

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D1056222	<b>(X3) Date Survey Completed</b>  12/09/2020
<b>Name of Provider or Supplier</b>  Ahc Waterford	<b>Street Address, City, State</b>  818 Forrest Ln, Waterford, 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 hematology records and interview with the technical consultant, the laboratory did not evaluate performance specifications for a replacement hematology analyzer prior to performing patient testing. Findings include: 1. Review of hematology maintenance logs showed the laboratory replaced their Poch-100i hematology analyzer with a Poch-100i hematology analyzer with serial number B0995 in June 2019. 2. Review of the hematology records showed no evidence the Poch-100i hematology analyzer with serial number B0995 had verification of performance specifications performed. 3. Interview with the technical consultant on December 9, 2020 at 10:10 AM confirmed the laboratory did not verify performance specifications for the Poch-100i hematology analyzer on serial number B0995.</p>