Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0048403	05/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Hood Memorial Hospital	301 West Walnut Street, Amite, 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 May 3, 2021 through May 6, 2021 at Hood Memorial Hospital, CLIA ID # 19D0048403. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to providers or patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Observation during laboratory tour on May 3, 2021 at 10:29 am revealed the laboratory performs SARS COV-2 testing utilizing the BD Veritor . 2. Review of the manufacturer's instructions for use under "Conditions of Authorization of the Laboratory" section revealed "Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. In interview on May 3, 2021 at 9:40 am, General Supervisor 2 stated the laboratory does not provide the "fact sheets" for the COVID test to patients. 4. Review of the laboratory's test menu revealed the laboratory performs 481 SARS COV-2 tests annually. II. Based on review of manufacturer's instructions, patient final test reports, test menu, and interview with personnel, the laboratory failed to include the Food and Drug Administration (FDA) Emergency Use Authorization statement on SARS COV-2 patient final reports. Findings: 1. Review of the manufacturer's instructions for the BD Veritor revealed the

	following statement: "In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories." 2. Review of random selection of patient final reports for SARS COV-2 revealed the laboratory did not include the identified Emergency Use Authorization statement on patient final reports. 3. In interview on May 4, 2021 at 2:22 pm, General Supervisor 2 confirmed the laboratory's patient final reports for SARS COV-2 did not include the identified statement. 4. Review of the laboratory's test menu revealed the laboratory performs 481 SARS COV-2 tests annually.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to ensure the Laboratory Director or qualified designee (if applicable) signed the attestation forms and/or performance evaluation forms for five (5) of seven (7) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) PT records for 2019, 2020, and 2021 first event revealed the Laboratory Director and/or qualified designee did not sign the attestation statements and/or performance evaluation forms for the following five (5) events: a) 2019: Immunology/Immunohematology 1st event; Laboratory Director did not sign the performance evaluation form b) 2019: Immunology/Immunohematology 2nd event; Laboratory Director did not sign the performance evaluation form c) 2020: Immunology/Immunohematology 3rd event; Laboratory Director did not sign the attestation statement form d) 2020: Chemistry-Miscellaneous 2nd event; Laboratory Director or qualified designee did not sign the performance evaluation form e) 2021: Hematology/Coagulation 1st event; Laboratory Director or qualified designee did not sign the performance evaluation form 2. In interview on May 3, 2021 at 1:13 pm, General Supervisor 2 confirmed the Laboratory Director and/or qualified designee, if applicable, did not sign the identified PT events.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's policies, nursing policies, and interview with personnel, the laboratory failed to ensure criteria for suspected transfusion reactions were defined in nursing policies. Findings: 1. Review of the laboratory's "Transfusion Reaction Investigation" policy indicated the following signs/symptoms: a) Fever (2 degree F increase) with or without chills associated with transfusion. Fever is the most common symptom of hemolytic transfusion reaction, but more frequently it has other causes. b) Shaking shills with or without fever c) Pain at the infusion site or in the chest, abdomen, or flanks d) Blood pressure changes, usually acute, either hypertension or hypotension. The laboratory did not define/specify the amount of change that would initiate a transfusion reaction procedure. e) Respiratory distress, including dyspnea, tachypnea, wheezing, or hypoxemia f) Skin changes, including urticaria, pruritis (itching), flushing, or localized edema (angioedema) g) Nausea with or without vomiting h) Darkened urine or jaundice i) Bleeding or other manifestations of a consumptive coagulopathy 2. Review of the "Blood /Blood Components Transfusion Reactions" for the "Medical Surgical Unit" policy revealed the following: "Notification of the physician must take place for the following types of transfusion reactions: hemolytic, allergic, febrile, bacterial, circulatory overload. In the event of a suspected transfusion reaction the nursing staff attending the patient shall notify the responsible physician. In the the event that the reaction involves a rise in the patient's temperature of 2 degrees C or higher the following protocol must be followed." 3. Further review of the "Blood/Blood Components Transfusion Reactions" for the "Medical Surgical Unit" policy revealed the policy did not include the same criteria as the laboratory's policy, such as blood pressure changes. 4. In interview on May 6, 2021 at 11:10 am, the General Supervisor 2 confirmed the criteria utilized by nursing for suspected transfusion reactions did not match the laboratory's criteria.
