Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1052358	07/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bhmg Ocean Hematology And Oncology	1255 Route 70 Suite 31-S, Lakewood, 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
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 surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to review and evaluate PT results obtained from Medical Laboratory Evaluation (MLE) for Hematology with Auto Differential events performed in 2019. The finding includes: 1. There was no evidence of evaluation documentated. The "CMS Performance Summary" was not signed and dated for MLE-M3 in 2019 2. The TP # 2 as listed on CMS form 209 confirmed on 7 /15/21 at 9:45 am that the laboratory did not review and evaluate all PT results.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. 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 review and evaluate results when they received an unacceptable score in Hematology tests performed with the Medical Laboratory Evaluation (MLE) Proficiency Testing for the first event in the calendar year 2019. The findings include: 1. The laboratory received an unacceptable score for Platelet Count sample HD-1 (* Result Unacceptable) 2. The laboratory received an unacceptable score for Hematocrit sample HD-1 (* Result Unacceptable) 3 There was no documented evidence that the laboratory investigated the failures. 4. The TP # 2 as

	listed on CMS form 209 confirmed on 7/15/21 at 9:30 am that the laboratory did not review and document an evaluation of unacceptable PT results. Note: This is a repeat deficiency from survey performed on 4/10/18
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. (c) The laboratory must document all analytic systems assessment activities. 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 follow the procedure to verify new Quality Control (QC) material before use from January 2020 to the date of the survey. The TP # 2 listed on CMS form 209 confirmed on 7/15/21 at 10:00 am the laboratory did not follow the procedure to verify new QC lots.
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 surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD), failed to ensure that all PT results received were reviewed by the appropriate staff to identify any problems that require corrective action for Hematology performed with Medical Laboratory Evaluation (MLE) for the first event in the calendar year 2019. The TP # 2 as listed on CMS form 209 confirmed on 7/15/21 at 9:45 am that the PT results were not reviewed.
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 established QC program was maintained for laboratory services provided from January 2020 to the date of the survey. The finding includes: 1. The assayed values of QC material were not verified before putting in use. 2. The TP # 2 listed on the CMS form 209 confirmed 7/15/21 at 10:00 am the LD did not ensure the QC plan was maintained .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(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 Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director failed to have education documented for four out of four TP from 4/10/18 to the date of the survey. The TP # 2 as listed on CMS form 209 confirmed on 7/15/21 at 9:30 am that all education records were not available.
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 Cell Dyn Emerald analyzer from January 2020 to the date of the survey. The TP #2 listed on CMS form 209 confirmed on 7/15/21 at 10:00 am that trends and shifts were not reviewed.