

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0265055	<b>(X3) Date Survey Completed</b>  02/23/2024
<b>Name of Provider or Supplier</b>  Waycross Urology Clinic	<b>Street Address, City, State</b>  1306 Alice Street, Waycross, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was performed on February 23, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. CONDITION LEVEL CITATIONS: D2016 493.803 (a)(b)(c) Successful Participation D6000 493.1403 Moderate Complexity Laboratory Director NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p>

	<p>This CONDITION is not met as evidenced by:  Based on review of the American Association of Bioanalysts (AAB), Medical Laboratory Evaluation (MLE), Proficiency Testing (PT) documents, and staff interview, the Laboratory failed Event 1 and 2, for the Subspecialty Prostate Specific Antigen (PSA) for the year 2023, and Event 3 for the subspecialty PSA for the year 2022. The laboratory failed to provide Corrective Action. This is a Condition level Deficiency RERENCE: D2087 Routine Chemistry 493.841(a) D2093 Routine Chemistry 493.841(d)</p>
<p><b>D2087</b></p>	<p><b>ROUTINE CHEMISTRY</b>  CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by:  Based on review of the American Association of Bioanalysts (AAB) and Medical Laboratory Evaluation (MLE), Proficiency Testing (PT) documents and staff interview, the Laboratory failed Event 1 and 2, for the Subspecialty Prostate Specific Antigen (PSA) for the year 2023. The laboratry failed to provide Corrective Action. Findings 1. Review of the AAB/MLA PT documents revealed laboratory received a score of 0% for 2023, Event 1, for the subspecialty PSA. There was no correction action provided to show the laboratory corrected the deficiency. The cause of the failure was not corrected to ensure that the failure would not reoccur. 2. Interview with Testing Personnel #1, on the February 23, 2024 Laboratory Personnel Report, at approximately 11 am in the Provider office, confirmed the aforementioned statement.</p>
<p><b>D2093</b></p>	<p><b>ROUTINE CHEMISTRY</b>  CFR(s): 493.841(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by:  Based on review of the American Association of Bioanalysts (AAB) and Medical Laboratory Evaluation (MLE), Proficiency Testing (PT) documents and staff interview, the Laboratory failed to participate in event 3 for the subspecialty PSA for the year 2022. The laboratory failed to provide Corrective Action. Findings 1. Review of the AAB/MLA PT documents show that for the year 2022, the laboratory failed to submit the results of the PT testing samples for for Event 2, for the subspecialty PSA, in 2022., receiving a FAILURE TO PARTICIPATE, on the evaluation report 2. Interview with Testing Personnel #1, on the February 23, 2024 Laboratory Personnel Report, at approximately 11 am, in the Provider office, confirmed the aforementioned statement.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b>  CFR(s): 493.1441</p>

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the American Association of Bioanalysts (AAB), Medical Laboratory Evaluation (MLE), Proficiency Testing (PT) documents and staff interview, the Laboratory Director (LD) failed to ensure that the Laboratory had a plan of correction for the unsuccessful Events 1 and 2, for the Subspecialty Prostate Specific Antigen (PSA) for the year 2023, and unsuccessful Event 3 for the subspecialty PSA for the year 2022. This is a Condition level Deficiency  
REFERENCE: D6092 Laboratory Director Responsibilities 493.1445 (e)(4)(iv)

**D6092**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the American Association of Bioanalysts (AAB) and Medical Laboratory Evaluation (MLE), Proficiency Testing (PT) documents and staff interview, the Laboratory Director (LD) failed to ensure that the Laboratory had a plan of correction for the unsuccessful Events 1 and 2, for the Subspecialty Prostate Specific Antigen (PSA) for the year 2023, and unsuccessful Event 3 for the subspecialty PSA for the year 2022. Findings 1. Review of the AAB/MLA PT documents revealed that the laboratory received a score of 0% for 2023, Event 1, for the subspecialty PSA. There was no correction action provided to show the laboratory corrected the deficiency. The cause of the unsuccessful score was not corrected to ensure the failure would not reoccur. There was no corrective action available. 2. Review of the AAB/MLA PT documents revealed the laboratory failed to submit the results of the PT testing samples for 2022, Event 2. The subspecialty PSA, in 2022, Event 3, receiving a FAILURE TO PARTICIPATE, on the evaluation report There was no corrective action provided. 3. Interview with Testing Personnel #1, on the February 23, 2024 Laboratory Personnel Report, at approximately 11 am, in the Provider's office, confirmed the aforementioned statement.