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 policies, personnel records, and interview with personnel, the laboratory failed to ensure procedures to assess competency for one (1) of two (2) General Supervisors reviewed were complete . Findings: 1. Review of the laboratory's "Evaluation & Competency" policy revealed "Each employee is evaluated by supervisor annually. Each new employee is evaluated after 90 days. Competency will be done one time on Technical Supervisor as long as they hold that position. These requirements will be reviewed by the Lab Director in order to maintain competency of employees." 2. In interview on May 3, 2021 at 1:13 pm, General Supervisor 2 stated he became a General Supervisor in 2020. 3. Review of personnel records for General Supervisor 2 revealed a competency assessment for the duties of General Supervisor was not performed. 4. In further interview on May 3, 2021 at 1:13 pm, General Supervisor 2 confirmed the Laboratory Director did not perform a competency assessment for his duties as General Supervisor prior to the laboratory's on-site survey.
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 and procedures, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: a) Manual INR calculation check to include procedure and frequency of performance b) Reporting of SARS COV-2 test results to state public health agency, to include but not limited to frequency and who is responsible 2. In interview on May 5, 2021 at 1: 37 pm, General Supervisor 2 confirmed the laboratory's policies did not include the identified procedures. II. Based on review of blood administration policies, blood transfusion patient records, and interview with personnel, the laboratory failed to ensure blood administration policies were complete and followed for two (2) of four (4) patients reviewed. Findings: 1. Review of the "BLOOD/BLOOD COMPONENTS - TRANSFUSION: WHOLE BLOOD AND PACKED CELLS" policy for the "Medical Surgical Unit" revealed the following: "Vital signs shall be measured prior to and after procedure. Vital signs will be taken at the start of the infusion, then every five (5) minutes x 3, then every fifteen (15) minutes x 2, then every thirty (30) minutes til infusion complete and upon completion of transfusion." 2. Further review of the identified policy revealed the specific vital signs required to be taken were not defined in the policy. 3. Review of random selection of blood transfusion patient records revealed the vital signs are documented during blood administration blood pressure, O2 Sat, respiration, pulse, and temperature. 4. Further review of random selection of blood transfusion patient records revealed the vital signs were not documented per policy for the following two (2) of four (4) patients: a) June 26, 2020: Patient 54629, no vital signs documented after completion of transfusion b) December 24, 2020: Patient 05214, no vital signs documented after completion of transfusion 5. In interview on May 5, 2021 at 1:40 pm, the Manager of the Medicine Unit confirmed the vitals were not documented after completion of transfusion for the identified patients.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on May 3, 2021 at 10:29 revealed the following expired items: a) Aptima Multitest Swab Specimen Collection Kit, Lot 265718, Expiration date: 2021-04-30, Quantity: one (1) box b) BD Veritor System SARS COV-2 Control Swab, Lot 0293028, Expiration date: 2021-04-22, Quantity: one (1) pack c) Viral Negative Control Swab, Lot 103466, Expiration date: 2020-21, Quantity: one (1) pack d) Alere RSV Positive Control Swab, Lot 102097, Expiration date: 2020-11, Quantity: one (1) pack e) BD Veritor System SARS COV-2 Negative

	Control Swab, Lot 0287647, Expiration date: 2021-04-20, Quantity: One (1) pack f) Copan ClassiQ swabs tip wrapped with traditional fiber, Lot, PS10323, Expiration date: 11/2020; Quantity: six (6) swabs 2. In interview on May 3, 2021 at 10:37 am, General Supervisor 2 confirmed the identified items were expired.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's performance verification studies, test menu, and interview with personnel, the laboratory failed to have complete reference range studies for Lactate Dehydrogenase (LDH), amylase, and lipase. Findings: 1. Observation by surveyor during the laboratory tour on May 3, 2021 at 10:29 am revealed the laboratory utilizes the Beckman Coulter DxC 700 AU for Chemistry testing of the following analytes: albumin, alkaline phosphatase, alanine aminotransferase, amylase, aspartate aminotransferase, total bilirubin, calcium, CO2, chloride, cholesterol, ethanol, glucose, HDL cholesterol, iron, lactate, lipase, magnesium, phosphorus, potassium, total protein, sodium, triglycerides, uric acid, blood urea nitrogen (BUN), creatine kinase, acetaminophen, salicylate, digoxin, phenobarbital, phenytoin, valproic acid, vancomycin, gentamycin, transferrin, prealbumin, HGB A1C, ammonia, D-dimer, urine creatinine, urine protein, urine microalbumin, urine sodium, urine potassium, urine chloride, amphetamine, barbiturate, benzodiazepine, cocaine, methadone, opiate, THC, C-reactive protein, and lactate dehydrogenase. 2. Review of the laboratory's performance verification (validation) studies revealed the laboratory did not complete the reference range studies for LDH, amylase, and lipase. 3. In interview on May 4, 2021 at 11:01 am, General Supervisor 2 stated the laboratory is using the manufacturer's reference ranges. General Supervisor 2 further stated the laboratory did not have enough patients to verify the manufacturer's reference ranges. General Supervisor 2 stated the Beckman Coulter DxC 700 AU was put into use on March 9, 2021. 4. Review of the laboratory's test menu revealed the laboratory performs 360 amylase, 480 lipase, and zero (0) LDH tests annually.
