Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464490	09/19/2024
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 conducted September 17, 2024 through September 19, 2024 at Madison Parish Hospital - CLIA ID # 19D0464490. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to perform assessment activities for unacceptable educational challenge proficiency testing results for one (1) of two (2) events reviewed in 2024. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "Corrective action is performed and documented for all unacceptable values. Results that are not formally evaluated by API (i.e. educational challenges, scientific committee decisions, etc.) are evaluated by the supervisors of that department for correctness." 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records for 2024 revealed the laboratory did not perform an assessment for the following unacceptable educational challenge: 2024 Hematology/Coagulation 2nd Event: Blood Cell Identification: Sample DIF-02 for Monocytes 3. In interview on September 17, 2024 at 12:05 pm, the Laboratory Manager stated the digital slide for the identified educational challenge was no longer available. The Laboratory Manager confirmed there was no performance of assessment activities for the identified educational challenge.
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:
I. Based on review of the laboratory's policies, quality control records, patient test logs, and interview with personnel, the laboratory failed to perform quality control (QC) each day of testing per laboratory policy for ketones for two (2) of nineteen (19) patients reviewed. Findings: 1. Review of the laboratory's "Quality Control Policies and Procedures" under the "AIMTAB Ketone (Serum) Tablet" section revealed "Ketone serum controls frequency 2 levels each day of use, positive and negative." 2. Review of the laboratory's quality control records and patient test logs revealed the following patients did not have QC performed the day of testing: May 16, 2024: Patient 50926 (QC last performed May 15, 2024) June 19, 2024: Patient 56660 (QC last performed June 18, 2024) 3. In interview on September 18, 2024 at 4:32 pm, the Assistant Laboratory Manager stated the laboratory has the quality control rule set up as every 24 hours in Orchard, their Laboratory Information System (LIS), for ketone testing. The Assistant Laboratory Manager confirmed the laboratory did not perform QC each day of testing for the identified two (2) patients. II. Based on observation by surveyors, review of the laboratory's policies, normal patient mean studies, test menu, and interview with personnel, the laboratory failed to follow their policy for verification of reference ranges for Coagulation testing. Findings: 1. Observation by surveyors during the laboratory tour on September 17, 2024 at 9:34 am revealed the laboratory utilizes the Stago STA Satellite for Coagulation testing. 2. In interview on September 17, 2024 at 10:56 am, the Technical Consultant stated the laboratory moved to the new building on March 28, 2023. The Technical Consultant stated the laboratory got a new Stago coagulation instrument, which was the same platform and utilized the same reagent as their old instrument. 3. Review of the laboratory's "Verification of Reference Ranges" policy revealed "Devise a questionnaire for prospective sample donors designed to exclude any unwanted samples. Questionnaires must be reviewed and the donors must be either included or excluded from the study." 4. Further review of the laboratory's "Verification of Reference Ranges" document revealed "Already had a reference range just verified" with "21" donor samples used. 5. Review of the laboratory's normal patient mean studies for the instrument's initial set-up revealed the following: a) Verification was completed on March 13, 2023: Neoplastine lot 261455: Seven (7) of twenty one (21) donor questionnaires were missing. The questionnaires were missing for the following donors: 205359, 205375, 205360, 205376, 205990, 205223, and 205476. 6. In interview on September 19, 2024 at 1:24 pm, the Technical Consultant confirmed the laboratory did not have the donor questionnaires for seven (7) donors for the initial set-up. 7. In interview on September 19, 2024 at 1:30 pm, the Assistant Laboratory Manager stated the laboratory switched lot numbers of Neoplastine reagent since the instrument's initial installation. 8. Review of the laboratory's "Lot Conversion Protocol" revealed "Lot conversion studies should be performed prior to starting a new lot number of Protime and/or APTT reagent. A new Geometric mean must be established with the following sample set: Run 20 screened normal samples with the New PT reagent. If there are 2 or more analyzers at the same site, the same normal samples should be run on each analyzer to account for any variability." 9. Review of "Verification or Establishing Assay Reference Ranges" revealed " Only outpatients considered in good physical health shall be used for the study. Each outpatient shall be given a questionnaire to fill out in order to establish that the patient is in good physical health and has no known health

