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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 11D0671837 | (X3) Date Survey Completed 02/06/2019 |
| Name of Provider or Supplier Waycross Regional Laboratory | Street Address, City, State 1751 Gus Karle Parkway, Waycross, 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 |
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| D2015 | <p>TESTING OF PROFICIENCY TESTING SAMPLES 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 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.</p> <p>This STANDARD is not met as evidenced by: Based on record review of Proficiency Testing (PT) documents for the years of 2017 and 2018 and an interview with the General Supervisor (GS) and Laboratory Director (LD), the laboratory failed to review records ensuring that the analyst performing the testing and the director have signed the statement attesting that PT samples were tested in the same manner as patient specimens. Findings: 1. Review of WSLH PT records revealed that the laboratory failed to ensure that the analyst performing the testing, signed the attestation form for "Blood Lead Combo" for 2017 Events 2 & 3. 2. Review of American Association of Bioanalysts records revealed that the laboratory failed to ensure that the analyst performing the testing, signed the attestation form for "Immunology" for 2017 Event 2 (B). 3. Review of WSLH PT records revealed that the laboratory failed to ensure that the director signed the attestation form for "Blood Lead Combo" for 2017 Events 1, 2 & 3; 2018 Events 1, 2 & 3. 4. Interview with GS and LD on 2/6/19 at approximately 330p, confirmed that the review of PT records had not been performed.</p> |
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D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review of competency documents for the years of 2017 and 2018 and an interview with the General Supervisor (GS) and Laboratory Director (LD), the laboratory failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens and annually thereafter. Findings: 1. Review of competency records revealed that 3 out of 3 testing personnel did not have competencies performed for the years of 2017 & 2018. 2. During an interview on 2/6/19 at approximately 3:30p with the GS and LD, it was confirmed that competencies were not performed for the years of 2017 & 2018 for 3 out of 3 testing personnel.