Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0984337	02/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hematology Oncology Assoc Of Brooklyn	1660 E 14th Street Ste 501, Brooklyn, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) Proficiency Testing (PT) summary reports, lack of CAP test result forms for test events in 2020 and 2021 and an interview with the general supervisor the laboratory failed to establish a written procedure that defines which Micros 60 analyzers is tested and reported for that specific CAP event.
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: Based on review of laboratory standard operating procedure (SOP) & QC, Calibration, Maintenance, records, direct observation of reagents in laboratory refrigerator and an interview with the general supervisor, the laboratory failed to: 1. Ensure that a SOP contain written procedures for the QC ranges when the reference limits are altered, Refer to D5401; 2 .Ensure that the laboratory's established a written procedure to back-up the Harvest LIS system, Refer to D5403; 3. Ensure that the reagent are not expired prior to use for testing, Refer to D5417; 4. Ensure that the laboratory performed the as needed and preventative maintenance for the microscope, Refer to D5431; 5. Ensure that the laboratory auxiliary maintenance is performed annually, Refer to D5435; 6. Ensure that the required calibration for the Horiba hematology analyzers are performed, Refer to D5437.
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: Based on a review of the laboratory's policy and procedure manual, QC records for the ABX Monitrol control assay sheets, and an interview with the general supervisor, the laboratory failed to establish written procedure for the criteria used to establish QC ranges, limits, and standard deviation of hematology Monitrol controls. FINDINGS: 1. The laboratory failed to establish a written procedure for criteria used to establish QC ranges, limits, and standard deviation for the Monitrol hematology controls. 2. The QC limits in the Harvest Orchard LIS program did not match manufacturers' control assay insert. a. The QC limits in the Harvest program for hematology Monitrol controls were much tighter by 2 SD. 3. The general supervisor confirmed on 2/1/22 at approximately 2:30 PM that the laboratory did not establish the above procedure.
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 the review of the laboratory's procedure manual, review of the LIS Harvest Orchard program for QC reports, startups, and calibration for the Pentra 60 and two Micros 60 hematology analyzers, the laboratory failed to establish a written procedure to back-up the LIS if needed when it is inoperable.
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 reagents stored in the laboratory's refrigerator and interview with the general supervisor, the laboratory failed to review reagent, control & calibration materials for expired dates. Findings: 1. The laboratory refrigerator located in phlebotomy room was observed to contained 10 expired reagent vials. K-Assay Ig-G Tris Buffer 1 vial Lot G064 Exp 12/31/2021 K-Assay Ig-A Tris Buffer 1 vial Lot K974 Exp 03/31/2021 K-Assay Ig-M Tris Buffer 1 vials Lot D095 Exp 9/20 /21, Lot G076 Exp 12/31/2021 Lymphcheck Immunoassay Plus Control Level 2 1 vial of Lot 40352 Exp 05/31/2020 Magnesium RTU 2 vials Lot 23068 Exp 01/31/2019 and Lot 26771 Exp 05/31/2021 DC-UIBC-CAL 1 vial Lot 53389 Exp 09/20/2021 K-Assay Ig-G 20% anti-human IgG 3 vials Lot G065 Exp 12/31/2021 2. The general supervisor confirmed on 2/1/22 at approximately 11:45am, the surveyor's findings of the expired reagents and confirmed that they were not used for patient testing. 3. Observed at 12:45 PM expired ABX Minoclair Lot# 200511 L expired 5/11/2 reagent for the 4th floor Micros 60.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory' s maintenance SOP, lack of microscope maintenance logs for 2019, 2020 and 2021, and an interview with the general supervisor, the laboratory failed to follow and maintain the microscope maintenance procedure in 2019, 2020 and 2021. FINDINGS: 1. The laboratory failed to follow and maintain the microscope maintenance procedure in 2019, 2020 and 2021. 2. The surveyor requested the microscope records for preventative & routine maintenance for the microscope used to evaluate the manual differentials slides for cell identification. No records were available. 3. The microscope used to review the manual differential slides was in a physician's office and not available to the surveyor.

D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the Bio reference centrifuge located in the phlebotomy room used to spin sample tubes and the labeled titled, "Centrifuge Performance Test" on the centrifuge and an interview with the general supervisor, the laboratory failed to maintain the annual maintenance for the Bio reference centrifuge. FINDINGS: 1. The labeled on the Bio- reference centrifuge had the following information recorded the max speed 3381 RPM, timer 10:00, technician's initial EB and was dated 6/24/ 15. 2. The general supervisor confirmed on 2/1/22 at approximately 11:30am that the laboratory failed to establish a procedure for the function checks for the centrifuge. a. The QC limits in the Harvest program for hematology Monitrol controls were much tighter by 2 SD. 3. The general supervisor confirmed on 2/1/22 at approximately 2:30 PM that the laboratory did not establish the above procedure.
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 the laboratory's calibration records for the ABX Horiba Micros 60 analyzers and the Pentra 60 and interview with the general supervisor, the laboratory failed to follow and maintain the Horiba manufacturer's required calibration procedure every six months in 2019, 2020 and 2021. FINDINGS: 1. The calibration for the two Horiba Micros 60 & Pentra was not performed as required by the Horiba Manufacturers every six months. 2. The calibration was performed only once in year as follows: a. 2019 on 7/1/2019 for Horiba ABX Pentra 60 c+ and 2 Micros 60. b. 2020, on 11/2/2020 for the Pentra 60 but performed every 6 months for both Micros 60. c. 2021, on 6/29/2021 for Horiba ABX Pentra 60 c+ and both Micros 60. 3. The general supervisor confirmed on February 1, 2022 at approximately 12:30 PM, that he only performs calibration once year for the three hematology analyzers.

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 reviewlaboratory's SOP, observation of axillary equipment & reagent expiration dates, review of equipment maintenance SOP and confirmed in an interview with the general supervisor, the laboratory director failed to ensure that remedial action was taken and documented when problems were identified. Refer to D5417, D5431 and D5435