Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1067693	02/28/2024
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
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 Testing Personnel (TP), the laboratory failed to document the evaluation of all incorrect scores and corrective action taken for Hematology events performed with the Medical Laboratory Evaluation (MLE) for the 2nd and 3rd events of 2023. The findings include: 1. The following samples were graded as incorrect for the 3rd Hematology event of 2023. a) Sample 15 for Lymphocyte % b) Sample 12 for Eosinophil % 2. Sample 6 for Monocyte % was graded as incorrect for the 2nd Hematology event of 2023. 3. There was no documented evidence for evaluation or corrective action performed for the aforementioned PT events. 4. TP #1 as listed on the CMS-209 form confirmed on 2/28//24 at 12:20 pm, the laboratory failed to evaluate and perform corrective action for the failed analytes for Hematology PT events in calendar year 2023.
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 Hematology Tests performed on the Beckman Coulter DxH520 analyzer from 4/29/22 to 2/28/24. The findings include: 1. The laboratory failed to have the established reportable range for test results for the Beckman Coulter DxH520 analyzer as established or verified in 493.1253. 2. The laboratory failed to have reference intervals in the PM that matched patient test records performed on the Beckman Coulter DxH520. 3. TP #1 as listed on the CMS 209 form confirmed on 2/28/24 at 12: 00 pm that the PM did not have all applicable procedures for the Beckman Coulter DxH520 analyzer.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Performance Specification (PS) records for the Beckman Coulter DxH520 and interview with the Testing Personnel (TP), the laboratory failed to ensure that all PS records were adequate for all analytes performed on the Beckman Coulter DxH520 analyzer from 4/29/22 to 2/28 /24. The findings include: 1. The laboratory is not using the manufacturers reference ranges and failed to have a source for the reference ranges currently in use. 2. The laboratory failed to verify the Reportable range of test results for the test system. 3. TP #1 as listed on the CMS-209 form confirmed on 2/28/24 at 11:30 am that the laboratory failed to ensure that all PS records were adequate.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on the lack of Maintenance Records (MR) for the Beckman Coulter DxH520 analyzer, surveyor review of Beckman Coulter DxH520 User Manual and interview with the Testing Personnel (TP), the laboratory failed to perform and document preventative maintenance as specified by the manufacturer for the Beckman Coulter DxH 520 analyzer used for Hematology tests from 1/30/23 to 2/28/24. The findings include: 1. There were no maintenance records for the DxH520 analyzer available for review for the aforementioned timeframe. 2. TP #1 listed on CMS form 209 confirmed on 2/28/24 at 12:15 pm that preventative maintenance as specified by the manufacturer was not performed and documented.