

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0694817	<b>(X3) Date Survey Completed</b>  03/02/2021
<b>Name of Provider or Supplier</b>  East Central Health District	<b>Street Address, City, State</b>  950 Laney Walker Blvd, Augusta, 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 March 2, 2021. 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>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the Laboratory Coordinator, the Laboratory Director(LD) failed to attest the routine incorporation of the proficiency test samples into the patient workload as required. The findings include: 1. American Associate of Bioanalysts(AAB) PT document review revealed that the LD failed to sign the attestation statement for Richmond County (Laney-Walker) for the following PT event: Chemistry 2020 Event 3-- KOH(potassium hydroxide) and wet preparation. 2. An interview with the laboratory coordinator on March 2, 2021 at approximately 6:35 PM in the conference room confirmed the aforementioned lack of LD signature on the attestation statement.</p>
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency</p>

testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:  
Based on proficiency test (PT) record review and staff interview, the laboratory failed to maintain a copy of all PT records as required. Findings include: 1. American Associate of Bioanalysts(AAB) PT document review revealed the lack of an attestation statement for Richmond County, for the following PT event: Chemistry 2020 Event 2-- KOH(potassium hydroxide) and wet preparation. 2. An interview with the laboratory coordinator on March 2, 2021 at approximately 6:30 PM in the conference room confirmed the aforementioned lack of attestation statement.

**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 the laboratory record review and staff interview, the laboratory failed to document quality assessment (QA) activities as required. Findings include: 1. Laboratory record review revealed the lack of QA documentation available at the time of survey for November and December of 2018, 2019, 2020, and 2021, thus far, for Screven County. 2. Laboratory records review revealed the lack of QA documentation available at the time of survey for November and December of 2018 for Warren County. 3. An interview with the laboratory coordinator on March 2, 2021, at approximately 6:20 PM in the laboratory, confirmed the lack of aforementioned QA documents available at the time of survey.

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(g)

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.

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 laboratory testing as required. Findings include: 1. Laboratory document review revealed the lack of KOH (potassium hydroxide) and wet preparation(wet prep) QC documentation available at the time of the survey for

the following clinics: Burke, Columbia, Emanuel, Glascock, Jefferson, Jenkins, Lincoln, McDuffie, Richmond (Laney-Walker), Screven, Taliaferro, Twin City, and Wilkes for 2018 November and December, 2019, 2020, and for 2021, thus far. 2. Laboratory document review revealed the lack of KOH (potassium hydroxide) and wet prep QC documentation at the time of survey, in 2018 November and December, 2019, 2020 for Richmond (South Augusta) and Warren County. These two counties were closed in 2021 due to COVID vaccinations. 3. An interview with the laboratory coordinator in a conference room on March 2, 2021 at 1:15 PM confirmed the lack of KOH and wet prep QC for the aforementioned time periods.

**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 competencies on TP as required. Findings include: 1. TP document review revealed the TC failed to perform onsite 2019 annual TP competencies in the following counties: Burke (CMS-209: Staff #3, 4,5, 6, and 8); Columbia (CMS 209: Staff #2,3, and 4); Emanuel (CMS 209: Staff #3 and Staff #4); Glascock (CMS 209: Staff #4); Jenkins (CMS 209: Staff #2, 3, and 4); McDuffie (CMS 209: Staff #3,4,5, and 6); Screven (CMS 209: Staff #3,4,6 and 7); Taliaferro (CMS 209: Staff #4); Twin City (CMS 209: Staff #3 and Staff #4). 2. TP document review revealed the TC failed to perform onsite 2020 annual TP competencies in the following counties: Burke (CMS-209: Staff #3,4,5,6, and 8); Glascock (CMS209: Staff #4); Jenkins (CMS 209: Staff #2, 3, and 4); CMS 209: Staff #3,4, 5, and 6); Taliaferro (CMS 209: Staff #4). 3. An interview with the Laboratory Coordinator on March 2, 2021 in the conference room at approximately 6:15 PM, confirmed the aforementioned lack of onsite TP competency documentation.