Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0672796	01/10/2019
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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Office Manager (OM), the laboratory failed to retain copies of all PT records for testing performed with the American Association of Bioanalysts (AAB) in the calendar year 2017 and 2018. The findings include: 1. The laboratory did not have graded PT results for Q 1,2 and 3 2017 and Q 1 2018 Hematology. 2. The laboratory did not have the attestation statements for Q 1,2 and 3 2017 and Q 1 2018. Hematology. 3. The laboratory did not have work records Q 1,2 and 3 2017 and Q 1 2018. Hematology. 3. The OM confirmed on 1/10/19 at 10:10 am that PT records were not retained.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to use the "Instrument Action Log" for corrective action documentation on failed Quality Control run on the Medonic Series-M analyzer used for Hematology tests from 4/20/18 to the date of the survey. The TP

	#1 listed on CMS form 209 confirmed on 1/10/19 the "Instrument Action Log" was not being used. b) Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to perform "QA scheduled Review" procedure from September 2018 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 1/10/19 the procedure was not followed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of the Maintenance Record (MR) and interview with the Testing Personnel (TP), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Medonic Series-M analyzer used in Hematology Testing from April 2018 to the date of survey. The findings include: 1. A review of the MR revealed there was no documented evidence of daily and monthly maintenance performed from April 2018 through January 2019. 2. The TP #1 listed on CMS form 209 confirmed on 1/10/19 at 11:10 am that maintenance as specified by the manufacturer was not performed.
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, Manufacture's Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment for Hematology testing performed on the Medonic Series-M analyzer from April 2018 on the date of survey. The finding includes: 1. The TP was unaware of QC verification. 2. The laboratory did not verify all QC materials used from April 2018 through January 2019. 3. The TP #1 Listed n CMS form 209 confirmed on 1/10/2019 at 12:00 pm that the assayed values of QC materials were not verified before putting in use.
D5803	TEST REPORT CFR(s): 493.1291(b)

	Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on the surveyor review of the Electronic Medical Records (EMR), Test Results (TR) and interview with the Testing Personel (TP), the laboratory failed to have TR on one out of five EMR reviewed from 9/1/2018 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 1/10/19 at 12:20 pm that the TR was not in all the EMR.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's review of the laboratory's records and interview with the Laboratory Director (LD), the LD failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from April 2018 to the date of the survey. 1. The LD failed to ensure Performance Specifications were adequate. Cross refer to D6013 2. The LD failed to have appropriate education on all testing personnel. Cross refer to D6029 3. The LD failed to have an approved procedure manual. Cross refer to D6031
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Medonic Series-M analyzer were adequate from April 2018 to the date of survey. The findings include: 1. Accuracy, Precision and Reference Range validation were not performed. 2. The LD did not review and sign the linearity study. 3. The TP #1 listed on the CMS form 209 confirmed on 1/10/19 at 11:15 am that PS records were not reviewed or adequate.
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 Office Manager (OM), the Laboratory Director failed to have appropriate education for all Testing Personnel (TP) on file from 1/30/17 to the date of the survey. The finding includes: 1. TP #1 listed on CMS form 209 did not have education records. 2. TP #1 listed on CMS form 209 had no training documentation on how to perform hematology tests on the Medonic Series-M analyzer. 3. The OM confirmed on 1/10/19 at 12:00 pm education and training records were not in the PF.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing personnel (TP), the Laboratory Director failed to have an approved procedure manual available for Hematology testing at the time of the survey. The TP #1 listed on CMS form 209 confirmed 1/10/19 at 10:15 am an approved PM was not available.
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 Testing Personel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Medonic Seires-M analyzer from April 2018 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 1/10/19 at 11:45 am that trends and shifts were not reviewed.