Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0677457	01/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Regional Cancer Care Associates	326 Professional View Drive, Freehold, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) evaluation records, work records and interview with Technical Consultant (TC) the laboratory failed to participate in PT Hematology event FH2-C-2024 with the College of American Pathologists (CAP) from 11/6/24 to 1/27/25. The findings include: 1. The laboratory failed to participate in PT Hematology event FH2-C-2024. 2. The laboratory did not take corrective action for the missed PT event. 3. The TC confirmed on 1/27/25 at 11: 30 am, the laboratory did not participate in PT event FH2-C-2024
D3031	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on surveyor review of the lack of Quality Control (QC) Verification records, lack of QC package inserts and interview with the Technical Consultant (TC) the laboratory failed to retain QC package inserts for Hematology tests run on the Medonic M series analyzer from 1/5/23 to 1/27/25. The finding includes: 1. There were no package inserts available for review for Hematology QC lots 2240331, 2240631 and 224081. 2. The TC confirmed on 127/25 at 10:00 am that the QC package inserts were not retained.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of the procedure manual, proficiency testing (PT) records, calibration records, quality control records and interview with the Technical Consultant (TC) the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 1/5/23 to 1/27/25. 1. The LD failed to ensure PT samples were tested and submitted for PT event FH2-C-24. Cross refer D6016. 2.The LD failed to ensure corrective action procedures were available to follow for missing PT event. Cross refer D6019. 3.The LD failed to ensure the quality assessment and quality control programs were maintained. Cross refer D6020. 4. The LD failed to ensure calibration was performed on the Medonic M series. Cross refer D6023.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure PT samples were tested for Hematology PT event FH2-C-2024 from the College of American Pathologists from 11/6/24 to 1/27/25. The finding includes: 1. The LD failed to ensure PT samples for Hematology event FH2-C-24 were tested or submitted

	in the required time frame. 2. The LD failed to ensure corrective action was taken for the missing PT event. 3. The TC confirmed on 1/27/25 at 12:00 pm, the LD did not ensure PT samples for Hematology were tested for PT event FH2-C-24.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on the surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the LD failed to ensure the PM had all applicable procedures for proficiency testing (PT) from 1/5/23 to 1/27/25. The findings include: 1) The PM lacked a procedure to follow if the laboratory did not participate in a PT event and corrective actions to take. 2) The TC confirmed on 1/27/25 at :20 pm, the above mentioned procedure was not available for review.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: A) Based on surveyor review of the Electronic Clinical Quality Assurance Program Reports (ECQAPR), Procedure Manual (PM), Quality Assesment Records (QAR) and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that the Quality Assessment program was maintained for laboratory services provided from 1/5/23 to 1/27/25. 1. Platelet low controls and Mean Platelet Volume low control were flagged for S1 for Quality Control (QC) lots 22309-31on the ECQAPR in December and November 2023. Lot # 22306-31 was also flagged in October 2023. 2. S1 codes states (SDI > +/- 2.0 results are outside of the defined reference limit. 3. There was no corrective action documented for shifts or trends on the ECQAPR. 4. The TC confirmed on 1/27/25 at 11:30 am, the LD did not ensure the QA plan was maintained. B) Based on the lack of Quality Control Verification (QCV) Records and interview with the TC, the LD failed to ensure that the Quality Control plan was maintained for laboratory services provided from 1/5/23 to 1/27/25. The findings include: 1. There was no documented evidence QC lots 2240331, 2240631. 224081 were verified before patient use for Hematology tests. 2. The TC confirmed on 1/27/25 at 11:40 am, the LD did not ensure the QC program was maintained. C) Based on the lack of Quality Assessment Records (QAR) and interview with the Technical Consultant (TC), the LD failed to ensure that the Quality Assessment (QA) plan was maintained for laboratory services provided from 1/5/23 to 5/1/24. The findings include: 1. There were no QAR available for review for the above mentioned timeframe. 2. The TC confirmed on 1/27/25 at 11:45 am, the LD did not ensure the QA program was maintained.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)

	(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on surveyor review of the Medonic M series Calibration records and interview with the Technical Consultant (TC) , the Laboratory Director (LD) failed to ensure the maintenance of acceptable levels of analytical performance for Hematology tests performed on the Medonic M Series from 1/1/24 to 1/27/25. The findings include: 1) The PM states "perform calibration as specified by manufacturer or at least once every 6 months." 2) There was no documented evidence calibration was performed every 6 months in calendar year 2024. 3) The TC confirmed on 1/27/25 at 11:00 am the LD failed to ensure the maintenance of acceptable levels of analytical performance for the Medonic M Series.