

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0912447	<b>(X3) Date Survey Completed</b>  06/11/2026
<b>Name of Provider or Supplier</b>  Augusta University	<b>Street Address, City, State</b>  989 St Sebastian Way Ef-201, Augusta, GA	
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>D0000</b>	A Validation Survey was performed on June 11, 2026. One standard level deficiency was cited.
<b>D5423</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(2)</p> <p>(b)(2) 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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of establishment test performance specifications records, review of the laboratory's specimen handling policy and interview with laboratory staff, the laboratory failed to perform specimen stability studies for three out of three laboratory developed tests (LDT) reviewed. Findings included: 1. Review of records for the establishment of test performance specifications for Variant Hemoglobin Identification by HPLC approved March 1, 2014, Sanger Sequencing by SeqStudio approved September 25, 2026 and NGS Hemostasis Gene Panel approved April 16, 2026, found no record of studies to determine the optimum conditions for specimen storage, preservation, or specimen transportation to ensure the integrity of the sample. 2. Review of "Specimen Collection, Handling and Reporting Policy" (GEN1004) provided to clients stated the following: "Specimen Collection and Handling: 3. ...The specimen should be shipped with frozen gel packs to keep the specimen refrigerated</p>

whenever possible, although specimen received at room temperature will not be rejected." The laboratory did not have a defined range for refrigerated or room temperature. 3. During interview on June 11, 2026, at 3 PM, the Technical Supervisor confirmed the laboratory failed to perform specimen stability studies when establishing test performance specifications for the three above named LDTs. The laboratory performs 3000 tests annually. Word Key: HPLC - High Performance Liquid Chromatography NGS - Next Generation Sequencing