

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0104198	<b>(X3) Date Survey Completed</b> 04/30/2019
<b>Name of Provider or Supplier</b> Regional Cancer Care Associates	<b>Street Address, City, State</b> 1 Bay Avenue, Montclair, NJ	
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>D2015</b>	<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 surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain the attestation statement for Hematology PT provided by the American Associations of Bioanalysts (AAB) for the calendar year 2018. The TP #3 listed on CMS form 209 confirmed on 4/30/19 at 9:50 am that attestation statements were not maintained.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL 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>

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow their Quality Assessment (QA) procedure from 5/10/17 to the date of the survey. The findings include: 1 The QA procedure stated "charts to document the effectiveness of these policies can be found throughout the manual" but there were no QA charts in the PM. 2. There was no documented evidence the laboratory followed the QA procedure which stated: a. The laboratory will develop a schedule for monitoring QA. b. All QA activities and meetings will be documented. c. The facility will review the QA procedure as needed or annually. d. QA problems identified will be corrected and new policies developed. 3. The TP #3 listed on CMS form 209 confirmed on 4/30/19 at 11:20 am that the laboratory did not follow the QA procedure.

**D6074**

**TESTING PERSONNEL RESPONSIBILITIES**

CFR(s): 493.1425(b)(5)

Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personal (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Cell Dyn Emerald analyzer from 5/10/17 to the date of the survey. The TP #3 listed on CMS form 209 confirmed on 4/30/19 at 10:45 am that trends and shifts were not reviewed.