Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 31D2115989	**(X3) Date Survey Completed** 06/17/2025
Name of Provider or Supplier Regional Cancer Care Assoc At Toms River	**Street Address, City, State** 40 Beylea Road, Toms River, 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**
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to follow its policies for assessing the competency of Testing Personnel (TP) from 1/1 /24 to 6/17/25. The findings include: 1. TP#4 and TP #5 as listed on the CMS 209 form, had incomplete CA for calendar year 2024. 2. TP #7 and TP#8 as listed on the CMS 209 form, did not have a CA performed in 2024. 3. The TC confirmed on 6/17 /25 at 11:25 am, the laboratory failed to follow its policies for assessing the competency of TP.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (a)(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 (a) (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(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 the Calibration records, Procedure Manual (PM), Medonic User Manual (MUM) and interview with the Technical Consultant (TC) the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Medonic analyzer from 7/1/24 to 1/1/25. The findings include: 1. A review of calibration records revealed that the laboratory did not perform calibration every 6 months as per the manufacturer. 2. The TC confirmed on 6/17/25 at 11:15 am, the laboratory failed to perform and document calibration of the analyzer at least every six months.
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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Instrument Correlation Records (ICR) and interview with the Technical Consultant (TC), the laboratory did not have acceptable criteria to evaluate and define the relationship for Hematology test results between the two Medonic analyzers from 1/7/24 to 6/17/25. The finding includes: 1. The procedure did not have written acceptability or rejection criteria for the delta values between the Medonic analyzers. 2. The TC confirmed on 6/17/25 at 11:50 am, the laboratory failed to have written criteria for acceptable differences in test values for correlation studies performed on the two Medonic analyzers.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. 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), the laboratory failed to make available and failed to follow the Corrective Action (CA) procedures for Distribution Indicators for Hematology tests performed on the Medonic Analyzer from 5/28/25 to 6/17/25. The finding includes: 1. Surveyor review of PTR revealed that specimen identification number 1052825976 had a Platelet result flagged for DE (Small particle interference). 2. The PM states for DE flags to reanalyze the sample. 3. There was no documented evidence the sample was repeated. 4. The TC confirmed on 6/17/25 at 11:45 am, the laboratory failed to follow the laboratory CA policy.