Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0938365	02/03/2023
Name of Provider or Supplier	**Street Address, City, State**	
Northern Westchester Internal Medicine	1872 Commerce Street, Yorktown, NY	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) records, documents for the 2020, 2021, and 2022 test events, as well as an interview with the laboratory testing person (TP1), the laboratory failed to rotate the API PT samples among the two testing personnel who routinely perform hematology testing. FINDINGS: 1. Based upon the review of the 2020, 2021, and 2022 API PT attestation forms and test result forms, the laboratory failed to rotate the API PT samples among the two testing personnel who routinely perform hematology testing. The laboratory failed to participate in the 2021 first and second events. This was addressed during the 2021 second PT Desk Review Statement of Deficiencies (SOD) and the plan of correction (POC) was accepted. 2. The laboratory testing person TP1 confirmed on February 3, 2023, at approximately 10:00 AM the laboratory failed to rotate the API PT samples among the two testing personnel who routinely perform hematology testing
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on a review of the API PT records for all three test events for years 2020, 2021, and 2022, and interviews with the laboratory director and testing personnel, the attestation forms attesting that the PT samples were tested in the same routine manner as patient specimens were not signed. FINDINGS: 1. Based upon the review of the printed hematology reports for calendar years 2020, 2021, and 2022, the laboratory failed to test the hematology proficiency testing samples in the same routine manner as patient specimens for all three events in 2020, 2021, and 2022. 2. TP1 confirmed on February 3, 2023, at approximately 10:00 A.M., that the attestation forms for all three events in years 2020, 2021, and 2022 were not signed by the laboratory director as well as the routine testing personnel. It could not be determined that the PT samples were tested in the same manner as patient specimens by the testing personnel.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the review of the Horiba Abx Micros 60 Quality Control (QC) records for 2019, 2020, and2021, the invoice records for QC and calibration material, and an interview with TP1, the laboratory failed to retain QC records from May through December 2020, as well as January through December 2021. Refer to D6020. FINDINGS: 1. The laboratory was not consistent with retaining the instrument startups, QC records, monthly QC graphs including Levey-Jennings, calibration records, and the Abx Micros control and calibration assay sheets from May through December 2020 as well as January through December 2021. 2. The laboratory testing person confirmed on February 3, 2023, at approximately 11:30 A.M., that the laboratory failed to retain QC records from May through December 2020 as well as January through December 2021. a. The laboratory director stated, in a letter, "that on 1/1/2022 the CBC testing was sent out to a reference laboratory and that temporarily they have ceased CBC testing.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(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 the review API PT records and an interview with TP1, the laboratory failed to retain API PT Summary reports for hematology first and third events of 2021 and the first event of 2022. Refer to D6021. FINDINGS: The laboratory failed to retain the following PT records: signed attestation forms by laboratory director and testing person, Abx PT printouts, and API test result forms for all three events in 2020, third event of 2021, and all three events in 2022.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)

	Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, Quality Assessment (QA) & QC procedures, lack of QA for hematology testing for the calendar years 2020, 2021, and 2022, and an interview with TP1, the laboratory failed to retain the following documents and records for the calendar years 2020, 2021, and 2022: FINDINGS: 1. The laboratory failed to retain QA records which include a review of the following records and documentation: Patient Test Management Relationship of Patient Information to Patient Test Results Procedure Manual Quality Control (QC) and Calibration Personnel Assessment Proficiency Testing (PT) Enrollment and Assessment and Comparison of Test Results Communication and Complaints Quality Assessment Review and Records 2. TP1 stated on February 3, 2023, at approximately 10:30 A.M. the laboratory did not retain the QA documents and records for the calendar years 2020, 2021, and 2022, confirming the surveyor ' s findings.
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 review of laboratory personnel records, the laboratory's competency evaluation policy, and an interview with TP1, the laboratory failed to follow the established, written competency policy including six required components to assess annual competency of testing personnel. Refer to D6029 and D6054. FINDINGS: 1. The laboratory failed to perform and document the 2020, 2021, and 2022 annual competency evaluations for the two testing personnel which perform hematology testing. a. No documents were available for review for the calendar years 2020, 2021, and 2022. 2. TP1 confirmed on February 3, 2023, at approximately 11:00 A.M., the laboratory director did not perform and document the annual competencies for the two testing personnel.
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 review of the third event of 2020, 2021, and all events of 2022 API PT summary reports, and an interview with TP1, the laboratory director failed to review and evaluate the API hematology PT results for the third event of 2020, 2021, and all three events in 2022. FINDINGS: 1. The API PT summary records did not include evidence of review and evaluation of the hematology PT results for the third event of

