

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0677796	<b>(X3) Date Survey Completed</b>  01/15/2020
<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 January 15, 2020. 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>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Waived testing Quality Control(QC) Documents and manufacturer's package inserts and staff interview, the laboratory was not performing QC in the testing facilities, on new lots, and new shipments, as required by the manufacturer's package insert, but in a central District Pharmacy. Findings: 1. Review of the Waived testing QC documents, all 19 counties had the same copies of QC logs in their facility documents. It was determined that the testing personnel was not performing the QC, but that the QC was being performed in a Central Pharmacy, by the Pharmacy Staff, and then the Waived test kits was sent out to the testing sites by courier. The environment of the courier vehicle was not being monitored for temperature. 2. Staff interview with the Assistant Clinical Coordinator, on January 15, 2020, at approximately 12 pm, in the conference room, confirmed that the QC on all Waived test kits was being performed at the Central District Pharmacy, by the Pharmacy staff and then sent out to each County Health Departments for patient testing, by courier, and the environment of the courier vehicle was not being monitored for temperature.</p>
<b>D5413</b>	<b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b>

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the temperature and humidity charts for the 19 County Health Department(HD) facilities that make up the Southeast Health District, Ware County Health Department, and staff interview, 17 of the laboratories did not document Humidity levels every day of patient testing. Findings: 1. Review of the temperature and humidity charts for the 19 County HDs, the following findings were noted: Out of the 19 County HDs; Three (3) facilities did not have Humidity documented from July 2018, to the current survey date. (January 15, 2020) 14 facilities did not have Humidity documented from January 2019 to April 2019. Two (2) facilities had documented both Humidity and Temperature from July 2018 to the current survey date. (January 15, 2020). 2. Interview with the Assistant Clinical Coordinator, in the Conference Room, on January 15, 2020, at approximately 4 pm, Confirmed the aforementioned findings.