

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1021626	<b>(X3) Date Survey Completed</b>  11/14/2019
<b>Name of Provider or Supplier</b>  Valley Physician Services, Inc	<b>Street Address, City, State</b>  400 Old Hook Road Suite 2-1, Westwood, 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>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>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 failed to ensure that all PS procedures were performed on the Horiba Micros 60 analyzer were adequate from 4 /15/19 to the date of survey. The finding includes: 1. There was no documented evidence Method Verification was performed. 2. The TP #1 listed on the CMS form 209 confirmed on 11/14/19 at 11:15 am that PS records were not adequate.</p>