Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0674146	02/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Regional Cancer Care Associates At Holmdel	723 N Beers Street, Holmdel, 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 Technical Supervisor (TS) via telephone at 10:00 am on 3/1/2021, the laboratory failed to follow the procedure for Critical Value (CV) Reporting from 10/16/2020 to the date of the survey. The findings include: 1. The PM stated "The following procedure is to be followed when calling critical values: Document in the comment box of the EMR the critical result notification and/or stamp analyzer printout with critical value stamp and fill in the appropriate information" 2. Three out of four patient test reports with a CV box stamped on the report did not have the CV box filled in with the appropriate information. 3. The TS confirmed via telephone at 10:00 am on 3/1/2021, the laboratory failed to follow the procedure for CV Reporting. b. Based on surveyor review of the PM and interview with the TS via telephone at 10:00 am on 3/1/2021, the laboratory failed to have the Medonic User Manual from 10/16 /2020 to the date of the survey. The TS confirmed via telephone at 10:00 am on 3/1 /2021 the laboratory did not have the Medonic User Manual.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Technical Supervisor (TS) via telephone at 10:05 am on 3/1/2021, the laboratory failed to have a procedure to verify new lots of controls before they were put in use for Hematology tests performed on the Medonic Analyzer from 10/16/2020 to the date of the survey. The TS confirmed via telephone at 10:05 am on 3/1/21 at that laboratory did not have the above procedure.
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) reagents and interview with the Testing Personnel (TP), the laboratory failed to put a new expiration date on the Boule Con Diff Tri-Level QC reagents in use on the Medonic analyzer on the date of the survey. The findings include: 1. The Manufacturers Package Insert (MPI) stated "open vial stability is 14 days after opening." 2. The laboratory did not put new expiration dates on the Boule Con Diff Tri-Level QC after opening. 3. The TP confirmed on 2/25/2021 at 11:00 am the laboratory failed to put new expiration date on the QC reagents.
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 Performance Specification (PS) record and interview with the Technical Supervisor (TS) via telephone at 10:10 am on 3/1/2021, the laboratory failed to ensure that all PS procedures were adequate on the Medonic analyzer before use from 10/16/2020 to the date of survey. The findings include: 1. There was no documented evidence Method Verification was performed. 2. There was no acceptable range for the Accuracy validation or review of acceptability. 3. There was no raw data found with the Accuracy, Precision and Linearity data to support the results. 4. The TS confirmed via telephone at 10:10 am on 3/1/2021 that all PS procedures were adequate before processing patient results.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Technical Supervisor (TS) via telephone at 9:55 am on 3/1/2021, the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Boule Con Diff Tri-Level QC material used on the Medonic Analyzer from 10/16/2020 until the date of survey. The TS confirmed via telephone at 9:55 am on 3/1/2021 that the assayed values of QC material were not verified before putting in use.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on surveyor review of Test Results and interview with the Technical Supervisor (TS) via telephone at 9:50 am on 3/1/2021, the laboratory failed to take and document Corrective Action (CA) when patient results were out of reportable range (linearity). The findings include: The laboratory did not document CA on results as below: 1. White Blood Cell (WBC) count upper Limit of Linearity (LL) was 80. WBC results were out of range as below: a. WBC of 117 was reported on patient 309655. b. WBC of 430.30 was reported on patient H000 (last four digits). 2. Platelet (PL) count lower (LL) was 30. PL results were out of range as below: a PL of 11 and 27 was reported on patient 322677. b. PL of 27 and 25 was reported on patient 324364. 3. The TS confirmed via telephone at 9:50 am on 3/01/2021 CA was not taken when results were reported outside the LL.
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 Technical Supervisor (TS) via telephone at 9:45 on 3/1/2021, the Laboratory Director (LD) failed to ensure that PS procedures performed on the Medonic analyzer were adequate from October 2020 to the date of survey. The findings include: 1. The LD did not review and sign the PS results. 2. There were no documented evidence method verifications was performed. 3. There were no work records to substantiate the reportable range study. 4, There was no raw data found for linearity, precision or accuracy. 5. There was no documentation which showed what were acceptable results for linearity, accuracy and precision. 5. There was no documented evidence or literature reference which stated where the reference range came from 6. The (TS) via telephone at 9:45 on 3/1/2021 confirmed that PS records were not adequate.
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 (PF) and interview with the Technical Supervisor (TS) at 9:40 am on 3/1/2021 via telephone, the Laboratory Director (LD) failed to have appropriate training and education documentation for all Testing Personnel (TP) performing laboratory testing from 10/16/20 to the date of survey. The findings include: 1. The laboratory did not have education records for two out of two TP listed on the CMS form 209. 2. The laboratory did not have training records for one out of two TP listed on the CMS form 209. 3. The TS confirmed via telephone on 3/1/2021 at 9:40 am the above records were not on file.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Technical Supervisor (TS) via telephone at 9:35 am on 3/1/2021, the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the six required elements from 3/20/18 to the date of the survey. The TS via telephone at 9:35 am on 3/1/ the laboratory did not establish CA procedure.