Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0672796	08/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Monmouth Hematology Oncology	456 Chestnut Street, Lakewood, 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
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. 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 participate in American Association of Bioanalysts (AAB) PT for the first and second events of 2021 for Hematology tests. The TC confirmed on 8/3/21 at 2:00 pm that the laboratory did not participate in the first and second events of 2021.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the

	reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the temperature logs and interview with the Technical Consultant (TC), the laboratory did not document Corrective Action (CA) taken when the Freezer Temperature (FT) log was out of range from August 2020 to December 2020. The findings include: 1. A review of the FT log revealed that the temperature was outside the established range as below: a. August 2020: 5 out of 11 days b. September 2020: 2 out of 13 days c. October 2020: 3 out of 8 days d. November 2020: 2 out of 7 days e. December 2020: 1 out of 4 days 2. There was no documented evidence of Corrective Action (CA) taken. 3. The TC confirmed on 8/3/21 at 2:30 pm the laboratory did not document CA when the FT was out of range.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that 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 Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that PT samples were tested for Hematology tests for the first and second events with the American Association of Bioanalysts (AAB). The TC confirmed on 8/3/21 at 2:00 pm that the LD did not ensure that PT samples were tested.
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 training and education documentation for all Testing Personnel (TP) performing laboratory testing from 1/10/19 to the date of survey. The findings include: 1. The laboratory did not have education records for two out of two TP listed on the CMS form 209. 2. The laboratory did not have training records for two out of two TP listed

	on the CMS form 209. 3. The TC confirmed on 8/3/21 at 1:30 pm the above records were not on file.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC), the Testing Personnel failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Medonic M series Hematology analyzer from January 2020 to the date of the survey. The TC confirmed on 8/3/21 at 1:30 pm that trends and shifts were not reviewed.