	2020, 2021, and all three events in 2022. 2. The laboratory had scored 100% for the third event in 2020 and 2021, and all three events in 2022, but did not sign the summary report as reviewed and evaluated.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: This CONDITION is not met as evidenced by: Based on review of Horiba Micros 60 operations manual & laboratory procedure manual, lack of QC, calibration & maintenance records, and an interview with TP1, The laboratory failed to ensure that: 1. The required temperatures for the laboratory room and humidity for the lab area were recorded. Refer to D5413. 2. Expired QC material was not used to performed QC testing on the hematology analyzer. Refer to D5417. 3. The laboratory did not perform the required preventative maintenance for Micros 60 analyzer. Refer to D5429. 4. The required calibration for the Horiba hematology analyzer was not performed every six months. Refer to D5437.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of the Abx Micros 60 operations manual for ambient temperature requirements, lack of laboratory room temperature and humidity log sheets for 2020, 2021, and 2022 through survey date, and an interview with TP1, the laboratory failed to monitor the room temperature and humidity for the laboratory area for the calendar years 2020, 2021, 2022 as well as through the survey date. FINDINGS: 1. The manufacturer of the Micros 60 requires an ambient temperature of 18-32O C or 65-90O F and a humidity of 10-80%. 2. No room temperature and humidity log sheets were available for review at the time of the survey. 3. TP1 confirmed on February 3, 2023, at approximately 11:30 A.M., that the room temperature and humidity were not documented for the calendar years 2020, 2021, and 2022 through survey date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	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. This STANDARD is not met as evidenced by: Based on observation of the Abx Mintrol control material stored in the laboratory's refrigerator, and an interview with TP1, the laboratory retained outdated control material. 1. The following expired control material was observed: Lot# MX434 3 levels (L/N/H 1 tube each) expiration date 5/5/2022; and Lot# MX431 expiration date 11/5/2021. 2. The general supervisor confirmed on February 3, 2023, at approximately 11:45 A.M., the surveyor's findings of the expired control material. The supervisor also confirmed that the control material was not used for patient testing. a. The laboratory director recorded a written statement that patient testing was discontinued on the ABX Micros 60 on 12/30/2021 and is currently sent out to reference laboratories.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based upon review of service reports and preventative maintenance(PM) reports for the Micros 60 analyzer, and an interview with the service technician for Horiba, the laboratory failed to retain the maintenance and PM service records for 2020, 2021, 2022 through survey date. FINDINGS: 1. The Horiba manufacturer's maintenance policy requires an annual PM to be performed by the Horiba technician. 2. No PM and service reports for the Micros analyzer were available for review at the time of the survey. 3. Surveyor interviewed the Horiba technician via phone on February 3, 2023, at approximately 10:15 A.M., and he stated, "that the practice needed to replace the Miniclean, SAS reagent, and Minidilute with current lot, order control, and calibration material before he performs PM on the analyzer."
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) 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. This STANDARD is not met as evidenced by:

	Based on review of Abx Micros 60 hematology analyzer records, and an interview with TP1, the laboratory failed to perform the required six month calibration for the Micros 60 due on April 23, 2020. FINDINGS: 1. The laboratory's calibration policy and the manufacturer policy for the Beckman Coulter AcT Diff hematology analyzer requires the analyzer to be calibrated every six months and/or as needed as preventative maintenance. a. The most recent calibration record available for review was dated October 15, 2021. therefore the laboratory is out of calibration from April 15, 2022, through survey date. 2. TP1 confirmed on February 3, 2023, at approximately 11:00 A.M. that the laboratory did not perform calibration as required despite the laboratory performing API PT testing in 2021 and 2022.
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 review of the laboratory procedure manual, QC & calibration records, lack of QA documentation, and confirmed in an interview with TP1, the director failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The laboratory director failed to ensure that the laboratory: 1. Reviewed the scored proficiency testing reports. Refer to D6018. 2. Maintained the QC program for hematology. Refer to D6020. 3. Maintained their written QA policy for all phases of laboratory testing. Refer to D6021. 4. Taken all necessary remedial and corrective actions when incidents are identified. Refer to D6024.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of API PT summary reports for all three events in calendar years 2020, 2021, and 2022, and an interview with TP1, the laboratory director failed to review the scored proficiency testing reports received from API to evaluate the laboratory's performance for the third event of 2020, 2021, and all three events in 2022. Refer to D2007, D2009, D3037 and D5211.
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 review of hematology QC and calibration records, and an interview TP1, the laboratory director failed to ensure that the QC program for hematology testing was maintained to assure the quality of laboratory services. Refer to D3031 and D5437.
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 review of the laboratory's QA policy, QA documentation, and an interview with TP1, the laboratory director failed to follow the established QA procedure for maintaining a mechanism to monitor, assess, and when detected, correct problems identified in the general laboratory system. Refer to D3039, D5413, D5417, D5429, and D5437.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on the review of laboratory QC, calibration records, and confirmed in an interview with TP1, the laboratory director failed to ensure that remedial action was taken and documented when problems were identified. Refer to D3039, D5413, D5417, D5429 and D5437.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's competency assessment policy, lack of competency evaluations for the two testing personnel, and confirmed in an interview with theTP1, the laboratory director, acting as the technical consultant, failed to assess the two laboratory testing personnel in calendar years 2021 and 2022. Refer to D5209.