Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0984337	10/27/2021
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
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 surveyor's review of 2020, 2021 College of American Pathologists (CAP) Proficiency testing (PT) attestation statements and an interview with the general supervisor/testing person, the laboratory failed to rotate the testing of PT samples among five personnel, who routinely perform hematology automated Complete Blood Count (CBC) tests. The same person performed all three events of 2020 and two 2021 events as indicated by the signed attestation statements. FINDINGS. The general supervisor/testing person confirmed on October 27, 2021 at approximately 10:00 AM, the surveyor's findings that the same testing person performed the PT hematology samples for all three events of 2020 and two 2021 events. 2. The laboratory did not rotate the testing of the PT samples for the five of six testing personnel, who routinely perform hematology CBC testing.
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's review of the third event of 2020 and second event of 2021 CAP PT summary reports, the laboratory failed to participate successfully in proficiency testing for the specialty Hematology and the test analyte's White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet and Cell Identification (Cell I.D.)/White Blood Cell Differential (WBC Diff.). The following scores were assigned: 2020 third event = 0% (non-participation) 2021 first event = 100% 2021 second event = 0% (non-participation) This is considered unsuccessful PT performance. Refer to D2130 and D2131.
D2130	HEMATOLOGY CFR(s): 493.851(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 surveyor's review of the CAP PT records for 2020 and 2021 events, the laboratory failed to participate successfully in proficiency testing for the test analyte's WBC, RBC, Hgb, Hct, Platelet and Cell I.D./WBC Diff. The following scores were assigned: 2020 third event = 0% (non-participation) 2021 first event = 100% 2021 second event = 0% (non-participation) This is considered unsuccessful PT performance.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor's review of the CAP PT records for 2020 and 2021 events, the laboratory failed to participate successfully in proficiency testing for the specialty Hematology. The following scores were assigned: 2020 third event = 0% (non-participation) 2021 first event = 100% 2021 second event = 0% (non-participation) This is considered unsuccessful PT performance
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 surveyor's review of Mintrol-16 Peer Review Quality Control (QC) records, current October hematology control QC records for the ABX Horiba Micros 60 instrument and an interview with the general supervisor/testing person, the laboratory failed to retain the monthly QC printouts, Levy Jennings graphs and the daily start-up printouts for the Micros 60 instrument from April 1, 2019 through September 30, 2021. FINDINGS: The general supervisor/testing person confirmed on October 27, 2021 at approximately 10:45 AM, the surveyor's findings that the laboratory failed to retain the monthly QC printouts, Levy Jennings graphs and the daily start-up printouts for the ABX Horiba Micros 60 instrument from April 1, 2019 through September 30, 2021. a. The general supervisor/testing person stated, "that he prints the 3 levels of Mintrol-16 QC monthly QC report and Levy Jennings graphs and submits them to ABX Diagnostic Peer Review Evaluation program. He then scans the Peer Review Result sheets into the Laboratory's Information System (LIS) LABDAQ and then discards the original hematology QC printouts." b. The general supervisor/testing person stated, "that he does not retain copies of the start-ups for the ABX Horiba Micros 60 instrument." c. Approximately 2,000 patient samples were tested and reported for automated CBC performed on the ABX Horiba Micros 60 from April 1, 2019 through September 30, 2021.
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's review of competency assessment records for the five of six testing personnel, the laboratory's competency assessment policy and an interview with the general supervisor/testing person, the laboratory failed to follow their written policies for competency assessment for five of six testing personnel for the calendar year 2019 and 2020. FINDINGS: The general supervisor/testing person confirmed on October 27, 2021 at approximately 11:30 AM, the surveyor's findings that the laboratory failed to follow their written competency assessment polices for the following: a .five of six personnel who routinely perform only hematology testing failed to be evaluated for 2019 and 2020 annual competency. b. the general supervisor /testing person performs the chemistry and endocrinology testing
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Assessment (QA) policy, QA review records for the calendar year 2019, 2020, 2021 and an interview with the general supervisor/testing person, the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. FINDINGS: 1. The general supervisor/testing person confirmed on September 29, 2021 at approximately 9:15 AM, that the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. 2. The laboratory's QA policy requires an annual review of all phases of laboratory's testing and take corrective action when problems are identified. The laboratory failed: a. to identify, take corrective action and address, that the same testing person tested the hematology PT samples for all three events in 2020 and two events in 2021. b.to perform the annual competency for five out six testing personnel in 2019 and 2020 c to identify the failure to participate in the CAP PT program for the specialty hematology and the six test analytes in 3rd event 2020 and 2nd event of 2021. Refer to D2007, D2016, D2130, D2131 and D5209
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's findings and confirmed in an interview with the general supervisor/testing person at this survey, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the: 1. laboratory participated successfully in PT program for specialty hematology and the six test analytes, refer to D6016. 2. laboratory's QC program was maintained, refer to D6020; 3. laboratory's QA program was maintained, refer to D6021; 4. laboratory maintained the competency assessment policy, refer to D6054.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor's review of the CAP PT records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the specialty Hematology and the test analyte's WBC, RBC, Hgb, Hct,

	Platelet and Cell I.D./WBC Diff. Refer to D2007, D2016, D2130, D2131 The following scores were assigned: 2020 third event = 0% (non-participation) 2021 first event = 100% 2021 second event = 0% (non-participation) This is considered unsuccessful PT performance.
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 a surveyor's review of hematology QC records and confirmed in an interview with the general supervisor/testing person, at the time of this survey, the laboratory director failed to ensure that the QC program for hematology was maintained to assure the quality of laboratory services. Refer to D3031
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 a surveyor's review of the laboratory QA policy, review of the QA documentation and confirmed in an interview with the general supervisor/testing person at the time of this survey, the laboratory director failed to ensure that the laboratory's QA program was maintained for all phases of laboratory testing. Refer to: D2007, D2016, D2130, D2130, D3031 and D5291
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 surveyor's review of the personnel files and confirmed in an interview with the general supervisor/testing person, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for five of six testing personnel in calendar year 2019 and 2020. Refer to D5209