Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0996062	(X3) Date Survey Completed 07/24/2024
Name of Provider or Supplier Regional Cancer Care Associates	**Street Address, City, State** 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), and interview with the Testing Personnel (TP), the laboratory failed to have a procedures for a method compression between the two Horiba analyzers for Hematology testing from April 2023 to the date of survey. The TP confirmed on 7/24/24 at 12:30 pm that the laboratory failed to have the above mentioned procedure.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyors observation of Quality Control (QC) material in use and interview with the Testing Personnel (TP), the laboratory failed to follow Manufacturers Specifications (MS) for controls from 6/1/22 to the date of survey. The finding includes: 1. Controls in use did not have correct expiration dates documented as per MS. 2. The TP confirmed on 7/24/24 at 11:20 am that MS were not followed.

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 Testing Personnel (TP), the laboratory failed to perform and document correlation studies for Complete Blood Counts (CBC) performed on the Horiba analyzers twice per year from April 2023 to the date of the survey. The TP confirmed on 7/24/24 at 11:20 am 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 surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed on Horiba analyzer were adequate from April 2023 to the date of survey. The findings include: 1. The LD did not review and sign the PS results. 2. There was no source for the patient Reference Range. 3. The TP confirmed on 7/24/24 at 10:35 am that PS records were not adequate.