Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1018141	09/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Regional Cancer Care Associates	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, Procedure Manual (PM) and interview with the Laboratory Manager (LM), the laboratory failed to follow its policies for assessing the competency of Testing Personnel (TP) from 1/1 /24 to 9/30/25. The findings include: 1. There was no documented evidence CA was performed on TP # 1 as listed on the CMS 209 form in calendar year 2024. 2. The LM confirmed on 9/30/25 at 11:30 am, the laboratory failed to follow its policies for assessing the competency of TP in calendar year 2024.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the laboratory failed to review all unsatisfactory scores and document corrective action taken for PT results obtained from the American Proficiency Institute (API) for Hematology tests from 9/1/24 to 9/30/25. The findings include: 1. The laboratory received unacceptable results for Platelet count sample Hem-14 for the 3rd Hematology event of 2024. 2. There was no documented corrective action taken by the laboratory. 3. The LM confirmed on 9/30/25 at 11:15

	am, the laboratory did not review all unsatisfactory scores and document any corrective action taken.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Horiba Abx Micros 60 Performance Specification (PS) records and interview with the Laboratory Manager (LM), the Laboratory failed to ensure that all PS records were adequate after relocation of the two Horiba Abx Micros 60 analyzers from 12/12/24 to 9/30/25. The findings include: 1. The laboratory failed to provide procedures for verifying the PS for the analyzers. 2. There was no documented evidence the laboratory reviewed and evaluated the verification data before patient testing. 3. The LM confirmed on 9/30/25 at 10:50 am that the laboratory failed to ensure that all PS records were adequate.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of the Horiba Abx Micros 60 Performance Verification (PV) records and interview with the Laboratory Manager (LM), the Laboratory failed to have documentation of all records used in the PV of the two relocated Horiba Abx Micros 60 analyzers from 12/12/24 to 9/30/25. The findings include: 1. The laboratory failed to provide raw data reports for acccuracy and precision perfomed on both analyzers. 2. The laboratory failed to provide lot numbers and expiration dates of quality control and calibration materials used. 3. The LM confirmed on 9/30/25 at 10:55 am the laboratory did not document all PV activities.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can

	demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Horiba Operators Manual, and interview with the Laboratory Manager (LM) Personnel (TP), the laboratory failed to follow the Manufacturers instructions for calibration verification for the Horiba Micros Abx-60 analyzer from 7/29/24 to 9/30/25. The finding includes: 1. The PM stated "Perform a concentrated cleaning cycle. Perform 2 start up cycles to ensure the system is clean with no background counts." 2. There was no documented evidence the laboratory followed the procedure before the analyzer was calibrated. 3. The LM confirmed on 9/30/25 at 11:00 am, the laboratory did not follow the manufacturers instructions for calibration verification.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of Patient Test Records (PTR), Procedure Manual (PM), and interview with the Laboratory Manager (LM), the laboratory failed to have accurate Reference Intervals (RI) for Hematology tests performed on the Horiba Abx 60 Micros analyzer from 9/16/24 to 9/30/25. The findings include: 1. Surveyor review of PTR revealed the PM and PTR did not have matching RI for complete blood count tests for 5 out of 5 PTR. 2. The PTR had different RI for male and female patients, but the PM only had one set of RI. 3. The following analytes on the PTR did not have RI that matched in the PM: a)White Blood Cell for female patients only. b) Hematocrit for female patients only. c) Lymphocyte percentage for male and female patients. d) Lymphocyte number for both male and female patients. e) Monocyte percentage for both male and female patients. f) Monoctye number for both male and female patients. g) Mean Corpuscular Volume for female patients only. h) Mean Corpuscular Hemoglobin for female patients only. i) Mean Corpuscular Hemoglobin Concentration for female patients only. j) Red Cell Distribution width for female patients only. 4. The LM confirmed on 9/30/25 at 12:00 pm, the laboratory did not have accurate RI on PTR.