Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0110609	(X3) Date Survey Completed 12/12/2018
Name of Provider or Supplier Regional Cancer Care Associates, Llc	**Street Address, City, State** 260 Old Hook Road, Suite 301, Westwood, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing records and interview with the Testing Personnel (TP), the laboratory failed to evaluate coded results obtained for Hematology proficiency testing performed with the American Proficiency Institute (API) in the calendar years 2017 and 2018. The findings include: 1. The laboratory did not evaluate code 6 "Not Graded" for Blood Cell Identification - Educational Challenge on any event. 2. The TP #1 listed on CMS form 209 confirmed on 12/12/18 at 10:30 am that the laboratory failed to evaluate coded results.
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 follow the procedure for flags on the Beckman Coulter AcT Diff 2 analyzer used for Hematology tests from 12/8/16 to the date of the survey. The finding includes: 1. The PM stated samples flagged with an asterisk or plus sign were to be repeated but the there was no documented evidence

	patient results with flags were repeated. 2. The TP #1 listed on CMS 209 confirmed on 12/12/18 at 1:10 pm that the PM was not followed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 test reports, procedure manual and interview with the Testing Personnel (TP), the laboratory failed to report patient test results accurately when results were above the linearity for platelets performed on the Beckman Coulter AcT2 Diff2 analyzer in the calendar year 2018. The finding includes: 1. The laboratory reported four out four platelet values which were above the laboratory's linearity limit of 805 for patient number 29209. 2. The TP # 1 listed on the CMS form 209 stated on 12/12/18 at 1:40 pm that the laboratory reported platelets above the linearity limit.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to correct problems in the postanalytic system for reporting Hematology results from 12/8/16 to the date of the survey. The findings include: 1. The laboratory reported the collection time of specimens on the FR when the office was closed as follows: . Patient Number 29209 collected 7/17/18 at 6:08 am b. Patient Number 11278 collected 9/19/18 at 7:39 am c. Patient Number 9511 collected 8/15/18 at 3:46 am d. Patient Number 101345 collected 10/25/18 at 5:00 am e. Patient Number 604426 collected 10/25/18 at 5:21 am f. Patient Number 503113 collected 12/10/18 at 5:10 am g. Patient Number 30238 collected 10/23/18 at 4:32 am h. Patient Number 100321 collected 10/9/18 at 4:38 am 2. The TP # 1 listed on CMS form 209 confirmed on 12/12/18 at 11:30 am that the laboratory failed to correct problems in the FR. b. Based on surveyor review of the FR, Reference Ranges (RR) and interview with the Testing Personnel (TP), the laboratory failed to correct problems in the postanalytic system when the test results flagged as abnormal were within the RR from 12/8/18 to the date of the survey. The finding includes: 1. A review of the FR revealed samples flagged abnormal as follows: a. White Blood Cell Count: Results 7.6 and 9.3 flagged as abnormal but were within RR of 4.5/10.5. b. Absolute Neutrophil Count (ANC): Results 6.5, 3.0, 4.9, 1.4 and 1.7 flagged as abnormal but were within RR of 1.4/6.5. c. Lymphocyte Number (#): Result 2.8

	flagged as abnormal but were within RR of 1.2/3.4. d. Monocyte #: Results 0.3 and 0.5 flagged as abnormal but were within RR of 0.1/0.6. e. Granulocyte % Results: 52.9, 52.7, 42.4, 7 and 59.8 flagged as abnormal but were within RR of 42.2/75.2. f. Lymphocyte % Results: 30.1 and 52.9 flagged as abnormal but were within RR of 20.5 /51.5. g. Monocyte % Results: 4.6, 3.3, 4.4, 8.8, and 9.0 flagged as abnormal but were within RR of 1.7/9.3. 2. The TP #1 listed on CM'S form 209 confirmed on 12/12/18 at 1:40 PM that the laboratory failed to correct problems in the FR.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 Records (PR) and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that one of two TP had appropriate education documented prior to patient testing from 12/8/16 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 12/12/18 at 10:20 am that education was not documented for all TP.