Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1018141	01/31/2023
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM), and interview with the Practice Administrator (PA), the laboratory failed to to have a procedure written for correlation studies for Complete Blood Counts (CBC) performed on the ABX Micros 60 analyzers from Jun 2020 to the date of survey. The PA confirmed on 1/31/23 at 11: 30 am that the laboratory did not have the aforementioned procedure. b) Based on surveyor review of the Procedure Manual (PM), and interview with the Practice Administrator (PA), the laboratory failed to to follow their procedure for "Quality Assurance" for Complete Blood Counts (CBC) performed on the ABX Micros 60 analyzers from Jun 2020 to the date of survey. The findings include: 1) The PM stated "Monthly Quality Control (QC) is reviewed by lab director using Level Jennings Monthly Print". 2) There was no documented evidence that the aforementioned procedure was performed. 3) The PA confirmed on 1/31/23 at 11:30 am that the laboratory did not follow the above mentioned procedure.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The

	laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Practice Administrator (PA), the laboratory failed to perform and document correlation studies for Complete Blood Counts (CBC) performed on the ABX Micros 60 analyzers twice per year from June 2020 to the date of the survey. The PA confirmed on 1/31/23 at 12: 20 pm that the laboratory did not do correlation studies.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the lack of Performance Specification (PS) records and interview with the Practice Administrator (PA), the Laboratory Director (LD) failed to ensure that PS procedures performed for Hematology tests performed on the ABX Micros 60 analyzers Micros 1 and Micros 2 were adequate from June 2020 to the date of survey. The findings include: 1. There was no evidence that linearity was performed on both analyzers. 2. There was no evidence that a Reference Range was verified on both analyzers 3. There was no evidence that precision and accuracy were performed on on both analyzers 4. The PA confirmed on 1/31/23 at 12:15 pm that PS records were not adequate.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Practice Administrator (PA), the Laboratory Director (LD) failed to ensure that the QC program was maintained for laboratory services provided from June 2020 to the date of the survey. The findings include: 1. There was no documented evidence that the QC program defined in the PM was followed. Cross refer D5401 2. The PA confirmed on 1/31/23 at 11:30 am the LD did not ensure the QC plan was maintained. .