

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D1107141	<b>(X3) Date Survey Completed</b>  03/10/2026
<b>Name of Provider or Supplier</b>  Bagwell Medical Clinic	<b>Street Address, City, State</b>  2670 Mcingvale Rd Suite H, Hernando, MS	
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><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> 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 observation of the laboratory procedure manual, quality control (QC), patient test log, lack of performance specifications, and interview with the Laboratory Director, the laboratory failed to verify performance specifications for Serum HCG pregnancy testing using the Consult HCG Combo Test Cassette, before it was put in use for patient testing on 11/13/2025. Findings include: 1. Observation of the Laboratory Procedure Manual revealed the Consult HCG Combo Test Cassette procedure was added to the manual and introduced to the laboratory by performing QC on 11/4/2025. 2. Review of quality control and patient test records for the Consult HCG Serum Pregnancy revealed the laboratory performed the first patient's serum pregnancy on 11/13/2025. 3. On the day of the survey, 3/10/2026, there was no documentation available for review of verification of performance specifications, to include accuracy, precision, and reportable range, for the Consult HCG Combo (serum) Test Cassette. 4. In an interview on 3/10/2026 at 2:30 p.m., the Laboratory Director confirmed the Consult HCG Combo Test Cassette was used for serum pregnancy, and performance specifications were not verified for Serum Pregnancy testing, before it was put in use for patient testing on 11/13/2025.</p>