

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2001478	<b>(X3) Date Survey Completed</b>  02/13/2019
<b>Name of Provider or Supplier</b>  Ramon Ramos, Md	<b>Street Address, City, State</b>  460 Mall Boulevard, Savannah, 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 February 13, 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:
<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 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 review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the laboratory failed to document each step of the testing and reporting of proficiency testing samples in the speciality of hematology on the 1st testing event of 2018. Findings include: 1. Review of API PT records for the 1st testing event of 2018 revealed no attestation statement signed by the testing personnel and laboratory director. 2. Review of PT records for the 1st testing event of 2018 also revealed no instrument printouts showing the actual results obtained on the hematology analyzer. 3. Interview with the office manager and testing</p>

	<p>personnel #1 (see CMS 209) on February 13, 2019 at 1 pm in the break room confirmed the attestation statement and instrument printouts for PT event 1 of 2018 are not available.</p>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) reports from the American Proficiency Institute (API) and staff interview, the laboratory failed to maintain satisfactory performance in two of three consecutive events (2nd and 3rd events of 2017), resulting in the first unsuccessful occurrence for white blood cell count (WBC) # 805. Findings include: Refer to D 2130</p>
<b>D2130</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) reports from the American Proficiency Institute (API) and staff interview, the laboratory failed to maintain satisfactory performance in two consecutive events (2nd and 3rd events of 2017), resulting in the first unsuccessful occurrence for white blood cell count (WBC) # 805. Findings include: 1. Review of the laboratory's PT results from API revealed the laboratory failed WBC on event 2 of 2017 with a score of 0% for non-participation and event 3 of 2017 with a score of 60%. 2. Interview with the office manager and testing personnel #1 (see CMS 209) on February 13, 2019 at 1 pm in the break room confirmed the laboratory failed WBC on events 2 and 3 of 2017 resulting in the first unsuccessful performance.</p>
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p>

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of laboratory records, lack of records to review and staff interview, the laboratory director failed to provide overall management and direction of the laboratory. Note: This is a repeat Condition level deficiency and was also cited on the 2014 and 2016 surveys. Findings include: Refer to: D 6016, D 6019, D 6021

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) reports and staff interview, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two of three consecutive events (2nd and 3rd events of 2017), resulting in the first unsuccessful occurrence for white blood cell count (WBC) # 805. Findings include: 1. Review of the laboratory's PT results from API revealed the laboratory failed WBC on event 2 of 2017 with a score of 0% for non-participation. 2. Review of the laboratory's PT results from API revealed the laboratory failed WBC on event 3 of 2017 with a score of 60%. 3. Interview with the office manager and testing personnel #1 (see CMS 209) on February 13, 2019 at 1 pm in the break room confirmed the laboratory failed WBC with a score of 0% on event 2 of 2017 for non-participation and event 3 of 2017 with a score of 60% resulting in the first unsuccessful performance.

**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 review of the laboratory proficiency testing (PT) records, lack of records to review and staff interview, the laboratory director failed to ensure corrective action was taken when the laboratory received an unsatisfactory score. Findings include: 1. Review of PT records revealed the laboratory received a score of 60 % for white

blood cell count on event 3 of 2017. No documentation of corrective action is available. 2. Interview with the office manager and testing personnel #1 (see CMS 209) on February 13, 2019 at 1 pm in the break room confirmed the score of 60% and that no documentation of corrective action is available.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual, review of laboratory records, lack of records to review and staff interview, the laboratory director failed to ensure the quality assurance program was established and maintained. Note: This is a repeat deficiency and was also cited on the 2014 survey. Findings include: 1. Review of laboratory records revealed a Quarterly Quality Assurance Checklist in each testing personnel's records. 2. Review of the laboratory's policy and procedure manual revealed the quality assurance policy did not contain instructions on how to complete the Quarterly Quality Assurance Checklist. 3. Interview with the office manager on February 13, 2019 at 1 pm in the break room confirmed there are no instructions for completing the checklist and it has been used for employee competency assessment instead of laboratory quality assessment.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Note: This is a repeat deficiency Based on review of the laboratory's policy statement for determining staff competency, review of personnel records and staff interview, the technical consultant/laboratory director failed to establish and follow policies and procedures to determine staff competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills and failed to ensure the competency assessment contained the 6 required criteria.. Note: This is a repeat deficiency and was cited at the October 2016 survey. Findings include: 1. Review of the laboratory's policy statement for competency assessment revealed it only states that employees will be evaluated yearly, results will be recorded and corrective action will be taken if necessary. It does not include the steps to be taken or mechanism used to determine competency. 2. Review of personnel records revealed the Quarterly Quality Assurance Checklist was used for competency assessment and no competency assessment checklist or forms are available. This checklist does not contain 3 of the 6 required criteria. 3. Interview with the office

manager and testing personnel #1 (see CMS 209) on February 13, 2019 at 1 pm in the break room confirmed a competency assessment policy and procedure is not available. and confirmed the competency assessment does not include all 6 of the required criteria.