

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0671837	(X3) Date Survey Completed 02/16/2023
Name of Provider or Supplier Waycross Regional Laboratory	Street Address, City, State 1751 Gus Karle Parkway, Waycross, 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 conducted on 2/15/2023 - 2/16/2023. The facility was found NOT in compliance with the following 42 CFR Part 493, Requirements for Laboratories for the specialties/subspecialties for which it was surveyed: 493.1240 - Pre-Analytic Systems
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) Plan, QA records and interview with the laboratory director, the laboratory failed to have a written procedure for complaint investigations. Findings include: 1. During record review of the policy titled, "Quality Assessment (QA) Plan" the surveyor found the plan did not include a process for submission of complaint investigations. The QA Plan section titled, "III. Evaluation of the Effectiveness of Policies and Procedures, D. Customer Satisfaction" states, " ... All customer complaints will be documented. The Client Complaint Investigations Form, or some other appropriate form, should be used. Each unit will monitor the number and type of complaints and will be responsible for taking the necessary corrective actions." The laboratory failed to provide a written procedure to ensure for clients or public to submit complaints to the laboratory. 2. Interview with the laboratory director in the conference room on February 16, 2023 at 10:00AM, confirmed the laboratory did not have a written procedure in place for complaint investigations.</p>
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p>

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on direct observation, review of manufacturer's instructions, laboratory policies, "Georgia Public Health Laboratory Service Manual", test reports and staff interview, the laboratory failed to meet the requirements for the preanalytical system, as evidenced by: 1. The laboratory failed to ensure specimen storage and transportation maintained specimen integrity when received from outside submitters for specimens received on 2/15/2023. Refer to D5311 I. 2. The laboratory failed to define the temperature ranges for room, frozen, cold and ambient for 9 or 9 tests performed. Refer to D5311 II.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(a)

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.

This STANDARD is not met as evidenced by:

I. Based on direct observation, review of laboratory policies, Georgia Public Health Laboratory (GAPHL) Service Manual and staff interview, the laboratory failed to ensure specimen storage and transportation maintained specimen integrity when received from outside submitters for 291 of 295 specimens received on 2/15/2023. Finding include: 1. During direct observation on February 15, 2023 at 4:00PM of laboratory contract courier delivery of patient specimens, the laboratory staff did not use a temperature measuring device to check the specimens temperature range after opening the coolers. The laboratory failed to verify specimen integrity upon receipt of patient specimens in the specimen processing area for 291 of 295 specimens received. 2. The laboratory implemented a new policy on February 9 2023, for all submitters to include a cold pack in all the specimen containers delivered by the courier. The new laboratory procedure for specimen collection is titled, "Specimen Storage Conditions Transport Guidance For Testing" states, "Refrigerated Specimens - All specimens must be submitted under refrigerated conditions using frozen cold packs EXCEPT for specimens listed under the frozen and ambient of this document". The laboratory tests performed at the Waycross Regional Laboratory (WRL) are SARS-CoV-2, Chlamydia /Gonorrhea, Trichomonas, Mumps IgG, Measles IgG, Rubella IgG, Varicella Zoster IgG, Syphilis RPR, and Treponemal antibody. None of the test performed at WRL are listed under the Frozen or Ambient test list. 3. The laboratory courier has a policy for transporting specimens titled, "Category B Specimen Submission Outfit, Courier Packaging and Shipping Instruction. The couriers meet at a designated location to consolidate patient samples into one or more coolers. During observation on February

15, 2023 at 4:00PM of the laboratory staff checking samples to determine if they were cold to the touch found the specimens from Tipton, GA did not have cold packs included in the cooler for 4 of 4 specimens (23YD045021, 23YA045003, 23YE046009, 23Y7045003). 4. An interview with the laboratory manager in the specimen processing area on February 15, 2023 at 4:00PM, confirmed the laboratory submitter did not follow specimen storage and transportation requirements for cold packs. II. Based on record review, Quality Assessment (QA) Plan and Georgia Public Health Laboratory (GPHL) Service Manual and interview with the laboratory director, the laboratory failed to define the temperature ranges for room, frozen, cold and ambient for 9 or 9 tests performed. Findings include: 1. A Review of the QA Plan and GAPHL Service Manual found the laboratory failed to define the temperature ranges for room, frozen, cold/cold packs and ambient temperatures. 2. A review of the GAPHL Service Manual procedure section, titled "Shipment of Specimens" list the shipping temperature for transportation to the Waycross Regional Laboratory. The temperature range for tests C. trachomatis/N. gonorrhoeae, Trichomonas, Syphilis, Treponemal Antibody, Infectious Disease specimens should be stored at room temperature if delivered the same day or cold if delivered within 7 days. 3. In an interview on February 16, 2023, at 2:00 PM in the conference room, with the laboratory director, confirmed the temperature ranges were not defined in the policies and procedures.