waived settings." Review of the laboratory's quality control documents showed the laboratory did not

	have documentation of the calibration of the Abbott i-Stat instrument. The i-Stat Chem 8+ Intended for Use instructions noted that calibration verification "may be required by regulatory or accreditation bodies." The Chem 8+ i-Stat cartridges included the following chemistry analytes: sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide. On 07/12/2023 at 2:15 PM, Testing Personnel C stated she thought the test was a waived test and that calibrations on the i-Stat were not performed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control documents and interview, the laboratory failed to perform two levels of quality controls at least daily on days when patient specimens were tested on the Abbott i-Stat instrument for 184 patients from 9/1/2021 to 07/12 /2023. Findings: Review of a letter to i-Stat customers dated September 2021 noted the "i-Stat Chem8+ (blue) cartridge is now also U.S. FDA 510 (k) cleared for use with venous and arterial whole blood samples collected in non-anticoagulated syringes and blood collection tubes in non-waived settings." Review of the laboratory's quality control records for the Abbott i-Stat instrument showed the laboratory performed the electronic simulator check each day of patient testing and two levels of controls when new shipment of cartridges arrived. The Chem 8+ i-Stat cartridges included the following chemistry analytes: sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide. On 07/12/2023 at 2:21 PM, Testing Personnel C stated she thought the test was a waived test and two levels of controls were run only when the laboratory received a new shipment. Testing Personnel C also stated the lab did not have an Individualized Quality Control Plan.