

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D1032286	<b>(X3) Date Survey Completed</b> 06/25/2025
<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 University (WSLH) in WSLH PT 2025-Bacti_Viral 1 event. The findings include: 1. The PT program assigned an artificial score of 100%, sample ST-4 in event 1, 2025 was reported with the comments "Non-consensus - Self-assessment Needed". 2. There was no documented evidence the laboratory evaluated sample ST-4. 3. The TP confirmed on 6/25/25 at 10:20 am that the accuracy of the PT results were not verified and the PT program assigned an artificial score of 100%,</p>
<b>D5781</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the</p>

reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Temperature Logs (TL) and interview with the Testing Personnel (TP), the laboratory did not document corrective action taken when the Incubator Temperature (IT) was out of range in October 2023 and April 2024. The findings include: 1. The Incubator temperature range is 35-37C 1. A review of the TL revealed that IT was outside the established range: a. 10/3/23 at 32C b. 10/11/23 at 34C c. 10/15/23 at 34C d. 4/12/24 at 30C 2. There was no documented evidence of corrective action taken. 3. The TP confirmed on 6/25/25 at 11:00 am the laboratory did not document corrective action.