Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0925953	08/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Barnabas Health Medical Group	804 West Park Avenue, Ocean, 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 Testing Personnel (TP), the laboratory failed to follow written procedures to perform a CA on one of seven TP for the calendar year 2020. The TP # 2 as listed on CMS form 209 confirmed on 8/17/21 at 1:00 pm that the CA procedure was not followed .
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 Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Hematology QC used on the Beckman Coulter Act diff 2 analyzer from 4/18/19 to the date of the survey.The findings include: 1. Coulter 4C-ES Cell Controls had no documented evidence that QC verification was performed. 2. Coulter 4C-ES Cell Controls lots expire every three months. 3. The TP #2 listed on CMS form 209 confirmed on 8/17/21 at 12:30 pm that assayed QC material was not verified before putting in use.