

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  51D2047184	<b>(X3) Date Survey Completed</b>  01/22/2018
<b>Name of Provider or Supplier</b>  Eastern Pathology	<b>Street Address, City, State</b>  94 Brookshire Lane, Beckley, WV	
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>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE 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 review of the laboratory's validation/verification records for Immuno-Histochemical (IHC) stains and interview with the Laboratory Manager (LM), the laboratory failed to verify the accuracy of new lot numbers of 5 of 5 IHC stains prior to analyzing patient specimens. Record review was from February 2016 to January 2018. The findings include: 1. Review of the IHC validation/verification records identified a lack of documentation of the verification of accuracy for new lot numbers of 5 of 5 IHC stains (Ep-CAM/Epi, Melan A, p53, CD34, and Factor XIIIa). 2. On 1 /22/18 at approximately 2:30 PM, the LM confirmed the findings.</p>