	problems. Verification of the normal range is complete when a minimum of 20 normal patients have been tested." 10. Review of the laboratory's normal patient mean studies for the current lot of reagents revealed the following: a) Put in use March 20, 2024: Current lot of Neoplastine 264585: The laboratory used sixteen (16) donors, not twenty (20). For two (2) of the sixteen (16) donors, the sample ID numbers on the summary worksheet and instrument printouts did not match those utilized on the donor questionnaires. Donors 248551 and 248077 were not included on the summary worksheet. 11. In interview on September 19, 2024 at 2:05 pm, the Laboratory Manager stated they were aware that twenty (20) donors were not used and of the sample ID numbering issue for the current lot of Neoplastine reagent. 12. Review of the laboratory's test menu revealed the laboratory performs 456 prothrombin time (PT) and 322 activated partial thromboplastin time (APTT) tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have detailed written instructions for the Platelet Poor Plasma procedure. Findings: 1. Review of the laboratory's "Centrifuge Platelet Verification" policy revealed the laboratory did not include detailed written instructions on how to obtain an acceptable plasma sample for testing, including, but not limited to, speed of the centrifuge and length of time to spin. 2. In interview on September 18, 2024 at 3: 44 pm, the Compliance Personnel stated the laboratory follows the manufacturer's guidelines for platelet poor plasma testing. The Compliance Personnel confirmed the laboratory's procedure did not include detailed instructions for platelet poor plasma testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of manufacturer's requirements, and interview with personnel, the laboratory failed to ensure blood collection tubes were stored per manufacturers' requirements. Findings: 1. Observation by surveyors during the laboratory tour on September 17, 2024 at 10:10 am, revealed the laboratory had the following items stored in the Thermo Scientific freezer at -14.4 degrees Celsius located in the Blood Bank room : BD Vacutainer Sodium Fluoride blood collection tubes, lot 3257749, Quantity: ten (10) tubes Vacuette K2EDTA blood collection tubes, lot B2401304, Quantity: forty nine (49) tubes Vacuette K2EDTA blood collection tubes, lot B2307358, Quantity: two (2) tubes 2. In interview on September 17, 2024 at 10:14 am, the Assistant Laboratory Manager stated the lab stored the empty blood collection tubes in the freezer for lactic acid testing. 3. Review of the BD Vacutainer and Vacuette manufacturers' storage requirements revealed the acceptable range was 4-25 degrees Celsius. 4. Review of the Siemens Dimension package insert for lactic acid revealed "Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes. If the testing cannot be performed immediately, refrigerate the separated plasma sample for up to 24 hours or freeze it for up to 1 month. Follow the instructions provided with your specimen collection device for use and processing." 5. In further interview on September 17, 2024 at 10:14 am, the Assistant Lab Manager confirmed the blood collection tubes were not stored at the correct temperature per the manufacturers' requirements.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to label in-use Complete Blood Count (CBC) controls with an expiration date. Findings: 1. Observation by surveyors during the laboratory tour on September 17, 2024 at 9:32 am revealed the laboratory utilizes the following analyzers and controls for Complete Blood Count (CBC) testing: a) Beckman Coulter DxH 690t with Coulter 6C Cell Controls b) Beckman Coulter DxH 800 with Coulter 6C Cell Controls 2. Futher observation during the laboratory tour on September 17, 2024 at 10:15 am revealed the following Beckman Coulter 6C Cell controls loaded in an instrument rack in the Helmer Refrigerator Single without the expiration dates included: a) Low Level - Lot 123175580, Expiration 10/19/2024, Put in use 09/09/2024 b) Normal Level - Lot 133185580, Expiration 10/19/2024, Put in use 09/09/2024 c) High Level - Lot 143195580, Expiration 10/20/2024, Put in use 09/09/2024 3. Review of Beckman Coulter 6C Cell

