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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>11D0866868 | <b>(X3) Date Survey Completed</b><br><br>11/06/2018 |
| <b>Name of Provider or Supplier</b><br><br>Forsyth County Health Department  | <b>Street Address, City, State</b><br><br>428 Canton Highway, Cumming, 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>   |
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| <b>D0000</b>              | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on November 6, 2018. 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>D5401</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory policy and procedure manual (SOP), peer review documents, and staff interview, the laboratory failed to follow laboratory policy and procedure as required. Findings include: 1. Review of the laboratory SOP and peer review document review revealed three of six counties (White, Dawson, and Towns) failed to perform Potassium Hydroxide (KOH)/wet mount peer reviews every six months in 2017 and 2018, thus far. 2. SOP review and peer review document review revealed three of six counties (Union, Forsyth, and Lumpkin) failed to follow the SOP policy and procedure for nurse practitioners versus registered nurses to perform twice yearly KOH/wet mount peer reviews in 2017 and 2018 thus far. 3. An interview with the County Nurse Manager on 11/6/18 in a conference room at the Town County Health Department at approximately 2:30 p.m. confirmed the aforementioned lack of peer review performance per the laboratory SOP.</p> |
| <b>D5413</b>              | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>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 temperature log document review and staff interview, the laboratory failed to monitor laboratory temperature as required. Findings include: 1. Temperature document review revealed laboratory temperature was not documented for the following counties: 2017 -- White, Dawson, and Union; 2018 counties (thus far) -- White and Union. 2. An interview with the County Nurse Manager in a conference room at the Towns County Health Department on 11/6/18 at approximately 2:30 p.m. confirmed the aforementioned undocumented temperatures.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on calibration document review and staff interview, the laboratory failed to calibrate laboratory equipment as required. Findings include: 1. Calibration document review revealed laboratory centrifuge calibration records were not available at the time of survey for 2017 and 2018, thus far, for the following counties: White, Dawson, Union, Forsyth, Lumpkin, and Towns. 2. Calibration document review revealed laboratory microscope calibration records were not available at the time of survey for 2017 for the following counties: White, Forsyth, Lumpkin, and Towns. 3. Calibration document review revealed laboratory microscope calibration records were not available at the time of survey for 2018 for the following counties: Lumpkin and Towns. 4. An interview with the County Nurse Manager on 11/6/18 in a conference room at the Towns County Health Department at approximately 2:30 p.m. confirmed the aforementioned undocumented centrifuge and microscope calibrations for 2017 and 2018.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
 Based on review of the policy and procedure manual (SOP), TP document review, and staff interview, the laboratory director (LD) failed to provide administrative oversight for the laboratory as required. Findings include: 1. Review of the laboratory SOP and TP document review revealed there were no designee letters for individuals qualified to perform TP competencies for 2017 and 2018, thus far, for the following counties: White, Dawson, and Forsyth. 2. White County TP document review revealed the 2018 six-month competency for Staff #2 was performed by unqualified TP. 3. Forsyth County TP document review revealed the following 2018 annual competencies were performed by unqualified TP: (CMS 209 -- Staff #1, Staff #2, and Staff #3). 4. An interview with the County Nurse Manager (CNM) on 11/6/18 in a conference room at the Towns County Health Department at approximately 2:30 p.m. confirmed there were no designee letters in the SOP for individuals qualified to perform TP competencies for 2017 and 2018 thus far. During the same interview, the CNM confirmed the aforementioned TP competencies were performed by unqualified TP.

**D6005**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(c)

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) document review and staff interview, the laboratory director (LD) failed to ensure TP initial training competencies were performed as required. Findings include: 1. TP document review revealed 2017 initial competencies were not performed in Forsyth County for the following : Staff #1 (CMS 209), Staff #2 (CMS 209), and Staff #3 ( CMS 209). 2. An interview with the County Nurse Manager on 11/6/18 in a conference room at the Towns County Health Department at approximately 2:30 p.m. confirmed the aforementioned initial competencies were not performed in 2017 at the Forsyth County Health Department laboratory..

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
 Based on proficiency test (PT) document review and staff interview, the laboratory

director (LD) failed to ensure that all PT reports were reviewed by the appropriate staff as required. Findings include: 1. Medical Laboratory Evaluation (MLE) PT document review revealed the LD failed to review the following 2018 PT events: KOH (Potassium Hydroxide) and Wet Prep -- Events 1 and 2. 2. An interview with the County Nurse Manager on 11/6/18 in a Towns County Health Department conference room at approximately 2:30 p.m. confirmed the LD failed to review the aforementioned PT reports in 2018.

**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 perform a six-month competency as required Findings include: 1. TP document review revealed six-month competencies were not performed in 2017 for the following Forsyth County TP: Staff #1 (CMS 209), Staff #2 (CMS 209), and Staff #3 (CMS 209). 2. An interview with the County Nurse Manager on 11/6/18 at approximately 2:30 p.m. in a Towns County Health Department conference room confirmed six-month competencies were not performed for the aforementioned TP in 2017.

**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 perform annual competencies as required. Findings include: 1. TP document review revealed annual competencies were not performed for the following: Staff #3 (CMS 209 - White County) for 2017; Staff #3 (CMS 209 - Dawson County) for 2017 and 2018 thus far. 2. An interview with the County Nurse Manager on 11/6/18 in a Towns County Health Department conference room at approximately 2:30 p.m. confirmed the aforementioned annual competencies were not performed.