Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0926312	02/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Bhmg/West Park Pediatrics	219 Taylors Mills Road, Manalapan, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records, Procedure Manual (PM) and interview with the Laboratory Manager (LM), the laboratory failed to ensure that all Testing Personnel (TP) who perform Hematology and Bacteriology testing participated in the Wisconsin State Laboratory of Hygiene (WSLH) PT events in the calendar year of 2023. The findings include: 1. The PM states "Clinical staff /testing personnel will randomly rotate and perform WSLH proficiency testing for in office laboratory testing." 2. A review of PT attestation records showed that one out of ten TP performed all Hematology and Bacteriology WSLH PT events in 2023. 3. The LM confirmed on 2/20/24 at 11:45 am that the laboratory failed to rotate all TP to participate for Hematology and Bacteriology WSLH PT events in 2023.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on the lack of Performance Specifications (PS) for the Beckman Coulter AcT diff 2 and interview with the Laboratory Manager (LM) the laboratory failed to retain

	PS records for the Beckman Coulter AcT diff 2 analyzer used to perform Hematology Testing from 2/20/2022 to 2/20/24. The findings include: 1. The laboratory failed to retain test PS for the Beckman Coulter AcT diff 2 analyzer and was not available for review. 2. The LM stated the PS for the Beckman Coulter AcT diff 2 analyzer were performed in 2009. 3. The LM confirmed on 2/20/24 at 10:45 am the laboratory failed to retain the PS for the Beckman Coulter AcT diff 2 analyzer and was not available for review.
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 Laboratory Manager (LM), the laboratory failed to document the evaluation of all unacceptable scores and corrective action taken for the 3rd event of 2023 performed with the Wisconsin State Laboratory of Hygiene (WLSH). The findings include: 1. Sample AT-12 for Erythrocytes was graded as unacceptable for the 3rd Hematology event of 2023. 2. Sample AT-12 for Hematocrit was graded as unacceptable for the 3rd Hematology event of 2023. 3. There was no documented evidence for evaluation or corrective action performed for the aforementioned PT event. 4. The LM confirmed on 2/20/24 at 11:20 am, the laboratory failed to evaluate and perform corrective action for the unacceptable scores for the 3rd Hematology event of 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 Laboratory Manager (LM), the laboratory failed to have all applicable procedures for Hematology Tests from 2/20/22 to 2/20/24. The findings include: 1. The PM did not have panic or alert values for Hematology tests. 2. The PM did not have a description

	of the course of action to take if the test system becomes inoperable for Hematology tests. 3. The LM on confirmed on 2/20/24 at 11:00 am that the PM failed to have all applicable procedures for Hematology tests.
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 surveyor review of the Quality Assessment (QA) plan, the Procedure Manual (PM), Proficiency Testing (PT) records and interview with Laboratory Manager (LM), the Laboratory Director (LD) failed to ensure the QA program was maintained to assure the quality of laboratory services provided from 2/20/22 to 2/20 /24. The findings include: 1. The Annual QA checklists for years 2022 and 2023 states " Proficiency testing results were evaluated, failures were investigated and remedial action taken." The statement was marked as yes and signed off by the LD. 2. The 3rd Hematology PT event of 2023 had unacceptable scores for sample AT-12 which was not investigated and remedial action taken. Cross refer D 5221. 4. The LD failed to review and sign the PT investigation failure report for the 2nd Hematology event of 2022. 5. The LM confirmed on 2/20/24 at 12:00 pm that the LD failed to ensure the QA program was maintained.