Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0674146	10/01/2024
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: Based on surveyor review of the Procedure Manual (PM), Patient Test Records (PTR) and interview with the Technical Consultant (TC) via phone, laboratory personnel failed to follow the procedure for Flagged Differentials for Hematology tests performed from 1/3/24 to 10/1/24. The findings include: 1. The PM states "For any reports that are flagged differentials (BD, NM,OM,TM), these must be reviewed by physicians/nurse practitioner, to either accept flag report or request slide to be sent out for review. Report must be documented (signature or initials of ordering physician /nurse practitioner) on any flagged report to be accepted by physician/nurse practitioner without further review." 2. PTR 1010324450 and 1051324711 had "OM" flags on the reports. There was no documented evidence the reports were reviewed by a physician/nurse practitioner to accept flagged reports or requested slides to be sent out for review. 3. The TC confirmed via phone on 10/1/24 at 12:20 pm, laboratory personnel failed to follow the PM.
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 (PM) and interview with the Technical Consultant (TC) via phone, the laboratory failed to have a source for Reference Intervals for Complete Blood Count (CBC) tests performed on the Medonic M series analyzer from 3/21/23 to 10/1/24 The findings include: 1. The laboratory failed to include a source for Reference Intervals (RI) for both male and females for CBC tests performed on the Medonic M series analyzer in the PM. 2. The TC confirmed via phone on 10/1/24 at 12:00 pm, there was no source for reference intervals used for CBC tests in the PM.
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 in use, Boule Con Diff Tri-Level Manufacuters Package Insert (MPI), and interview with the Technical Consultant via phone, the laboratory failed to put a new expiration date on the Boule Con Diff Tri-Level QC reagents in use for the Medonic analyzer on 10/1 /24. 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 TC confirmed via phone on 10/1/24 at 12:05 pm the laboratory failed to put new expiration dates on the QC reagents in use. Note: This deficiency was previously cited on the survey performed on 2/25/21
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Records (MR) , User Manual, and interview with the Technical Consultant (TC) via phone, the laboratory failed to perform and document daily, monthly and six month maintenance as specified by the manufacturer for the Medonic M series analyzer used for Hematology tests from 3/21 /24 to 10/1/24. 1. The laboratory failed to peform and document six month maintenance as per the manufacturer. 2. The laboratory failed to peform and document monthly maintenance as per the manufacturer 3. The laboratory failed to perform and document daily maintenance as per the manufacturer.from 7/20/24 to 10/1 /24 4. The TC confirmed via phone on 10/1/24 at 12:20 pm, the laboratory failed to perform maintenance as per the maufacturer for the Medonic M series analyzer.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Calibration records, Procedure Manual (PM) and interview with the Technical Consultant (TC) via phone, the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Medonic M series analyzer from 7/14/24 to 10/1 /24. The findings include: 1. A review of calibration records revealed that the laboratory last performed calibration of the analzyer on 1/14/24. 2. The PM states "Calibration is performed a minimum of every 6 months with commercial calibrator." 3. The TC confirmed via phone on 10/1/24 at 12:15 pm, the laboratory failed to perform and document calibration once every six months.
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 surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC) via phone, 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 M Series Analyzer from 8/12/24 to 10/1/24. The finding includes: 1. There was no documented evidence QC lots # 2240633, 2240632 and 2240631 were verified before use. 2. The TC confirmed via phone on 10/1/24 at 12:10 pm, the assayed values of QC material were not verified before putting into use. Note: This deficiency was previously cited on the survey peformed on 2/25/21.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC) via phone, the laboratory failed to take corrective action when QC were out of range for Hematology tests for the Medonic M series analyzer from 7/1/24 to 10/1/24. The findings include: 1. A review of the QC summary reports revealed QC values were out of range on 7/5/24, 7/16/24, 7/26/24 and 8/14/24. 2. Approximately 10 patients were run and reported each day of testing. 3. The TC confirmed via phone on 10/1/24 at 12:10 pm, laboratory personnel failed to perform corrective action for out of range QC results.