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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 11D0938125 | (X3) Date Survey Completed 08/24/2022 |
| 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 |
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| D0000 | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August 24, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: |
| D3011 | <p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Standard Operating Procedure(SOP) and staff interview, the laboratory failed to establish a safety procedure for an Eyewash. The Findings include: 1. SOP document review revealed that the laboratory failed to establish a safety procedure for an Eyewash for the laboratory. 2. During an interview with the Office Manager on August 24, 2022 in a back office, confirmed that the laboratory failed to establish a safety procedure for an Eyewash.</p> |
| D5311 | <p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> |

This STANDARD is not met as evidenced by:
Based on review of the general laboratory standard operating procedure manual (SOP) and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. The SOP did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, or how to obtain additional assistance) for staff to follow when sending specimens to reference laboratory (Quest Diagnostics, LabCorp, and PathGroup). 2. During an interview on August 24, 2022 at: 11:00 AM with the Office Manager in a back office, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to reference laboratories.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on the review of the Standard Operating Procedure(SOP) and staff interview, the laboratory failed to have procedures approved, signed, and dated by the current laboratory director(LD) before use. The Findings include: 1. SOP document review revealed the laboratory failed to have procedures approved, signed, and dated by the laboratory director (LD). 2. During an interview with the Office Manager in a back office, confirmed that the laboratory failed to have procedures approved, signed, and dated by the LD before use.