Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0996062	11/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Regional Cancer Care Associates	18 Newark Pompton Turnpike, Riverdale, 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: Based on surveyor review of the Procedure Manual (PM), Patient work records and interview with the Office Manager (OM), the laboratory failed to follow their PM policy for "Act Diff #2 Flags and Codes" for Hematology tests ran on the Beckman Coulter AcT diff 2 from 11/21/17 to the date of survey. The finding includes: 1) The PM stated "X flag indicates that one of the multiple Alert criteria was not met. 1. Thoroughly mix and rerun the sample. 2. If the flag does not repeat report result. 3. If flag repeats, clean the aperture as instructed in zapping the aperture. 4. if after cleaning, problem persists contact your Beckman Coulter Representative". a) A review of 10 Patients work records revealed that 10 out of 10 patients results with "X" flag were not rerun. 2) The OM confirmed on 11/12/19at 11:05 am the above mentioned procedures was not followed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) material in use and interview with the Office Manager (OM) the laboratory failed to label the control material used in Hematology testing with an open and new expiration date after opening at the time of survey. The finding includes: 1) There was no open and expiration date written on the QC material. 2) The OM confirmed on 11/12/19 at 10: 10 am controls were not labeled.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 Calibration Verification (CV) records and interview with the Office Manager (OM), the laboratory failed to perform and document CV procedures at least once every six months for Hematology Testing on the Beckman Coulter AcT diff 2 analyzer in the calendar year 2019. The finding includes: 1. The laboratory performed CV 10/5/18 and 10/2/19. 2. There was no documented evidence that CV was performed every six months. 3. The OM confirmed on 11/13/19 at 11:30 pm CV was not performed every six months.