Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2314324	03/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Hackensack Meridian Urgent Care Plus	769 Northfield Ave, West Orange, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records, CASPER 155 report and interview with the Techincal Consultant (TC), the laboratory failed to enroll in an Health and Human Services (HHS) approved PT program for Hematology tests for the third PT event of 2025. The TC confirmed on 3/11/26 at 10:40 am the laboratory was not enrolled in PT for Hematology for the above mentioned PT event.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on the surveyor review of the Proficiency Testing (PT) records and interview with the Techincal Consultant (TC), the laboratory failed to ensure that attestation statements were maintained from 11/18/24 to 3/11/26. The finding includes: 1. There

	were no Attestation statements, work records and graded results available for PT provider American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Non-Chemistry, Hematology 1st and 2nd events in 2025 . 2. The TC confirmed on 3/11/26 at 11:15 am that the Attestation statements, work records and graded results were missing for the above mentioned events.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of the procedure manual (PM) the lack of Proficiency tasting (PT) records office review of the CASPER 155 report and interview with the Techincal Consultant (TC), the laboratory failed to achieve 80% or more in two out of three events for the analyte Hemoglobin (HGB) with the Association of Bioanalysts /Medical Laboratory Evaluation (AAB-MLE). Cross refer D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CASPER 155 report and graded results from Association of Bioanalysts/Medical Laboratory Evaluation (AAB-MLE). The laboratory failed to achieve satisfactory performance (80% or greater) for two out of three events in the specialty Hematology for the analyte Hemoglobin (HGB) resulting in initial unsuccessful inital performance. The findings include: 1) A review of the CASPER 155 report revealed the following. a) The laboratory scored 60% for HGB in event 1-2025. b) The laboratory was not enrolled in a Health and Human Services (HHS) approved Proficiency Testing (PT) program for event 3-2025. 2. A review of AAB-MLE graded results and CASPER 155 report confirmed the laboratory failed two out of three PT events.

D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (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 Technical Consultant (TC), the laboratory lacked copies of all PT records for testing performed with the American Association of Bioanalysts/Medical Laboratory Evaluation (AAB-MLE). for the 2nd and 3rd Hematology PT events of 2025. The findings include: 1. The laboratory lacked the work records, attestation pages and graded results for the 2nd and 3rd Hematology PT events of 2025. 2. The TC confirmed on 3/11/26 at 11:30 am, all PT records were not retained.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records, Procedure Manual (PM) and interview with the Techincal Consultant (TC), the laboratory failed to follow its policies for assessing the competency of Testing Personnel (TP) from 11 /18/24 to 3/11/26. The findings include: 1. There was no documented evidence CA was performed on three out of three TP listed on the CMS 209 form 11/18/24 to 3/11 /26. 2. The TC confirmed on 3/11/26 at 11:30 am, the laboratory failed to follow its policies for assessing the competency of TP as mentioned above.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the lack of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to review PT results obtained from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Non-Chemistry, Hematology 1st and 2nd events in 202. The finding includes; 1) There was no documented evidence that PT results for AAB-MLE Non-Chemistry, Hematology 1st and 2rd event in 2025 were reviewed. 2) The TC confirmed on 3/11 /26 at 10:30 am that the laboratory did not review PT results stated above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test

	system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of Performance Specification (PS) records and interview with the Techincal Consultant (TC), the laboratory failed to ensure that all PS records were adequate for Hematology tests performed on the Horiba ABX Micros 60 from 11/18/24 to 3/11/26. The findings include: 1. The laboratory failed to perform a normal Patient range verification. 2. The laboratory failed to perform a normal Precision. 3. The TC confirmed on 3/11/26 at 11:30 am, the laboratory failed to ensure that all PS records were adequate.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the lack of of Calibration Verification (CV) records, User Manual (UM) and interview with the Technical Consultant (TC), the laboratory failed to perform, document and meet acceptable limits for all Calibration results and procedures at least once every six months for Hematology Tests performed on the Horiba ABX Micros 60 analyzer from 11/18/24 to 3/11/26. The findings include: 1. There was no documented evidence that CV was performed. 2. The TC confirmed on 3/11/26 at 11:32 am that the laboratory failed to perform, document CV every six months.
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 11/18/24 to 3/11/26. The findings includes: 1. There was no documented evidence that the laboratory verify commercially assayed QC material. 2. The TC confirmed on 3/11/26 at 11:10 am, the assayed values of QC material were not verified before putting into use.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to follow the Corrective Action (CA) policy for Quality Control Corrective Action Form for Hematology tests performed from 11/18/24 to 3/11/26. The finding includes: 1. The PM stated "Repeat QC one time only to rule out random error. Repeated testing trop force acceptable results is prohibited." 2. 10/20/26 and 10/19/26 the Normal control was run five times until results were acceptable. 3. 10/22/26 the Low control was run five times until results were acceptable. 4. 9/18/26 the Low control was run seven times until results were acceptable 5. 9/16/26 the Low control was run four times until results were acceptable. 6. The laboratory did not follow the laboratories CA policy for QC. 7. The TC confirmed on 3/11/26 at 10:45 am, the laboratory failed to follow the laboratory's CA policy.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Technical Consultant (TC), the laboratory failed to take corrective action when two out of three levels levels of controls were out of range for tests performed on the Horiba ABX Micros 60 analyzer from 8/30/26 to 10/28/26. The findings include: 1. Control levels were out as follows: a) ABX Minotrol 16 controls Low Normal and High were out of range for Red blood cell count (RBC), on 8/30/2026. b) ABX Minotrol 16 controls Low and Normal were out of range for Platelet (PLT) on 9/26

