Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1052358	04/10/2018
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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. 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 attain at least 80% or more for Hematology test performed on the Abbott Cell Dyn Emerald analyzer with the American Association of Bioanalysts. The finding includes: 1. The laboratory received an unacceptable grade in the MLE-M2 2016 event for sample HD-6 through 10 for Red Blood Cell Count and received an CMS analyte score of 0%. 2. The laboratory received an unacceptable grade in the MLE-M2 2016 event for sample HD-6-7 and HD-9-10 for Hematocrit and received a CMS analyte score of 20%. 3. The TP #1 confirmed on 4/10/18 at 10:55 am that the laboratory failed to achieve at least 80% for Hematology testing.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

	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 undertake appropriate training and employ technical assistance necessary to correct problems associated with PT failures performed with the American Association of Bioanalysts (AAB). The findings include: 1. There was no remedial action taken and documented for unacceptable grade in the MLE-M2 2016 event for sample HD-6 through 10 for Red Blood Cell Count and received an CMS analyte score of 0%. (Refer to D 2121). 2. There was no remedial action taken and documented for unacceptable grade in the MLE-M2 2016 event for sample HD-6-7 and HD-9-10 for Hematocrit and received a CMS analyte score of 20%. (Refer to D 2121). 3. The TP #1 confirmed on 4/10/18 at 10:55 am that corrective action was not documented for the unsatisfactory PT performance.
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 review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform a CA on one out of two TP for the calendar year 2017. The TP #1 listed on CMS form 209 confirmed on 4 /10/18 at 1:05 pm that the CA was not performed.
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 Proficiency Testing (PT) results and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when the laboratory received an unacceptable score for Hematology Testing performed with the Medical Laboratory Evaluation (MLE) in 2017 and 2016. The findings include: 1. The laboratory received an unacceptable grade in the MLE-M2 2016 event for sample HD-9 Platelet count. 2. The laboratory received an unacceptable grade in the MLE-M1 2017 event for sample HD-4 and MLE-M3 2017 event for sample HD-15 for Platelet count. 3. The laboratory received an unacceptable grade in the MLE-M3 2017 event for sample HD-15 Platelet count. 4. No evaluation was documented for any of the unacceptable analyte scores mentioned above. 5. The TP #1 confirmed on 4/10/18 at 10:55 am that the laboratory did not perform and document corrective action of unacceptable PT results.
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 a procedure for corrective action on Quality Control failures (QCF) from 2/24/2016 to the date of survey. The TP #1 confirmed on 4/10/18 at 10:55 am on 4/12/18 at 10:45 am that am was no corrective action procedure for QCF.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. 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 a procedure to verify manually entered results into electronic medical records for accuracy from 2/24/2016 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 4/10/18 at 12:15 pm that the laboratory did not have the procedure mentioned above.
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 lack of a Quality Assessment (QA) polices and interview with the Testing

	Personnel (TP), the Laboratory Director failed to ensure that a QA program was established from 2/24/16 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 4/10/18 at 12:00 pm that the laboratory did not have a QA program.