

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0108387	<b>(X3) Date Survey Completed</b>  03/12/2019
<b>Name of Provider or Supplier</b>  Regional Cancer Care Associates	<b>Street Address, City, State</b>  1 Clara Maass Drive, Belleville, 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>D2007</b>	<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 surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to ensure that all Testing Personnel (TP) who perform Hematology Tests participated in the American Association of Bioanalysts (AAB) PT events in the calendar years from 4/2/17 to the date of the survey. The finding includes: 1. A review of the PT attestation forms revealed that six of eight TP did not perform PT. 2. The TC confirmed on 3/12/19 at 10:50 am that PT events were not rotated amongst TP.</p>
<b>D3037</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to retain all PT records performed with the American Association of Bioanalysts (AAB) in the Q3 2018 and Q1 2019 events. The finding includes: 1. The laboratory did not retain the attestation statements for the events listed above. 2. The TC confirmed on 3/12/19 at 10:40 am that all PT records were not retained.</p>

D5209	<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 Technical Consultant (TC), the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel (TP) from 4/28/17 to the date of the survey. The findings include: 1. Four of eight TP did not have a CA in 2017. 2. A review of 2019 CA revealed the tools listed on the laboratory's CA form to evaluate competency were not used for eight of eight TP. 3. The TC confirmed on 3/12/19 at 10:25 am that the laboratory did not follow its CA procedure.</p>
D5401	<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: a) Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to follow their policy for "Alert or Panic Values" from 4/28/17 to the date of the survey. The finding includes: 1. The PM stated "The laboratory has established panic values for tests performed" but there was no documented evidence panic values were established. 2. The TC confirmed on 3/15/19 at 11:20 am the PM was not followed. b) Based on surveyor review of the PM and interview with the TC, the laboratory failed to follow their policy for flagging of Hematology results run on the Sysmex XN - 430 from 4/28/17 to the date of the survey. The finding includes: 1. The PM stated a smear review is required with a Blast/ Abnormal Lymphocyte flag but a review of results with those flags revealed a smear review was not performed on two of two patients. 2. The TC confirmed on 3/12/19 at 11:20 am the PM was not followed.</p>
D5415	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of Quality Control (QC) material in use, review of the Sysmex Control Kit Manufacture Package Insert (MPI) and interview with the</p>

	<p>Technical Consultant (TC), the laboratory failed to put expiration dates on QC material for the Hematology tests at the time of survey. The findings include: 1. The expiration date of the QC material shortens once opened. 2. The laboratory did not put new expiration dates on the Sysmex controls in use. 3. The TC confirmed on 3/12/19 at 11:10 am the laboratory failed to put expiration dates on the control material.</p>
<p><b>D5421</b></p>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b>  CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by:  Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Consultant (TC), the laboratory failed to ensure that Precision was performed on the Sysmex XN - 430 analyzer from January 2019 to the date of survey. The TC confirmed on 3/12/19 at 11:15 am that Precision was not performed.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>  CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:  Based on surveyor review of the Personnel Files, Competency Assessment records and interview with the Technical Consultant (TC), the TC failed to perform CA from 4/28/17 to the date of survey. The findings include: 1. The CA was not performed by the TC but was done by a non qualified testing personnel 2. The TP #6 listed on CMS form 209 performed CA on seven of eight TP but was not qualified to perform CA. 3. The TC confirmed on 3/12/19 at 10:15 am that the CA was not performed by the TC.</p>
<p><b>D6102</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must 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.</p> <p>This STANDARD is not met as evidenced by:  Based on surveyor review of the Personnel Records (PR) and interview with the</p>

Technical Consultant (TC), the Laboratory Director failed to ensure that education and training records for two out of eight Testing Personal were available from 4/28/17 to the date of survey. The findings include: 1. TP #3 and # 5 listed on CMS form 209 did not have education records in their PR. 2. TP #3, 5 and 8 listed on CMS form 209 did not have training records on file. 3. The TC confirmed on 3/12/19 at 10:20 am that education and training was not documented for all personnel performing testing.