Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 25D0317728	**(X3) Date Survey Completed** 10/31/2018
Name of Provider or Supplier Claiborne County Hospital Dba Claiborne Co Med Ctr	**Street Address, City, State** 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**
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory personnel documented annual evaluations/competency and interview with the technical consultant, the laboratory failed to follow written policies to assess employees and technical consultant competency at least annually since employment of the new technical consultant in April 2017. On the day of survey, there was no competency evaluation for the technical consultant performed by the laboratory director.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the

	range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of chemistry laboratory records from 2/3/17 through the day of survey, and confirmation with staff at 1:30 pm on 10/31/18, the laboratory failed to perform calibration verification on the Dimension EXL 200 chemistry analyzer every 6 months. Calibration verification should be performed using at least 3 levels of calibrator every 6 months as per the regulations. Findings include: Review of laboratory chemistry calibration records, revealed Sodium (NA), Potassium (K), and Chloride (CL) calibrate on the Dimension EXL 250 analyzer every 2 hours but does not yield 3 points. The last calibration verification was performed on 2/3/17. This time frame does not meet the calibration verification requirements specified in the regulations.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of immunohematology (blood bank) records from 1/1/17 through 10 /31/18, the laboratory failed to have available evidence of monthly inspections of the Jewett refrigerator alarm system to ensure appropriate temperature conditions for blood and blood product storage were maintained. Findings include: Review of blood bank records and alarm recorder log, from 1/1/17 through 10/31/18 revealed the laboratory performed monthly Jewett temperature alarm system checks, but the actual recorder graphs did not reveal at what temperature the alarm was activated. There was no obvious peak indicated on the graph paper representing a low and high activation of the alarm system. The laboratory's written procedure for Hi/Lo alarm check state the high temperature activation is set at 6.0 degrees Celsius and the low temperature activation is set at 1.0 degree Celsius. This could not be supported by the documentation on the recorder graphs.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

	This STANDARD is not met as evidenced by: Based on review of laboratory records (including quality control, calibrations, temperature logs, maintenance logs and proficiency testing results), since the last survey, 12/7/16, through the day of survey, 10/31/18, and confirmation with staff at 3: 30 pm, the Technical Consultant (TC) listed on the CMS-209 (Centers of Medicare and Medicaid) form or the TC appointed at the time failed to document as reviewed the following laboratory records: 1. Horiba AB Pentra 60 + hematology calibrations from 12/7/16 through 6/27/18 2. Horiba AB Pentra 60 + hematology maintenance from 1/1/17 through 10/29/18 3. Dimension EXL 200 chemistry Quality Control records from 2/1/17 through 10/30/18 4. Dimension EXL 200 chemistry maintenance 1/1/17 through 10/30/18 5. Dimension EXL 200 chemistry calibrations 1/31/17 through 10/18/18 6. iSTAT blood gas calibration verification 6/7/17 through 6/28/18