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 the laboratory's blood bank temperature charts and interview with personnel, the laboratory failed to monitor the back-up refrigerator's temperature for the storage of blood products for one (1) of thirty one (31) days in March 2021. Findings: 1. Review of the laboratory's circular temperature charts for March 2021 revealed the following comment for March 26, 2021: "See Temp Sheet. Refrigerator wouldn't stay on units moved." Fluctuations in the temperature were recorded on the circular chart from 2:00-4:00 pm and 10:00 pm -11:00 pm. 2. Review of the laboratory's "Blood Bank Temp." log for March 2021 revealed the laboratory did not have documentation of comments or corrective actions for March 26, 2021. 3. Review of the laboratory's "Backup Blood Bank Temperature Log (For When Blood Bank Refrigerator Is Out)" revealed "Must BE Within 2 degrees (2-6 c) * Must Record Every Four Hours*" 4. Further review of the laboratory's "Backup Blood Bank Temperature Log (For When Blood Bank Refrigerator Is Out)" revealed the laboratory did not have documentation of back-up refrigerator's temperature every four hours on March 26, 2021. 5. In interview on May 6, 2021 at 11:10 am, General Supervisor 2 stated he did not find documentation of verification of the temperature of the back-up refrigerator for March 26, 2021.
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 by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to ensure blood administration policies were complete and followed for two (2) of four (4) patients reviewed. Refer to D5401 II. 3. The laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Refer to D5417. 4. The laboratory failed to have complete reference range studies for Lactate Dehydrogenase (LDH), amylase, and lipase. Refer to D5421. 5. The laboratory failed to monitor the back-up refrigerator's temperature for the storage of blood products for one (1) of thirty one (31) days in March 2021. Refer to D5555.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5417.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure all proficiency test report attestation statements and/or performance evaluation forms were signed by the Laboratory Director. Refer to D2015.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was

	maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401 I.
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 Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5417.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultants failed to ensure performance specification verification studies were complete. Refer to D5421.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed

	to ensure the laboratory personnel were performing test methods as required. Findings: 1. The laboratory failed to ensure blood administration policies were complete and followed for two (2) of four (4) patients reviewed. Refer to D5401 II. 2. The laboratory failed to monitor the back-up refrigerator's temperature for the storage of blood products for one (1) out of thirty one (31) days in March 2021. Refer to D5555.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure all proficiency test report attestation statements and/or performance evaluation forms were signed by the Laboratory Director. Refer to D2015.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D5209.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D3025.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, personnel records, policies and procedures, and interview with personnel, the Laboratory Director failed to delegate responsibilities of the General Supervisor to one (1) of two (2) General Supervisors reviewed. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed two (2) General Supervisors. 2. Review of personnel records for General Supervisor 2 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks of General Supervisor to him. 3. In interview on May 3, 2021 at 1:13 pm, General Supervisor 2 confirmed the Laboratory Director did not have documentation of the Laboratory Director delegating the General Supervisor responsibilities to him.