

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2311701	(X3) Date Survey Completed 10/10/2025
Name of Provider or Supplier Hackensack Meridian Urgent Care Plus, Pc	Street Address, City, State 5 Marine View Plaza, Hoboken, 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
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Proficiently Testing (PT) records and interview with the Technical Consultant (TC) the Laboratory Director (LD) failed to ensure that the laboratory participated in an accurate split sample assessment for Hematology testing. from 9/26/24 to 10/10/25. The findings include: 1. A review of AAB-MLE PT events 3-2024, and 1,2,3-2025 revealed that the laboratory did not verify accuracy of the following analytes. a) Mean Corpuscular Volume (MCV) b) Mean Corpuscular Hemoglobin (MCH) c) Mean Corpuscular Hemoglobin Concentration (MCHC) d) Red Cell Distribution Width (RDW) e) Mean Platelet Volume (MPV) f) Granulocytes absolute (GRA#) g) Monocytes absolute (MON#) h) Lymphocytes Absolute (LYM#) 2. The TP confirmed on 10/10/25 at 11:00 am that the LD did not ensure the laboratory participated in an accurate split sample assessment for the above mentioned tests.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:
 Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) and interview with the Technical consultant (TC) the laboratory failed to have a Corrective Action (CA) procedure for failed Quality Control (QC) runs for the Horiba ABX Micros 60 analyzer used to perform Hematology testing from 9/26/24 to 10/10/25. The findings include: 1. QC was run as follows: a) Level 1 QC was run four times on 9/10/25. b) Level 2 QC was run seven times on 9/12/25 c) Level 2 QC was run seven times on 8/16/25 d) Level 2 QC was run five times on 8/15/25. e) Level 3 QC was run four times on 9/25/25. f) Level 3 QC was run five times on 9/12/25. g) Level 3 QC was run eight times on 8/18/25. h) Level 3 QC was run four times on 8/17/25. i) Level 3 QC was run twenty-six times on 8/16/25. j) Level 3 QC was run five times on 8/13/25. 2. No corrective action was documented for the above QC failures 3. The TC confirmed on 10/10/25 at 10:55 am, the laboratory failed to have a CA procedure for failed QC.

D5469

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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.

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 laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of ABX Mintrol 16 QC material used on the Horiba ABX Micros 60 Analyzer from 9/26/24 to 10/10/25. The findings includes: 1. There was no documented evidence that the laboratory verify commercially assayed QC material. 2. The TC confirmed on 10/10/25 at 11:10 am, the assayed values of QC material were not verified before putting into use.

D5479

CONTROL PROCEDURES
 CFR(s): 493.1256(e)(5)(g)

(e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

This STANDARD is not met as evidenced by:
 Based on surveyors observation of Quality Control (QC) material in use and interview with the Technical Contulant (TC), the laboratory failed to follow Manufacturers Specifications (MS) for controls from 9/26/24 to 10-10-25. The findings include: 1. Controls in use did not have open or expiration dates documented as per MS. 2. The MS for ABX Mintrol 16 controls stated "Open-vial stability 30 days" 3. The TC confirmed on 10/10/25 at 11:20 am that MS were not followed.

D5803

TEST REPORT

CFR(s): 493.1291(b)

(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 Work Records (WR), Final Reports (FR) and interview with the Technical consultant (TC), the laboratory failed to have FR on all patients reviewed on 10/10/25. The finding includes: 1) Four out of nine WR did not have a FR. 2) The TC confirmed on 10/10/25 at 11:30 am that the laboratory did not maintain all FR.

D5805

TEST REPORT

CFR(s): 493.1291(c)

(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 Test Reports (TR) for Hematology and interview with the Technical Consultant (TC) the laboratory failed to ensure TR included all the required information from 9/26/24 to 10/10/25. The findings include: 1. TR did not include the address of the laboratory where Hematology testing was performed. 2. The TC confirmed on 10/10/25 at 11:00 am, the laboratory failed to ensure the TR included all the required information.