Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2115989	10/23/2018
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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. 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 failed to undertake appropriate training and employ technical assistance necessary to correct problems associated with PT failures performed with the College of American Pathologists (CAP). The findings include: 1. There was no remedial action or documented taken for unacceptable grade in the FH1-A 2017 event for samples FH1-01 through 05 for Hematocrit % and received an CMS analyte score of 0%. 2. The TC confirmed on 10/23/18 at 10:55 am that corrective action was not documented for the unsatisfactory PT performance.
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 Technical Consultant (TC), the laboratory failed to take corrective action when controls were out of range for Hematology Testing on the Cell Dyn 1700 from January 2018 to the date of survey. The findings include: 1. A review of the QC records revealed: a. On 1/22/18 the Red Blood Cell (RBC), Hemoglobin (HGB) and Hematocrit (HCT) were out of range on two out of three levesl of controls run. b. On 7 /2/18 the RBC and HGB control was out of range on two out of three levels of controls. 2. Approximately 40 patients were run on the above days. 3. The TC confirmed on 10/23/18 at 11:00 am that corrective action on failure of QC was not performed.