Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2115989	11/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Regional Cancer Care Assoc At Toms River	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 Competency Assessment (CA) records and interview with the Technical Consultant (TC), the laboratory failed to perform CA for all Testing Personnel (TP) from 10/23/18 to the date of the survey. The finding includes: 1. One out of five TP did not have a CA performed from 10/23/18 to the date of the survey. 2. The TC confirmed on 11/1/21 at 10:00 am that the CA was not performed.
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records (LR) and interview with the Technical Consultant (TC) ,the laboratory failed to perform correlation studies for Complete Blood Counts (CBC) performed on the Medonic M series Hematology A and B analyzers twice per year in the calendar years 2020 and 2021. The finding includes: 1. A review of the LR revealed there was no documented evidence that an

	instrument correlation study was performed from 10/23/18 to 10/1/21. 2. The TC confirmed on 11/1/21 at 11:00 am that the laboratory did not perform a correlation study twice a year.
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 Consultant (TC), the Laboratory Director (LD) failed to have appropriate education documentation for all Testing Personnel (TP) performing laboratory testing from 10/23/18 to the date of survey. The findings include: 1. The laboratory did not have education records for one out of five TP listed on the CMS form 209. 2. The TC confirmed on 11/1/21 at 10:00 am the above records were not on file.