Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464490	04/29/2021
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 Recertification Survey was performed on April 26, 2021 through April 29, 2021 at Madison Parish Hospital, CLIA ID # 19D0464490. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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: Based on record review and interview with personnel, the laboratory failed to document quarterly alarm check on the circular chart as required by laboratory policy. Findings: 1. Review of the laboratory's policy for "Blood Bank Refrigeration Alarm Check" revealed "Ensure a spike is registered on the chart, write on chart: 'Manual Alarm Check,' date, time, and tech initials". 2. Review of the laboratory's "Manual Alarm Check Worksheet" for 2020 revealed the laboratory performed an alarm check on July 2, 2020; however, the laboratory did not document information required by policy on the circular chart to include: a) "Manual Alarm Check" b) Date and Time c) Tech initials 3. In interview on April 28, 2021 at 1:30 pm, Personnel 3 confirmed the manual alarm check was not documented on the circular chart for the above date.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to utilize acceptable donors as required by the manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean. Findings: 1. Observation by surveyor during the laboratory tour on April 26, 2021 at 9:16 am revealed the laboratory utilized the Stago STA Compact Max analyzer for Prothrombin Time (PT) and International Normalized Ratio (INR) testing. 2. Review of the CLSI 28-A3 recommendations for donor requirements revealed the following requirements for donor testing: a) Minimum of 120 donors b) Use well screened samples c) No medications (CLSI states "including oral contraceptives and estrogen") d) Healthy (CLSI states "Donors should have no pathological conditions or include inpatient or pre surgery patients") e) Should include samples that are representative of your patient population (CLSI states "The donors used should span the adult age range within a fairly even distribution of males and females") f) CLSI also includes that samples should be collected over a period of time and include variability ao age of reagents. 3. Review of the laboratory's policy "Verification or Establishing Assay Reference Ranges" revealed the laboratory did not have written, detailed instructions for establishing a normal donor population. 4. Review of the laboratory's "Selection of Individuals for Reference Range Studies" revealed the following questionnaire: a) Do you consider yourself to be healthy? b) Have you recently been ill? When? c) Details of recent illness... d) Are you taking any prescribed or over the counter medications, including aspirin? Please list all medications... e) Do you have a medical condition that requires on going treatment by a physician? If yes, please describe... f) Have you recently exercised? 5. Further review of the laboratory's "Selection of Individuals for Reference Range Studies" revealed the laboratory did not include the following criteria: a) Not taking any aspirin related products b) Not taking any oral contraceptives or estrogen 6. Review of the laboratory's donor questionnaires revealed the laboratory utilized the following donors who did not meet the acceptable criteria: a) PID 49995: documented taking oral contraceptives b) PID 48531: documented taking aspirin related products 7. In interview on April 28, 2021 at 3:35 pm, Personnel 3 stated she was unaware that the above donors listed medications that were unacceptable. 8. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 722 PT/INR tests annually.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on direct observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to document quarterly alarm check on the

	circular chart as required by laboratory policy. Refer to D5401. 2. The laboratory failed to utilize acceptable donors as required by the manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean. Refer to D5411.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to document quarterly alarm check on the circular chart as required by laboratory policy. Refer to D5401. 2. The laboratory failed to utilize acceptable donors as required by the manufacturer to verify reference interval and establish normal Prothrombin Time (PT) mean. Refer to D5411.