

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0677796	<b>(X3) Date Survey Completed</b>  07/14/2022
<b>Name of Provider or Supplier</b>  Ware County Health Department	<b>Street Address, City, State</b>  604 Riverside Avenue, 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 Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on July 12, 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:
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: This condition level citation is not met based on review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) documents, and staff interview the laboratory failed to perform testing in the same manner as they tested patient specimens for the years 2021 and 2022 for the speciality of microbiology, subspecialties- mycology and bacteriology. Only one testing personnel performs the testing on patient samples but more than one testing personnel performed testing on the PT samples. Reference: D2006</p>
<b>D2006</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it</p>

receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

This STANDARD is not met as evidenced by:  
Based on review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) documents and staff interview, the laboratory failed to perform testing in the same manner that they test patient specimens for the years 2021 and 2022 for the speciality of microbiology, subspecialties-mycology and bacteriology. Only one testing personnel performs the testing on patient samples but more than one testing personnel performed the testing on the PT samples. Findings: 1. Review of the MLE attestation statements for 2021, event M1, there were seven names on the attestation statement performing testing. In the year 2021, event M2, there were seven names on the attestation statement performing the testing. In the year 2021, event M3, there were 4 names on the attestation statement performing the testing. 2. In the year 2022, event M1, there were eight names on the attestation statement performing the testing. In the year 2022, event M2, there were seven names on the attestation statement performing testing. 3. Interview with the Assistant Clinical Coordinator, Southeast Health District, on July 14, 2022, at approximately 3pm in the conference room, confirmed the above aforementioned statements.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) documents, and staff interview the Laboratory Director (LD) failed to recognize that the laboratory was not performing testing in the same manner that they test patient specimens for the years 2021, and 2022 for the speciality of microbiology, subspecialties- mycology and bacteriology. Only one testing personnel performs the testing on patient samples but more than one testing personnel performed testing on the PT samples. Reference: D6016

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) documents, and staff interview the Laboratory Director (LD) failed to insure that the laboratory was performing testing in the same manner that they test patient specimens for the years 2021 and 2022 for Speciality Microbiology, subspecialties- mycology, and bacteriology. Only one testing personnel performs the testing on patient samples but more than one testing personnel performed the testing on the PT samples. Findings: 1. Review of the MLE attestation statements for 2021, event M1, there were seven names on the attestation statement performing the PT testing. In the year 2021, event M2, there were seven names on the attestation statement performing the PT testing. In the year 2021, event M3, there were 4 names on the attestation statement performing PT testing. 2. In the year 2022, event M1 there were eight names on the attestation statement performing the PT testing. In the year 2022, event M2, there were seven names on the attestation statement performing the PT testing. 2., Interview with the Assistant Clinical Coordinator, Southeast Health District, on July 14, 2022 at approximately 3pm in the conference room, confirmed the above aforementioned statements.