

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0110609	(X3) Date Survey Completed 07/11/2023
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</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 review and evaluate PT results obtained from the American Proficiency Institute (API) for Hematology/Coagulation at the time of survey. The findings include: 1. The laboratory did not evaluate "Not Graded 6", "See Data Summary" and "See commentary" responses from API for the following: a. Educational Blood Cell Identification sample ECI-02, ECI-05 in event 1, 2023. b. Educational Blood Cell Identification sample ECI-13 in event 3, 2022. c. Blood Cell Identification sample BCI-13 in event 3, 2022. d. Educational Blood Cell Identification sample ECI-07 in event 2, 2021. e. Blood Cell Identification sample BCI-07 in event 2, 2021 f. Educational Blood Cell Identification sample ECI-15 in event 3, 2021. 2. The TP confirmed on at 10:30 am on 7/11/23 that the laboratory failed to evaluate the above mentioned coded results.</p>
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>

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 verify the accuracy of Hematology test results obtained from the American Proficiency Institute (API) 1st event 2023.

The findings include: 1. The PT program assigned an artificial score of 100%, results were reported with the comments "See commentary", "Not Graded 6". 2. There was no documented evidence the laboratory verified: a. "Educational Blood Cell Identification" samples ECI-02, and ECI-05 in event 1, 2023. 3. The TP confirmed on 7/11/23 at 10:20 am that the accuracy of the PT results were not verified.