

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0693066	<b>(X3) Date Survey Completed</b>  05/07/2019
<b>Name of Provider or Supplier</b>  DeKalb County Board Of Health	<b>Street Address, City, State</b>  445 Winn Way, Room 167, Decatur, 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 May 7, 2019. 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>D5441</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 all control procedures performed as required. Findings include: 1. QC document review revealed there were no 2019 QC documents available at the time of survey for gram stains and microscopic urinalysis for the Clifton Springs laboratory. 2. An interview with the technical consultant in a conference room on 5/7 /19 at approximately 5:00 p.m. confirmed the aforementioned lack of QC documentation.</p>
<b>D6005</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c)</p>

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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

This STANDARD is not met as evidenced by:  
Based on testing personnel (TP) competency review and staff interview, the laboratory director (LD) failed to ensure employment of TP who are competent to perform test procedures as required. Findings include: 1. TP/TC (technical consultant) competency review revealed there was no 2017 or 2018 annual competency documentation available at the time of survey for Staff #7(CMS 209)TP/TC for the following laboratories: East Dekalb Health Center, Clifton Springs Health Center, North Dekalb Health Center, and Dekalb County Board of Health/Richardson. 2. An interview with the TC in a conference room on 5/7/19 at approximately 5:00 p.m. confirmed the lack of aforementioned competencies for 2017 and 2018.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure all TP receive the appropriate training for the type and complexity of the services offered prior to testing patients' specimens as required. Findings include: 1. TP competency document review revealed there were no 2018 initial training competency documents available at the time of survey for Staff #5 (CMS 209) and Staff #6 (CMS 209) for the following laboratories: North Dekalb Health Center, Clifton Springs Health Center, and East Dekalb Health Center. 2. TP competency document review revealed there were no 2018 initial training competency documents available at the time of survey for Staff #6 (CMS 209) for the Dekalb County Board of Health/Richardson. 3. An interview with the technical consultant in a conference room on 5/7/19 at approximately 5:00 p.m. confirmed the lack of initial training competency documents for the aforementioned TP.

**D6053**

**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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
 Based on testing personnel (TP) document review and staff interview, the technical consultant (TC) failed to evaluate and document the performance of TP responsible for moderate complexity testing at least semiannually as required. Findings include: 1. TP competency document review revealed there were no 2018 six-month competency documents available at the time of survey for Staff #6 (CMS 209) for the following laboratories: North Dekalb Health Center, Clifton Springs Health Center, and East Dekalb Health Center. 2. TP competency document review revealed there were no 2019 six-month competency documents available at the time of survey for Staff #5 (CMS 209) for the following laboratories: East Dekalb Health Center, Clifton Springs Health Center, and North Dekalb Health Center; Staff #6 (CMS 209) - Dekalb County Board of Health/Richardson; Staff #4 (CMS 209) T. O. Vinson Health Center. 3. An interview with technical consultant 5/7/19 at approximately 5:00 p.m. in a conference room confirmed the aforementioned lack of competency documents at the time of survey.

**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 testing personnel (TP) document review and staff interview, the technical consultant (TC) failed to evaluate and document annual TP competency as required. Findings include: 1. TP competency document review revealed there were no annual TP competency documents available at the time of survey for the following laboratories for 2017: East Dekalb Health Center, Clifton Springs, North Dekalb Health Center -- 4 of 5 TP/ per laboratory; Dekalb County Board of Health -- 4 of 7 TP. 2. TP competency document review revealed there were no annual TP competency documents available at the time of survey for the following laboratories for 2018: East Dekalb Health Center, Clifton Springs (4 of 5 per laboratory); North Dekalb Health Center (4 of 6 per laboratory); Dekalb County Board of Health (6 of 7). 3. An interview with the TC on 5/7/19 in a conference room at approximately 5:00 p.m. confirmed the aforementioned lack of TP competency documents for 2017 and 2018.