

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0693402	(X3) Date Survey Completed 01/08/2019
Name of Provider or Supplier Cornerstone Medical Group	Street Address, City, State 914 Vista Drive, Dalton, 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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 8, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) attestation statements for 2017 and 2018, the laboratory failed to ensure all testing personnel (TP) participated in the PT testing. Findings include: 1. Review of the proficiency testing (PT) attestation statements for 2017 and 2018 revealed all of the testing events were performed by staff #4 (CMS 209). 2. Interview with staff #4 (CMS 209) on 1/8/19 at approximately 4 PM in the spare office, confirmed she performed all of the 2017-2018 PT testing.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <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. (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;</p>

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) document review and staff interview, the lab director (LD) failed to review performance evaluation on PT results received. Findings include: 1. Review of the American Proficiency Institute (API) PT evaluation documents revealed the LD did not review results of 2017 Event #2; 2017 Hematology Event #3; 2017 General Immunology Event #3; or 2018 General Immunology Event #1. 2. Interview with staff #4 (CMS 209) on 1/8/19 in the spare office at approximately 4 PM, confirmed the lack of PT result review by the LD.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
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 proficiency testing (PT) document review and staff interview, the lab director (LD) failed to ensure that the corrective action plan is followed when any proficiency testing results are found to be unacceptable. Findings include: 1. Review of the American Proficiency Institute (API) PT evaluation documents revealed the LD did not follow the corrective action plan when the 2017 General Immunology Event #3 was scored at 80%. 2. Interview with staff #4 (CMS 209) on 1/8/19 in the spare office at approximately 4 PM, confirmed the lack of corrective actions for a score of 80% on the 2017 General Immunology Event #3.

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 review of testing personnel (TP) documents and staff interview, the technical consultant (TC) (lab director) failed to perform semiannual competency on all testing personnel. Findings include: 1. Review of the testing personnel documents revealed the TC did not perform a semiannual competency on staff #5 (CMS 209) in the year 2017. 2. Interview with staff #4 (CMS 209) on 1/8/19 in the spare office at 3:45 PM, confirmed the TC did not perform the semiannual competency on staff #5 (CMS 209) 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 review of testing personnel (TP) documents and staff interview , the technical consultant (TC)(lab director) failed to perform annual competency on all testing personnel. Findings include: 1. Review of the testing personnel documents revealed the TC did not perform an annual competency on staff #4 (CMS 209) in the year 2017. 2. Interview with staff #4 (CMS 209) on 1/8/19 in the spare office at 3:45 PM, confirmed the TC did not perform the 2017 competency.