

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0703582	<b>(X3) Date Survey Completed</b>  03/10/2021
<b>Name of Provider or Supplier</b>  District 4 Public Health	<b>Street Address, City, State</b>  301 Main Street, Lagrange, 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>	Based on a CLIA recertification survey performed on March 10, 2021, this facility was found to not be in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
<b>D3011</b>	<p><b>FACILITIES</b> 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 laboratory maintenance document review and staff interview, the laboratory failed to ensure protection from physical, chemical, and electrical hazards as required. Findings include: 1. Laboratory maintenance document review revealed the lack of eyewash maintenance logs available at the time of survey for 2018 (October through December). 2. An interview with the District 4 Health Coordinator in the conference room on 3/10/2021 at approximately 1:30 p.m. confirmed the lack of aforementioned eyewash logs.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the laboratory failed to ensure PT results were reviewed upon receipt from</p>

the PT agency. Findings include: 1. Review of 2019 American Academy of Family Physicians (AAFP) PT records reveals the lab failed to ensure the results received for the subspecialty of Mycology & Parasitology Event B had documented review by appropriate staff to evaluate the laboratory's performance in the following counties: Heard and Coweta 2. Review of 2019 American Academy of Family Physicians (AAFP) PT records reveals the lab failed to ensure the results received for the subspecialty of Mycology & Parasitology Event C had documented review by appropriate staff to evaluate the laboratory's performance in the following county: Pike 3. Review of 2020 American Academy of Family Physicians (AAFP) PT records reveals the lab failed to ensure the results received for the subspecialty of Mycology & Parasitology Event B had documented review by appropriate staff to evaluate the laboratory's performance in the following county: Upson 4. Review of 2020 American Academy of Family Physicians (AAFP) PT records reveals the lab failed to ensure the results received for the subspecialty of Mycology & Parasitology Event C had documented review by appropriate staff to evaluate the laboratory's performance in the following counties: Heard and Upson 4. An interview with the District 4 Health Coordinator in the conference room on March 10, 2021, at approximately 1 p.m. confirmed the lack of documented result review for the aforementioned PT events.

**D5293**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:  
 Based on review of standard operating procedures(SOP), quality assurance(QA) records review, and staff interview the laboratory failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the laboratory as required. Findings include: 1. Review of the 2019, 2020 SOP and QA records revealed that the laboratory's current QA policy does not indicate the steps to be taken to identify and correct problems to ensure the prevention of reoccurrences for the following Counties: Meriwether and Spalding. 2. There is no evidence or documentation that corrective actions are being performed in the laboratory. 3. An interview with Staff #1(CMS 209) on March 10, 2021 at approximately 2:30 PM in the breakroom, confirmed the lack of aforementioned QA documents available at the time of survey.

**D5400**

**ANALYTIC SYSTEMS**

CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	<p>This CONDITION is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as required. Findings include: For details refer to D5449.</p>
<p><b>D5449</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to document QC for qualitative testing as required. Findings include: 1. Laboratory document review revealed the lack of KOH (potassium hydroxide) and Wet Preparation (wet prep) 2019 QC documentation available at the time of the survey for the following counties: Troup, Carroll, Lamar, and Upson. 2. Laboratory document review revealed the lack of KOH (potassium hydroxide) and Wet Preparation (wet prep) 2020 QC documentation available at the time of the survey for the following counties: Troup, Lamar, and Upson. 3. Laboratory document review revealed the lack of KOH (potassium hydroxide) and Wet Preparation (wet prep) 2021 QC documentation available at the time of the survey for Upson County. 4. An interview with the District 4 Health Coordinator in the conference room on March 10, 2021, at approximately 1 p.m. confirmed the lack of KOH and Wet Prep QC documentation available at the time of survey for the aforementioned time periods.. This is s REPEAT DEFICIENCY.</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on lab report reviews and staff interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Review of the in-house patient reports #198681, #231096, and #230915 reveals the lack of the health department's address, where the test was performed. 2. Interview with the District 4 Health Coordinator in the conference room on March 10, 2021, at approximately 1:30 p.m. confirmed the lack of the health department address.</p>
<p><b>D6019</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b></p>

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the 2020 proficiency testing (PT) reports and staff interview, the laboratory failed to document corrective action when unsatisfactory results were obtained for testing of Potassium Hydroxide (KOH). Findings include: 1. Review of the 2020 American Academy of Family Physicians (AAFP) PT Event B records reveals there was no documentation that corrective action was taken when the lab received a score of 0% for KOH by Upson county. 2. Interview with the District 4 Health Coordinator in the conference room on March 10, 2021, at approximately 1 p. m. confirmed the lack of corrective action taken for the failed proficiency testing results.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) documents and staff interview, the technical consultant (TC) failed to perform annual competency on all testing personnel. Findings include: 1. Review of TP documents reveals the TC failed to document annual competency reviews on the following staff : Heard Co. #1 (CMS 209) for 2019 and 2020; Pike Co.#1 (CMS 209) for 2020. 2. Interview with the District 4 Health Coordinator in the conference room on March 10, 2021, at approximately 2:30 p.m. confirmed the lack of competency for the aforementioned staff.