

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D0986978	<b>(X3) Date Survey Completed</b>  09/25/2019
<b>Name of Provider or Supplier</b>  Pathology Biomedical Consulting, Inc	<b>Street Address, City, State</b>  7436 N La Cholla Blvd, Tucson, AZ	
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>D5423</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation for test system performance specifications and interview with the facility personnel, the laboratory failed to establish the performance specifications for the Ventana DP200 Slide Scanner which is used in conjunction with patient testing. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 1,700. The laboratory began using the Ventana DP Slide Scanner in July 2019 to electronically send slide images to the pathologist for reading and issuing a preliminary diagnosis. 2. No documentation was provided for review during the survey to indicate the laboratory established the test performance specifications for the Ventana DP200 Slide Scanner prior to testing patients. 3. The laboratory personnel presented documentation of an installation check sheet completed by the vendor at the time of installation, however the laboratory personnel confirmed that the laboratory failed to establish the test performance specifications as required.</p>