

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D1032849	<b>(X3) Date Survey Completed</b>  09/27/2018
<b>Name of Provider or Supplier</b>  Amg Brown County (Bay Settlement)	<b>Street Address, City, State</b>  4070 Equestrian Rd, New Franken, WI	
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>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE 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 performance verification records for the pocH-100i hematology analyzer and interview with the technical consultant, the laboratory did not verify the reference intervals for this test system prior to performing patient testing. Findings include: 1. Review of performance verification records for the pocH-100i show no evidence that the reference ranges were evaluated prior to testing patient samples. 2. Interview with the technical consultant on September 27, 2018 at 10:15 AM confirmed that the reference ranges were not evaluated prior to testing patient samples.</p>