

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0110609	(X3) Date Survey Completed 07/22/2025
Name of Provider or Supplier Regional Cancer Care Associates, Llc	Street Address, City, State 260 Old Hook Road, Suite 301, Westwood, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy of all not graded results for PT events for Hematology performed on the DxH 520 analyzer with the American Proficiency Institute (API) from 1/10/24 to 7/22/25. The findings include: 1. Review of PT records revealed the laboratory received Not Graded scores from API for the 3rd Hematology event of 2023. 2. There was no documented evidence the laboratory evaluated all Not Graded scores received from the PT provider. 3. TP #1 as listed on the CMS 209 form confirmed on 7/22/25 at 11: 20 am, the laboratory failed to verify the accuracy of all Not Graded PT scores from API.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</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 establish procedures when the Proficiency Testing (PT) program assigned the laboratory an artificial score of 100% from 7/11/23 to 7/22/25. The finding includes: 1. The laboratory lacked a procedure for review of its reported PT results against the PT provider's participant summary results. 2. TP #1 as listed on the CMS- 209 form confirmed on 7/22/25 at 10:35 am, the laboratory did not establish procedures in the general laboratory systems requirements for review of its reported PT results against the PT provider's participant summary results.