

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D1021693	<b>(X3) Date Survey Completed</b>  04/22/2019
<b>Name of Provider or Supplier</b>  Dr David Barnes Internal Medicine	<b>Street Address, City, State</b>  3719 E Meridian Loop, Suite A, Wasilla, AK	
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 review of verification data and interview with the technical consultant, the laboratory did not verify performance specifications for the Bayer DCA Microalbumin /Creatinine cartridge prior to reporting patient test results. Findings: 1. A review of the verification documentation showed the Bayer DCA 2000 was put into use testing patient specimens on 11/2/2018. 2. The verification did not include precision and reportable range for Microalbumin, and did not include accuracy, precision, and reportable range for Creatinine. 3. The laboratory does approximately 2 microalbumin /creatinine tests per month. 4. The technical consultant confirmed these findings at 11: 15 am on 4/22/19.</p>