

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1069749	(X3) Date Survey Completed 12/09/2021
Name of Provider or Supplier Hackensack Meridian Health Network	Street Address, City, State 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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Office Manger (OM), the laboratory failed to retain graded results for Hematology /coagulation PT event 2-2021 performed with the American Proficiency Institute. The OM confirmed on 12/9/21 at 11:45 am that all PT graded results were not retained.</p>
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of Manufactures Instructions (MI), Procedure Manual, Quality Control (QC) Records, Calibration Records (CR) and interview with the Office Manager (PM), the laboratory failed to ensure that quality systems for the pre-analytic, analytic and post-analytical phases of Hematology testing were monitored at the date of survey. 1. The laboratory failed to maintain Proficiency Testing (PT) records. Cross refer to D3037. 2. The laboratory failed to follow the manufacturer's instructions for the Medonic M-Series analyzer used fro hematology testing. Cross refer to D5411. 3. The laboratory failed to put open and expiration dates on QC material. Cross refer to D5415. 4. The laboratory use expired QC for Hematology tests. Cross refer to D5417. 5. The laboratory failed to perform and document</p>

Calibration procedures . Cross refer to D5437 6. The laboratory failed to take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. Cross refer to D5783.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
a) Based on surveyor review of the Manufacturers Instructions (MI), Background Check Records (BCR) and interview with the Office Manager (OM), the laboratory failed to follow the MI for "Reagent Pipette Indicators (RBC,PLT,WBC)" on 4/1/21. The finding includes: 1. The BCR coded DP "Diluent system problem - run prime cycle", for White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HGB), and Platelets (PLT)". 2. The MI stated the the "action" for DP codes were as follows "Verify instrument is filled run a "Prime Cycle" and then re-analyze sample". 3. There was no documented evidence that the aforementioned procedure was performed. 4. The OM confirmed on 12/9/21 at 11:10 am the laboratory did not follow the MI. b) Based on surveyor review of the MI, Quality Control (QC) records and interview with the OM, the laboratory failed to follow the MI for "Reagent Pipette Indicators (RBC,PLT,WBC)" on 4/8/21. The finding includes: 1. Boule Con-Diff Tri-Level, Level 2 Lot 2201030 QC results coded LP "Lyse system problem - run prime cycle", for WBC and HGB. 2. The MI stated the the "action" for LP codes were as follows "Verify instrument is filled run a "Prime Cycle" and then re-analyze sample". 3. There was no documented evidence that the aforementioned procedure was performed. 4. The OM confirmed on 12/9/21 at 11:10 am the laboratory did not follow the MI.

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 Office Manager (OM), 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 OM confirmed on 12/9/21 at 11:45 am the laboratory failed to put open and expiration dates on the control material.

D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) results and interview with the Office Manager (OM), the laboratory use expired QC for Hematology tests run on the Medonic M-series analyzer on 8/19/21. The findings include: 1. Boule Con-Diff Tri-Level controls Lot 2210330 run on 8/19/21 where coded EC "Expired Quality Control" 2. Approximately 10 patients were run and reported. 3. The OM confirmed on 12/9/21 at 11:50 am that the laboratory used expired QC.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Calibration (C) records, Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Modonic M-series analyzer in the calendar year 2020. The findings include: 1. A review of C records revealed that the laboratory performed C once in the calendar year 2020. 2. The OM confirmed on 12/9/21 at 10:32 am that the laboratory failed to perform and document C once every six months.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by:</p>

a) Based on surveyor review of the Quality Control (QC) records and interview with Office Manager (OM), the laboratory failed to take corrective action when two out of three levels of controls were out of range for Complete Blood Count (CBC) tests performed on Medonic-M series analyzer from 1/14/21 to the date of survey. The findings include: 1. Boule Con-Diff Tri-Level Control level 1 and 3 Lot number 2201120 was out of range for Red Blood Cell Count (RBC) on 1/14/21. 2. Boule Con-Diff Tri-level Control level 1 and 2 Lot number 2201130 was out of range for white Blood Cell Count (WBC) on 4/8/21. 3. Boule Con-Diff Tri-level Control level 1 and 2 Lot number 2201130 was out of range for Platelets (PLT) on 8/19/21. 4. Boule Con-Diff Tri-level Control level 1 and 2 Lot number 22010730 was out of range for PLT on 10/28/21. 5. There was no corrective action documented for the above failures. 6. Approximately 6-10 patients run and reported each day of testing. 7. The OM confirmed on 12/9/21 at 11:00 am that no corrective action was taken for out of range QC. b) Based on surveyor review of the Background Check (BC) Report records and interview with OM, the laboratory failed to take corrective action when BC failed on 4/8/21 on the Medonic-M series analyzer. The findings include: 1. BC results fagged High as follows: a. RBC - $0.04 \times 10^9/L$ b. WBC - $0.2 \times 10^9/L$ c. PLT - $151 \times 10^9/L$ 2. The OM confirmed on 12/9/21 at 11:05 am that no corrective action was taken when BC failed. c) Based on surveyor review of the Calibration Records (CR) and interview with OM, the laboratory failed to take corrective action when calibration failed on 12/7/21 on the Medonic-M series analyzer. The findings include: 1. Calibration failed as follows: a. RBC failed three out of five calibration parameters. b. MCV failed five out of five calibration parameters. c. HGB failed two out of five calibration parameters. 2. The OM confirmed on 12/9/21 at 11:15 am that no corrective action was taken when Calibration failed.

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 review of the Laboratory records and interview with the Office Manager (OM), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 10/15/19 to the date of survey. The findings include: 1. The LD failed to ensure that PS procedures performed on the Medonic M-series analyzer were adequate. Cross refer to D6013. 2. The LD failed to ensure that a Quality Control program was maintained. Cross refer to D6020. 3. The LD failed to ensure that the Quality Assurance program was maintained. Cross refer to D6021. 4. The LD failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for Hematology tests. Cross refer D6074.

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 Office Manager (OM), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Medonic M-series analyzer were adequate from January 2021 to the date of survey. The findings include: 1. The LD did not review and sign the PS results. 2. The OM confirmed on 12/9/21 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 surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the Laboratory Director failed to ensure that a QC program was maintained for laboratory services provided from March 2021 to the date of the survey. The findings include: 1. There was no documented explanation as to why all three levels of Hematology controls were run six times consecutively on 3/19/21. 2. There was no documented explanation as to why all three levels of Hematology controls were run five times consecutively on 3/25/21. 3. There was no documented explanation as to why all three levels of Hematology controls were run four times consecutively on 7/1/21. 4. There was no documented explanation as to why all three levels of Hematology controls were run two times consecutively on 3/19/21. 5. The OM confirmed on 12/9/21 at 11:20 am the LD did not ensure a QC plan was maintained.

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 surveyor review of the Quality Assessment (QA) policy and interview with the Office Manager (OM), the Laboratory Director failed to ensure that the QA program was maintained from January 2021 to the date of survey. The finding includes: 1. The QA policy stated "QC will be checked monthly" but there was no

documented evidence QC was reviewed for June and November 2021. 2. The OM confirmed on 12/9/21 at 10:20 am that the laboratory did not maintain the QA program.

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 Office Manager (OM), 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 January 2021 to the date of survey. The OM confirmed on 12/9/21 at 11:35 pm that trends and shifts were not reviewed.