

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1032286	<b>(X3) Date Survey Completed</b>  09/26/2023
<b>Name of Provider or Supplier</b>  Bhmg/West Park Pediatrics	<b>Street Address, City, State</b>  921 East County Line Road, Lakewood, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>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 verify the accuracy of Bacteriology test results obtained from the Wisconsin State Laboratory of Hygiene (WSLH) 3rd event of 2021. The findings include: 1. The PT program assigned an artificial score of 100%, results were reported with the comments "Unable to obtain result". 2. The TP#1 on CMS form 209 confirmed on 9/26/23 at 1:20 pm that the accuracy of the PT results were not verified and the PT program assigned an artificial score of 100%.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: A) Based on surveyor review of the Procedure Manual (PM), Work Records (WR)</p>

and interview with the Testing Personnel (TP), the laboratory failed to follow their procedure for "Complete Blood Count (CBC) results with flags" from 7/27/21 to the date of survey. The findings include: 1. The PM states "Should Flags occur on CBC, inform MD repeat test" 2. Three out of five WR for CBC had flags of "M", "3" and "\*". 3. There was no documented evidence that the aforementioned procedure was followed. 4. The TP confirmed on 9/26/23 at 2:30 pm that the laboratory failed to follow the aforementioned procedure. B) Based on surveyor review of the Procedure Manual (PM), Quality Control Verification (QVC) procedure and interview with the TP, the laboratory failed to follow their procedure for QVC from 7/27/21 to the date of survey. The findings include: 1. The PM stated "Before using new controls, run 3 daily samples in patient mode to assure values are within the limits for level of control. The mean of the 3 samples must be within control limits." 2. There as no documented evidence that control values obtained by the laboratory were verified against manufactures assayed control value ranges. 3. The TP confirmed on 9/26/23 at 2:30 pm that the laboratory failed to follow the aforementioned procedure.

**D5411**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
 CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:  
 Based on surveyor review of the Operators Manual (OM), and interview with the Testing Personnel (TP), the laboratory failed to follow the OM for "Calibration" from 7/27/21 to the date of survey. The findings include: 1. The OM stated to "5.2 BEFORE CALIBRATING Before calibrating, you must first prepare the instrument: 1. Do Heading 5.3, PRECALIBRATION CHECKS. 2. Do Heading 5.4, REPRODUCIBILITY. 3. Do Heading 5.5, CARRYOVER." 2. There was no documented evidence that the "Reproducibility" or "Carryover" was completed on the dates that calibration was performed. 3. The TP#1 listed on CMS from 209 confirmed on 9/26/23 at 2:32 pm that the laboratory did not follow the OM.

**D5469**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	<p>This STANDARD is not met as evidenced by:  Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Hematology tests performed on the Beckman Coulter Act diff II analyzer from 7/27/21 to the date of survey. The finding includes: 1. There was no documented evidence that all levels of QC was verified before being put into use. 2. The TP#1 listed on CMS from 209 confirmed on 9/26/23 at 1:20 pm that the QC material was not verified before putting in use.</p>
<p><b>D5479</b></p>	<p><b>CONTROL PROCEDURES</b>  CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:  Based on surveyors observation of controls in use and interview with the Testin Personnel (TP), the laboratory failed to follow Manufacturers Specifications (MS) for controls at the time of the survey. The finding includes: 1. Controls in use did not have an open or expiration dates documented as per MS. 2. The TP confirmed on 9/26 /23 at 2:20 pm that MS were not followed.</p>
<p><b>D6074</b></p>	<p><b>TESTING PERSONNEL RESPONSIBILITIES</b>  CFR(s): 493.1425(b)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:  Based on the surveyor review of Quality Control (QC) records and interview with the testing Personnel (TP), the Laboratory Director (LD) failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Beckman Coulter Act 2 Diff analyzer from 7/27/21 to the date of survey. The TP confirmed on 9/26/23 at 2:35 pm that trends and shifts were not reviewed.</p>