Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0317728	04/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Claiborne County Hospital Dba Claiborne Co Med Ctr	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on review of the laboratory Blood Bank Procedure Manual, the Blood Bank checklist log from 11/1/18 through 4/14/21, and confirmation with the general supervisor (GS) listed on the Centers for Medicare & Medicaid Services (CMS) 209 form at 1:00 pm on 4/15/21, the laboratory did not follow their blood bank procedure for performing the serofuge RPM and timer checks since the last survey on 10/31/18. Findings include: 1. Review of the Blood Bank Procedure Manual revealed the serofuge RPM and timer used for centrifugation in Blood Bank is to be checked quarterly. 2. Review of the Blood Bank maintenance checklist from 11/1/18 through 4 /15/21 revealed the serofuge RPM and timer check had not been documented as performed since 10/31/18. 3. Interview with the GS listed on the CMS-209 personnel form at 1:00 pm on the day of survey confirmed that the Blood Bank serofuge RPM and timer check had not been documented as performed since 10/31/18. B. Based on the review of the laboratory Blood Bank Procedure Manual, the Blood Bank checklist log from 11/1/18 through 4/15/21 and confirmation with the GS at 1:00 pm on the 4/15 /21, the laboratory did not follow the blood bank procedure for performing the serofuge calibration. 1. Review of the Blood Bank Procedure Manual revealed calibration must be performed on the serofuge at 20, 30 and 45 seconds for saline, albumin, AHG and washing stage every 6 months. 2. Review of the Blood Bank maintenance checklist from 11/1/18 through 4/15/21 revealed the serofuge calibration had not been documented as performed since 10/31/18. 3. Interview with the GS at 1:

	00 pm on the day of survey, confirmed the the Blood Bank serofuge had not been documented as calibrated since 10/31/18. This timeframe exceeds the 6 month intervals required by the laboratory procedure manual.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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. 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 on 4/15/21 at 1:00 pm, the laboratory failed to include a positive and negative control on each day of patient testing for the Consult Combo HCG Pregnancy test when performed with serum samples between 12 /27/19 and 3/21/21. The Consult Combo hCG Pregnancy test is categorized as moderate complexity when used with serum samples. Findings Include: 1. Interview with GS on 4/15/21 at 1:00 pm 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. 2. There was no IQCP (Individualized Quality Control Plan) available for review on the day of survey. An IQCP is required after 1/1/16 if two levels of quality control (QC) are not performed each day of use for moderate/high complexity testing. 3. Review of the Consult Combo HCG patient test log and QC log from 12/27/19 through 3/21/21 revealed that on the 5 days listed below, pregnancy tests were performed on serum samples. No QC was performed on these days. 05/20/2020 - 1 patient tested 12/10 /2020 - 1 patient tested 01/03/2021 - 1 patient tested 02/13/2021 - 1 patient tested 03 /22/2021 - 1 patient tested