Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2059087	03/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Regional Cancer Care Associates	211 N Main St, Cape May Court House, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log, Electronic Medical Records and interview with the Testing Personnel (TP), the laboratory failed to retain patient test records for Complete Blood Count tests on 7/30/18. The finding includes: 1. 23 out of 23 patient work records were not available for review. 2. The TP #2 listed on CMS form 209 confirmed on 3/26/19 at 11:30 pm all patient test records were not retained.
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: Based on surveyor review of the Procedure Manual (PM), the lack of corrective action documentation records, and interview with the Testing Personnel (TP), the laboratory failed to established a procedure for documenting corrective action performed on the Beckman coulter act 2 analyzer from 3/17/17 to the date of survey . The TP #2 listed on CMS form 209 confirmed on 3/26/19 at 11:15 am that the laboratory did not have a procedure to document corrective action.

D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on Surveyor review of Background Function Checks (BFC) and interview with the Testing personnel (TP) the function checks were not within the manufacturer's established limits before patient testing for Complete Blood Count was performed on 7 /30/18. The findings include: 1. The BFC failed for Platelet test. 2. 23 patient were run and reported, 3. The TP#1 listed on CMS form 209 confirmed on 3/26/19 at 11:30 am that function checks failed before Patient testing.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the lack of a Quality Assessment (QA) policy and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the QA program was maintained from 3/17/17 to the date of survey. The TP#2 listed on CMS form 209 confirmed on 3/26/19 at 11:10 am the QA program was not maintained.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have education documented for two out of five TP from 3/17/17 to the date of survey. The TP#2 on CMS from 209 confirmed on 3/26/19 at 10:00 am that all TP did not have education documented.