Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1067693	11/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bhmg Ocean Hematology And Oncology	67 Rt 37 W, Toms River, 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
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to participate in a PT event for Hematology tests from 12/18/17 to 10/28/21. The TP as listed on CMS form 209 confirmed on 11/10/21 at 12:00 pm the laboratory did not participate in the aforementioned PT.
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 surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP) the laboratory failed to have all applicable procedures for from 12/18/17 to the date of the survey. The findings include: 1. The laboratory did not have a procedure for: a. The reportable range for Hematology tests as established or verified b. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability c Policy to interpret flagged results d. The course of action to take if the test becomes inoperable. 2. The TP as listed on CMS form 209 confirmed on 11/10/21 at 1:30 pm that the PM did not have all applicable procedures.
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 surveyor review of Calibration Verification (CV) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Beckman Coulter Act Diff 2 analyzer in the calendar year 2020. The findings include: 1. There was no documented evidence CV was performed in 2020. 2. The TP #1 as listed on CMS form 209 confirmed on 11/10/21 at 12:30 pm that the laboratory failed to perform and document CV.
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 Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory. The findings include: 1. The LD failed to ensure that the laboratory was enrolled in a Proficiency Testing (PT) Program. Cross refer to D 2123 and D 6015 2. The LD failed to ensure the Quality Control programs were maintained. Cross refer to D6020. 3. The LD failed to ensure Quality Assurance programs were established. Cross refer to D6021
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the laboratory was enrolled in an approved PT program from 12/18/17 to 10/28/21. The TP # 1 as listed on CMS form 209 confirmed on 11/10/21 at 1:00 pm the laboratory was not enrolled in PT.
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 surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the QC program is maintained for laboratory services provided from 12/18/17 to the date of the survey. The findings include: 1. There was no documented evidence that Complete Blood Count (CBC) QC was reviewed. 2. There was no documented evidence that QC verification was reviewed. 3. The TP # 1 listed on CMS form 209 confirmed on 11/10 /21 at 12:45 pm the LD did not ensure the QC program was maintained.
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 lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 12/18/17 to the date of the survey. The TP # 1 as listed on CMS form 209 confirmed on 11/10 /21 at 1:15 pm that a QA plan had not been established.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Beckman Coulter AcT Diff 2 analyzer from 12/18/17 to the date of survey. The TP # 1 as listed on CMS form 209 confirmed on 11/10/21 at 1:30 pm that trends and shifts were not reviewed.