Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0679767	08/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hackensack Meridian Health Network	1030 St Georges Ave, Avenel, 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
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), calibration records, and interview with the Nurse Manger (NM), the laboratory failed to follow the procedure for calibration of the Medonic analyzer from 11/30/18 to the date of survey. The finding includes: 1. The PM maintenance and calibration schedule stated calibration was due in month 6 and 12 but the laboratory had no record of calibration after 11/30 /18. 2. The NM confirmed on 8/15/19 at 1:15 pm that the laboratory did not follow the calibration procedure. b. Based on surveyor review of the PM, lack of corrective action records, and interview with the NM, the laboratory failed to follow the procedure for documenting corrective action performed on the Medonic analyzer from 8/17/17 to the date of survey. The findings include: 1. The PM stated "out of control" QC should be repeated, if still out calibrate instrument and rerun QC "record all corrective action " but there was no evidence corrective action was documented when the laboratory ran QC five times on 12/18/19 and six times on 12/19/19. 2. The NM confirmed on 8/15/19 at 2:15 pm that the laboratory did not follow the PM. c. Based on surveyor review of the PM and interview with the NM, the laboratory failed to follow the procedure for flags on the Medonic analyzer used for Hematology tests from 8/17/17 to the date of the survey. The finding includes: 1. The PM stated White Blood Differential (WBC) flags were to be crossed out and a note added "not for diagnostic purposes" but a review of five patient results with WBC flags revealed five out of five were not crossed out or noted. 2. The NM confirmed on 8/15/19 at 1:10 pm that the PM was not followed.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Nurse Manager (NM) the laboratory failed to have all applicable procedures for Hematology Tests from 8/17/17 to the date of the survey. The findings include: 1. The laboratory did not have a procedure for: a. Critical Values b. The course of action to be taken if the test system becomes inoperable. 2. The NM confirmed on 8/15/19 at 2: 20 pm that the PM did not have all applicable procedures.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Nurse Manager (NM), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from 8/17/17 to the date of survey. The NM confirmed on 8/15/19 at 2:30 pm that the TRD was not on the FR.
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 Personnel Files and interview with the Nurse Manager (NM), the Laboratory Director failed to have education documented for one out of three Testing Personnel from 8/17/17 to the date of the survey. The NM confirmed on 8/15/19 at 12:40 pm that all education records were 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 Nurse Manager (NM), the Testing Personal failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Medonic analyzer from 12/30/18 to 4/8/19 and 5/31/19 to the date of the survey. The NM confirmed on 8/17/19 at 1:45 pm that trends and shifts were not reviewed.