	Controls package inserts revealed "When stored at 2 to 8 degrees celsius, sealed /unopened tubes are stable until the expiration date shown on the Table of Expected Results. For opened vial stability, refer to the Table of Expected Results which is 16* Open Vial Days (* Assumes that the Instructions for Use section of the package insert is performed a maximum of 18 times within 16 days)". 4. In interview on September 17, 2024 at 10:30 am, Laboratory Supervisor 1 confirmed the identified controls were not labeled with an expiration date. 5. Review of the task 1&3 form provided to surveyors revealed the laboratory performs 4,684 Complete Blood Count (CBC) tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the maintenance logs and interview with personnel, the laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for one (1) of twenty (20) months reviewed in 2023 and 2024. Findings: 1. Observation by surveyors during the laboratory tour on September 17, 2024 at 10:15 am revealed the laboratory utilizes the BioMerieux Vidas 2 analyzer for Procalcitonin testing. 2. Review of the laboratory's maintenance logs from 2023 and 2024 for the BioMerieux Vidas 2 analyzer revealed the following monthly maintenance procedures: a) Clean SPR Block b) Change Waste Container 3. Further review of the 2023 and 2024 maintenance logs revealed the monthly maintenance was not performed for the following one (1) of twenty (20) months reviewed: a) June 2024: Change Waste Container 4. In interview on September 18, 2024 at 2:00 pm, Laboratory Supervisor 1 confirmed the monthly maintenance for the identified month above was not performed as required by the manufacturer.
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 observation by surveyor, review of the laboratory's blood bank platelet incubator chart and alarm check records, as well as interview with personnel, the laboratory failed to ensure high and low alarm verifications were performed on the blood bank platelet incubator quarterly. Findings: 1. Observation by surveyors during the laboratory tour on September 17, 2024 at 10:15 am revealed the laboratory utilizes a platelet incubator for the storage of platelets. 2. Review of the laboratory's blood bank platelet incubator chart revealed the following: "Test the high and low temperature alarms.(Manual High/Low Performed Quarterly)". 3. Review of the blood

	bank alarm check records from April 2024 through September 2024 revealed the laboratory did not have a quarterly alarm check documented for the platelet incubator in June 2024. 4. In interview on September 19, 2024 at 11:00 am, Laboratory Supervisor 2 confirmed the laboratory did not perform the quarterly alarm check for the platelet incubator as required by laboratory policy.
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 observation by surveyors, review of manufacturer's instructions, records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to follow their policy for verification of reference ranges for Coagulation testing. Refer to D5401 II. 2. The laboratory failed to ensure blood collection tubes were stored per manufacturers' requirements. Refer to D5413. 3. The laboratory failed to label in-use Complete Blood Count (CBC) controls with an expiration date. Refer to D5415.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D5221.
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 record review and interview with personnel, the Laboratory Director failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5401 I.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of laboratory policy, maintenance records, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for one (1) of twenty (20) months reviewed in 2023 and 2024. Refer to D5429. 2. The laboratory failed to ensure high and low alarm verifications were performed on the blood bank platelet incubator quarterly. Refer to D5555.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
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 surveyors, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to follow their policy for verification of reference ranges for Coagulation testing. Refer to D5401 II. 2. The laboratory failed to

	have detailed written instructions for the Platelet Poor Plasma procedure. Refer to D5403. 3. The laboratory failed to ensure blood collection tubes were stored per manufacturers' requirements. Refer to D5413. 4. The laboratory failed to label in-use Complete Blood Count (CBC) controls with an expiration date. Refer to D5415. 5. The laboratory failed to perform monthly maintenance procedures per manufacturer's requirements for one (1) of twenty (20) months reviewed in 2023 and 2024. Refer to D5429. 6. The laboratory failed to ensure high and low alarm verifications were performed on the blood bank platelet incubator quarterly. Refer to D5555.
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 record review and interview with personnel, the Technical Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5401 I.