Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464490	07/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Madison Parish Hospital	900 Johnson Street, Tallulah, LA	

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
D0000	A CERTIFICATION SURVEY was performed at Madison Parish Hospital - CLIA # 19D0464490 on July 23, 2018 through July 27, 2018. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to retain the in-house data to support the precision studies for the STA Compact Max Stago analyzer for Coagulation testing. Findings: 1. Review of performance study records for the STA Compact Max Stago Coagulation analyzer revealed the laboratory performed studies for accuracy, precision, reference range and reportable range; However, the laboratory failed to retain the in-house data to support day-to-day precision and operator variance studies from October 30, 2017 through November 1, 2017. 2. In interview on July 25, 2018 at 3:47 pm, Personnel 3 confirmed the laboratory did not retain the supporting data for complete precision studies.
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: **REPEAT DEFICIENCY** Based on observation, record review, and interview with personnel, the laboratory failed to perform corrective action when quality control was unacceptable for Dilantin testing. Findings: 1. Observation by surveyor during laboratory tour on July 23, 2018 revealed the laboratory utilizes the Siemens Dimension EXL with LM with BioRad Multiqual controls for Dilantin testing. 2. Review of the laboratory's Quality Control Policies and Procedures revealed under "Liquid Unassayed Multiqual Quality Control - Levels 1 and 3" frequency two (2) levels of control are performed once a day (24 hour). 3. Review of the laboratory's Quality Control (QC) records for June 2018 revealed the laboratory did not take corrective action when only one (1) level QC was performed for the following date: * June 15, 2018: Control Level 2 not performed before patient testing (Control Level 1 performed June 15, 2018 at 3:00 am) 4. Review of patient records for Dilantin testing in June 2018 revealed the following patient was reported without corrective action: * Patient 1 reported June 15, 2018 at 9:24 am 5. In interview on July 25, 2018 at 1:40 pm, Personnel 3 stated she did not catch the missed Dilatin QC on the monthly Quality Assurance check. Personnel 3 confirmed only one level of Dilantin QC was performed and a patient was resulted that day.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues. Findings: 1. The laboratory failed to perform corrective action when quality control was unacceptable for Dilantin testing. Refer to D5447.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D5447.

D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5793.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical consultants Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D5447.