Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0317488	07/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson County Hospital	870 Main Street, Fayette, 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
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: 1. Based on review of calibration verification records for the Triage Meter Pro analyzer since installation on 3-23-17, interview with the technical consultant on 7-17-18 at 9:30 a.m., and review of quality control and patient test logs, the laboratory failed to document, as performed, calibration verification for D-dimer testing at least once every six months since 3-23-17. A total of fifteen patient D-dimer results were reported from 9-23-17, when D-dimer calibration verification was due, through 7-15-

	18. Findings include: Review of calibration verification records since installation of the Triage Meter Pro analyzer on 3-23-17 revealed no documentation of performance of calibration verification for D-dimer testing since 3-23-17. In an interview on 7-17-18 at 9:30 a.m., the technical consultant, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, confirmed calibration verification has not been performed for D-dimer testing on the Triage Meter Pro analyzer since 3-23-17. Review of D-dimer quality control and patient test logs revealed a total of fifteen patient D-dimer results were reported from 9-23-17, when D-dimer calibration verification was due, through 7-15-18. 2. Based on review of calibration verification records for Hemoglobin A1C testing performed on the Siemens Dimension EXL 200 analyzer since the last survey on 9-21-16 and interview with the technical consultant on 7-17-18 at 11:10 a.m., the laboratory failed to document, as performed, calibration verification for Hemoglobin A1C testing at least once every six months since 7-21-17. Findings include: Review of calibration verification records for Hemoglobin A1C testing performed on the Siemens Dimension EXL 200 analyzer since 9-21-16 revealed no documentation of performance of calibration verification since 7-21-17. In an interview on 7-17-18 at 11:10 a.m., the technical consultant confirmed calibration verification has not been performed for Hemoglobin A1C testing on the Siemens Dimension EXL 200 analyzer since 7-21-17.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control and patient test logs, patient test reports, instrument printouts for D-dimer testing with the Alere Triage Meter Pro from 5-10-17 through 7-15-18, lack of documentation of an Individualized Quality Control Plan (IQCP), and interview with the technical consultant on 7-17-18 at 9:30 a.m., the laboratory failed to include two levels of control material each day of patient testing from 5-10-17 through 7-15-18, when a total of twenty-six patient D-dimer results were reported. Findings include: Review of quality control and patient test logs, patient test reports, and instrument printouts for D-dimer testing with the Alere Triage Meter Pro from 5-10-17 through 7-15-18 revealed a total of twenty-six patient D-dimer results were reported on the following days with no documentation of performance of two levels of control each day of patient testing: 5-10-17--Patient #29210 5-18-17--Patient #1031728 5-19-17--Patient #10027244 5-20-17--Patient #10027271 6-14-17--Patient #1036407 9-14-17--Patients #0008763 and #1033962 9-15-17--Patient #0010545 9-20-17--Patient #10030858 9-21-17--Patients #213698 and #213665 10-18-17--Patient #1042996 10-26-17--Patient #10032101 11-30-17--Patient #10033285 12-18-17--Patients #1032272 and #1037385 1-5-18--Patient #1032817 1-17-18--Patient #1043184 1-24-18--Patient #1043184 2-17-18--Patients #1043269 and #1036710 2-19-18--Patient #1034564 3-3-18--Patient #1043293 7-12-18--Patient #1043531 7-15-18--Patients #1040193 and #1036266 There was no documentation of establishment of an IQCP, required after 1-1-16 if two levels of control are not included each day of patient testing. In an interview on 7-17-18 at 9:30 a.m., the technical consultant confirmed an IQCP was not developed for D-dimer testing.