Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2293072	(X3) Date Survey Completed 06/04/2025
Name of Provider or Supplier Bhmg Ocean Hematology And Oncology-2340	**Street Address, City, State** 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
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. 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 to verify the accuracy of tests not provided by a CMS approved PT program from 1/1/24 to 6/4/25. The findings include: 1. The laboratory participated in AAB Medical Laboratory Evaluation for PT. The following analytes were not offered by the PT program for the 1st event of 2025 and the 1st, 2nd and 3rd events of 2024; a) Mean Corpuscular Volume (MCV) b) Mean Corpuscular Hemoglobin (MCH) c) Mean Corpuscular Hemoglobin Concentration (MCHC) d) Red Cell Distribution Width - Standard Deviation (RDW-SD) e) Red Cell Distribution Width -Coefficient of Variations (RDW-CV) 2. The laboratory failed to verify the accuracy of the above listed analytes for the 1st event of 2025 and the 1st, 2nd and 3rd events of 2024. 3. The TP confirmed on 6/4/25 at 11:00 am, the laboratory did not verify the accuracy tests not provided by a CMS approved PT program.
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.

	This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control Verification (QCV) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow and establish written policies for Quality Control New Lot Verification from 11 /22/23 to 6/4/25. The finding includes: 1. The PM states " Before putting a new lot of control materials into use, verify that the new controls perform as expected by parallel testing with the current lot number. 2. The laboratory failed to verify lot numbers 352315411, 362315412, 372315413, 352415711, 362415712 and 372415713 before patient testing due to shipping issues. 3. The laboratory failed to establish an alternative policy for verifying new lots of controls if unable to perform parallel testing with current lot. 4. TP confirmed on 6/4/25 at 11:20 am, the laboratory did follow written policies and establish alternative procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Beckman Coulter DxH 520 analyzer were adequate from 10/1/23 to 6/4/25. The finding includes: 1. The Beckman Coulter DxH 520 analyzer was moved to the physical address of the laboratory in October 2023 and a linearity was performed to verify the analyzer. 2. There was no documented evidence the LD reviewed and approved the PS after the analyzer relocation. 3. The TP confirmed on 6/4/25 at 11:20 am, the LD failed to ensure the PS were adequate before being used for patient testing.