

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D0317728	<b>(X3) Date Survey Completed</b>  10/17/2024
<b>Name of Provider or Supplier</b>  Claiborne County Hospital Db a Claiborne Co Med Ctr	<b>Street Address, City, State</b>  123 Mccomb Avenue, Port Gibson, 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>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) logs, patient testing logs and interview with the laboratory general supervisor (GS) as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to include a positive and negative control on each day of patient testing for the Consult Combo HCG Pregnancy test performed for five of fifteen serum samples. The Consult Combo hCG Pregnancy test is categorized as moderate complexity when used with serum samples. Findings Include: 1. Review of the Consult Combo HCG patient test log and QC log from 1/5/2023 through 10/17/2024 revealed that on the 5 days listed below, pregnancy tests were performed on serum samples. Five of fifteen hCG patient tests were performed without quality control on these days. 4/22/2023 - 1 patient tested 4/30/2023 - 1 patient tested 6/22/2023 - 1 patient tested 2/09/2024 - 1 patient tested 3/25/2024 - 1 patient tested 2. Interview with GS on 10/17/2024 at 1:00 p.m., confirmed that testing personnel (TP) were not performing two levels of QC (positive or negative) each day of patient testing with the Consult Combo HCG test kit as required for moderate complexity testing. 3. There was no IQCP (Individualized Quality Control Plan) available for review on the day of survey. As IQCP is required after 1/1/2016 if two levels of quality control (QC) are not performed each day of use for moderate/high complexity testing.</p>