Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1069749	06/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hackensack Meridian Health Network	2 Hospital Plaza, Old Bridge, 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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM) and interview with Testing Personnel (TP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems from 12/9/21 to the date of survey. The TP confirmed on 6/18/24 that the laboratory failed to establish the aforementioned procedures.
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: Based on the lack of a Procedure Manual (PM) and interview with Testing Personnel (TP) the laboratory failed to have written procedures for all tests, assays, and examinations performed by the laboratory from 12/9/21 to the date of survey. The TP confirmed on 6/18/2024 at 10:30 am the laboratory did not have a PM.

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of Quality Control (QC) material in use, review of the Boule Con-Diff Tri-Level Control Kit Manufacture Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to put open and expiration dates on QC material for the Hematology tests at the time of survey. The findings include: 1. The expiration date of the QC material shortens once opened. 2. The laboratory did not put open or expiration dates on the Boule controls in use. 3. The TP confirmed on 6/18/24 at 11:45 am the laboratory failed to put open and expiration dates on the control material.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with Testing Personnel (TP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 12/9/21 to the date of survey. The findings include: 1. The laboratory did not have a policy with criteria on when to repeat a patient test. 2. The laboratory failed to have a procedure to verify new lots of controls before they were put in use. 3. The Laboratory failed to have a procedure on how Quality Control is reviewed, monitored and maintained. 4. The TP confirmed on 6/18/2024 at 11:45 am that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.
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 M-series analyzer were adequate from March 2024 to the date of survey. The findings include: 1. The LD did not review and sign the PS results. 2. The TP confirmed on 6/18/24 at 10:35 am that PS records were not adequate.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the lack of a procedure manual (PM) and interview with Testing Personnel (TP) the Laboratory Director (LD) failed to ensure that a Quality Control (QC) program was established and maintained to assure the quality of laboratory services provided from 12/9/21 to the date of survey. The TP confirmed on 6/18/24 at 11:00am that the LD failed to established and maintain a QC program.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM) and interview withe Testing Personnel (TP) the laboratory Director (LD) failed to ensure that Quality Assessment (QA) programs were established and maintained to assure the quality of laboratory services provided from 12/9/21 to the date of survey. The TP confirmed on 6/18/24 at 11:20 am that a QA program was not established and maintained.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for

	monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, the lack of a Procedure Manual (PM) and interview with the Testing Personnel (TP) the Laboratory Director (LD) failed to have established written procedures for assessing the competency of TP from 12/9/21 to the date of survey. The findings include: 1. There was no written procedure or policy for how to assess the competency of new employees and the annual competency of TP. 2. The TP confirmed on 6/18/2024 at 10: 30 am the LD failed to establish written policies and procedures for CA.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the lack of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to specify in detail the duties and responsibilities TP engaged in the performance of Hematology testing from 12/9/21 to the date of survey. The TP confirmed on 6/18/24 at 12:15 am that the LD did not specify the duties and responsibilities of TP.
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 Personnel (TP), the LD 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 analyzer from from 12/9/21 to the date of survey. The TP confirmed on 6/18/24 at 11:35 pm that trends and shifts were not reviewed.