	/26. c) ABX Minotrol 16 controls Low Normal and High were out of range for RBC on 10/28/26. d) ABX Minotrol 16 controls Low and Normal were out of range for White Blood Cell Count (WBC) on 11/19/26. e) ABX Minotrol 16 controls Low was out of range for WBC on 11/18/26. f) ABX Minotrol 16 controls Normal and High were not run on 11/18/26. g) ABX Minotrol 16 controls Normal and High were out of range for Hemoblgobin (HGB) on 11/13/26. h) ABX Minotrol 16 controls Low and Normal were out of range for WBC on 11/11/26. c) ABX Minotrol 16 controls Low Normal and high were out of range for RBC on 11/4/26. 2. There was no corrective action documented for the above failures. 3. Approximately 4 patient samples were run and reported daily. 4. The TC confirmed on 3/11/26 at 1:00 pm that no corrective action was taken for out of range QC.
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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with Techincal Consultant, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 11/18/24 to 3/11/26. The finding includes: 1. The laboratory failed to have a procedure to monitor and assess Quality Control (QC) shifts and trends for Hematology testing. 2. The TC confirmed on 3/11/26 at 10:40 am that the laboratory failed have an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system as mentioned above.
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 Techincal Consultant (TC) the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 11/1/21 to the date of survey. The findings include: 1. The LD failed to ensure that Performance Specifications procedures were adequate. Cross refer D6013. 2. The LD failed to ensure the laboratory was enrolled in HHS approved PT program for Hematology tests for the third PT event of 2025. Cross refer D6015. 3. The LD failed to ensure successful participation in a Department of Health and Human Services (DHHS) approved Proficiency Testing (PT) program for two out of three PT events for specialty Hematology. Cross refer D6016. 4. The LD failed to ensure that PT results were reviewed by the appropriate staff. Cross refer D6018. 5. The LD failed to ensure that corrective action plans were followed for unacceptable PT results. Cross refer D6019. 6. The LD failed to ensure

	the Quality Control Program was maintained for laboratory services. Cross refer D6020. 7. The LD failed to have appropriate education and training documentation on all TP to ensure they are competent. Cross refer D6029.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Consultant (TC) the Laboratory Director (LD) failed to ensure that PS procedures for Hematology testing performed on the Horiba ABC Micro 60 analyzer were adequate from 11/18/24 to 3/11/26. Cross refer: 5421
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records, CASPER 155 report and interview with Techincal Consultant (TC), the Laboratory Director (LD) failed to ensure the laboratory was enrolled in Health and Human Services (HHS) approved PT program for Hematology tests for the third PT event of 2025. Cross refer: D2000
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of the CASPER 155 report and graded results from American Proficiency Institute (API), the Laboratory Director (LD) failed to ensure successful participation in a Department of Health and Human Services (DHHS) approved Proficiency Testing (PT) program for two out of three PT events for specialty Hematology for the analyte Hemoglobin (HGB) resulting in initial unsuccessful performance. Refer to D2130.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and

	This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), the lack of Proficiency Testing (PT) records and interview with the Techincal Consultant (TC), the Laboratory Director (LD) failed to ensure that PT results were reviewed by the appropriate staff for 2025 PT events. The finding includes: 1. There was no documented evidence that the LD reviewed in the calendar year 2025. 2. The TC confirmed on 3/11/26 at 11:00 am that was no documented evidence that PT was reviewed by appropriate in the calendar year 2025.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on surveyor Review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the Laboratory Director failed to ensure that corrective action plans were followed for unacceptable PT results obtained from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Non-Chemistry, Hematology 1st event of 2025. The finding includes: 1. There was no corrective action documented when the laboratory achieved a 60% for Hemoglobin (HGB), for AAB-MLE event 1-2025 2. The TC confirmed on 3/11/26 at 12:15 pm that the laboratory did not perform and document corrective action for the unacceptable PT results.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Techincial comnsultant (TC), the Laboratory Director (LD) failed to ensure that the QC program was established and maintained for laboratory services provided from 11/18/24 to 3/11/26. The findings include: 1. The laboratory failed to take corrective action when two out of three levels levels of controls were out of range. Cross refer: D5783. 2. The laboratory failed to follow the Corrective Action (CA) policy for QC Corrective Action Form for Hematology tests. Cross refer: D5779. 3. The laboratory failed to verify commercially assayed QC material with each new lot and/or shipment. Cross refer D5469 4.The TC confirmed on 3/11/26 at 11:30 am the LD did not ensure the QC plan was established and maintained. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 Techincal Consultant (TC), the Laboratory Director (LD) failed to have appropriate education and training documentation on all TP performing laboratory testing from 11 /18/2024 to 3/11/26. The findings include: 1. The laboratory did not have education records for three out of three TP listed on the CMS form 209. 2. There was no documented evidence that three out of three TP were trained to perform Hematology testing on the Horiba ABX Micros es 60 analyzer. 3. The TC confirmed on 3/11/26 at 11:00 am the above records were not on file.