

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0237053	<b>(X3) Date Survey Completed</b>  06/06/2025
<b>Name of Provider or Supplier</b>  Atrium Health Children's Care One Health	<b>Street Address, City, State</b>  132 S Main Street, King, NC	
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>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 analyzer operating instructions, review of analyzer installation records, and interview with the Technical Consultant (TC) 6/6/06, the laboratory failed to validate performance specifications for the Reichert Bilirubinometer prior to testing patients. Findings: Review of the Reichert Bilirubinometer operating instructions revealed Section 5.2 Preparation for Use states, "Before analyzing patient samples, calibration verification (see Section 6.4) and quality control procedures (see Section 7.0) must be completed. Review of the Reichert Bilirubinometer installation records revealed the following: 1. Patient testing began on 11/14/22. 2. Calibration verification and quality control procedures were performed on 11/14/22 per the Reichert Bilirubinometer operating instructions 3. There was no documentation or raw data indicating verification of accuracy, precision, reportable range, or normal ranges for the patient population before 9/25/23. During an interview at approximately 10:45 a.m., the TC confirmed the necessary validation was not performed prior to testing patients. She explained the performance specifications were validated and reviewed on 9/25/23 after the laboratory was acquired by a new owner. During an interview at approximately 11:30 a.m., the TC confirmed that 22 patients were tested between 11/14/22 and 9/25/23.</p>