

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0938125	(X3) Date Survey Completed 07/11/2024
Name of Provider or Supplier Augusta Urology Associates Llc	Street Address, City, State 4350 Towne Centre Drive, Ste 2200, Evans, 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	A recertification survey was performed on , July 11, 2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Associates of Bioanalysts (AAB) Proficiency Testing (PT) provider and staff interview, the Laboratory failed to provide a copy of the Attestation Statement for the Specialty Chemistry- Subspecialties Testosterone (TEST), Prostate Specific Antigen (PSA), and Prostate Specific Antigen Free (PSAF), for the year 2023, all three events. Findings: 1. Review of the AAB, PT documents for 2023, failed to provide a copy of the attestation statements, for all three events. 2. Interview with the General Supervisor, on 07/11/2024 at approximately 12:16 in the staff breakroom, confirmed the above statement.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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</p>

identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the American Associates of Bioanalysts (AAB) Proficiency Testing (PT) provider and staff interview, the Laboratory Director (LD) failed to document review of the Specialty Chemistry- Subspecialties Testosterone (TEST), Prostate Specific Antigen(PSA), and Prostate Specific Antigen Free (PSAF), evaluation reports for the year 2023- all three events. The laboratory director failed to document review of the Specialty Microbiology, Subspecialties - Bacteriology (BACT), Mycology (MYCO), Molecular Resistance(MR), and Parasitology), for the year 2022, event 3. , Findings: 1. Review of the AAB PT results, for the year 2023, all three events, there was no documentation by the LD that the evaluation report for TEST, PSA, and PSAF was reviewed. 2. Review of the API PT results , for the year 2022, event 3, there was no documentation by the LD that the evaluation report for BACT, MYCO, MR. and PSAF was reviewed. . 3. Staff interview with the General Supervisor, on July 11, 2024, at approximately 12:16 in the staff breakroom, confirmed the above statements.

D6071

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(2)

Each individual performing moderate complexity testing must maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples.

This STANDARD is not met as evidenced by:

Based on review of the American Associates of Bioanalysts (AAB), Proficiency Testing (PT) provider and staff interview, the Testing Personnel (TP) and the Laboratory Director (LD) failed to provide documentation for the Specialty Chemistry- Subspecialties Testosterone (TEST), Prostate Specific Antigen(PSA), and Prostate Specific Antigen Free (PSAF), that PT testing samples were tested in the same manner as patient samples, for the year 2023, all three events. Findings: 1. Review of the AAB PT documents for the year 2023, all three events, there was no documentation by the TP or the LD that the PT samples for TEST, PSA, and PSAF were tested in the same manner as patient samples. 2. Interview with the General Supervisor, on July 11, 2024 at approximately 12:16, pm in the staff breakroom confirmed the above statement.