

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0108387	<b>(X3) Date Survey Completed</b> 03/18/2025
<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>D5219</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</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 Director (LD) failed to ensure that the laboratory participated in an accurate split sample assessment for Hematology testing. from 12/16/23 to 3/18/25 The findings include: 1. The laboratory did not verify accuracy of the following analytes. a) Mean Corpuscular Volume (MCV) b) Mean Corpuscular Hemoglobin (MCH) c) Mean Corpuscular Hemoglobin Concentration (MCHC) d) Red Cell Distribution Width - Standard Deviation (RDW-SD) e) Red Cell Distribution Width -Coefficient of Variations (RDW-CV) 3. The TP confirmed on 3 /18/25 at 11:00 am that the LD did not ensure the laboratory participated in an accurate split sample assessment for the above mentioned tests.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) 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), interview with the Testing</p>

Personnel (TP), the laboratory failed to follow the PM for "B. Frequency of Control, use and Review" from 12/19/23 to 3/18/25. The findings include: 1. The PM stated "The supervisor reviews the following quality Control (QC) reports at the follow intervals:" a) "Insight IQAP every period" b) "Continous Calibration Verification Certificate every period" 3. The Insight IQAP was performed once in the past two years in the following date range 12/11/14 - 2/3/25. 4. There was no documented evidence that Continous Calibration Verification Certificate was completed every period 5. The TP confirmed on 3/18/25 at 10:30 am that the laboratory did not follow the PM.