

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D1018141	<b>(X3) Date Survey Completed</b> 08/20/2019
<b>Name of Provider or Supplier</b> Regional Cancer Care Associates	<b>Street Address, City, State</b> 210 Woodport Road, Sparta, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform a CA on six out of six TP from May 2018 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 8/20/19 at 12:20 pm that CA was not performed on TP.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow the Quality Control (QC) Guidance procedure for Hematology tests performed on the ABX Micros 60 in the calendar year 2018. The finding includes: 1. The PM stated to verify new QC before use. 2. There was no documented evidence QC verification was performed from: a. 3/5</p>

/18 to 6/25/18 b. 6/25/18 to 11/5/18 3. Old QC expired 12/5/18 but the new QC lot was verified 12/31/18. 4. The TP #1 listed on CMS form 209 confirmed on 8/20/19 at 1:30 pm that the laboratory did not follow the PM.

**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 surveyor review of the Personnel Records (PR) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to delegate competency evaluation to a qualified person for the performance of Complete Blood Count analysis from 8/22/17 to the date of the survey. The TP # 1 confirmed on 8/20/19 at 1:00 pm that LD did not delegate the evaluation of competency to a qualified person.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director failed to have education and training documented for all Testing Personnel from 8/22/17 to the date of the survey. The findings include: 1. A review of PF revealed: a. Two out of six TP did not have diplomas. b. Three of four new TP did not have training records. 2. The TP #1 listed on CMS form 209 confirmed on 8/20/19 at 12:40 pm that all education and training records were not available.