Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D0868765	**(X3) Date Survey Completed** 01/11/2022
Name of Provider or Supplier Hood Memorial Hospital Respiratory Srv	**Street Address, City, State** 301 W Walnut St, 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 at Hood Memorial Hospital-Respiratory, CLIA # 19D0868765, on January 11, 2022. Hood Memorial Hospital-Respiratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1210 CONDITION: Routine Chemistry 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Chemistry. Findings: 1. The laboratory failed to establish complete written policies to assess competency for testing personnel. Refer to D5209. 2. The laboratory failed to ensure the Laboratory Director reviewed the proficiency testing performance evaluation results for five (5) of six (6) events reviewed. Refer to D5211. 3. The laboratory failed to establish a complete temperature monitoring policy. Refer to D5401. 4. The laboratory failed to ensure supplies did not exceed expiration date. Refer to D5417. 5. The laboratory failed to perform complete performance verification studies for the EG6+ cartridges utilized with the i-Stat analyzers for blood gas testing. Refer to D5421. 6. The laboratory failed re-evaluate the risk and quality assessments after a change in cartridge type for blood gas testing on the i-Stat. Refer to D5445. 7. The laboratory failed to ensure the Laboratory Director performed a review per policy. Refer to D5791 I. 8. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791 II.

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 policies and interview with personnel, the laboratory failed to establish complete written policies to assess competency for testing personnel. Findings: 1. Review of the laboratory's "Quality Assurance-Personnel Competency" policy revealed the laboratory did not include the following two (2) of the six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observation of performance of instrument maintenance and function checks. b) Assessment of problem solving skills. 2. In interview on January 11, 2022 at 10:50 am, the Respiratory Manager confirmed the laboratory's policies did not include the identified two (2) of six (6) procedures to assess competency of testing personnel.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency test records, and interview with personnel, the laboratory failed to ensure the Laboratory Director reviewed the proficiency testing performance evaluation results for five (5) of six (6) events reviewed. Findings: 1. Review of the laboratory's "I-Stat" policy under "Proficiency Testing" section revealed "The results are reviewed and signed by the Blood Gas Lab Director." 2. Review of the American Proficiency Institute (API) proficiency testing records for 2020 and 2021 revealed the laboratory did not have documentation of review of their results by the Laboratory Director for the following events: 2020 Chemistry Core 1st Event 2020 Chemistry Core 2nd Event 2020 Chemistry Core 3rd Event 2021 Chemistry Core 1st Event 2021 Chemistry Core 3rd Event 3. In interview on January 11, 2022 at 12:00 pm, the Respiratory Manager stated if the evaluation forms were not not in the binder, the laboratory did not have them. The Respiratory Manager further stated she did not know where the evaluations were.
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 review of the laboratory's policies, temperature log sheets, and interview

	with personnel, the laboratory failed to establish a complete temperature monitoring policy. Findings: 1. Review of the laboratory's policies and "Refrigerator and Humidity Log" revealed the laboratory did not define their acceptable room temperature range. 2. In interview on January 11, 2022 at 12:04 pm, the Respiratory Manager confirmed the laboratory's acceptable room temperature range was not indicated in the laboratory's policies or log.
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 supplies did not exceed expiration date. Findings: 1. Observation by surveyor during the laboratory tour on January 11, 2022 at 9:40 am revealed the laboratory had the following expired item: SAFE-T-Fill Blood Gas Capillaries , Lot 07A4078, Expiration Date: 2009-01, Quantity: 1 container 2. In interview on January 11, 2022 at 9:44 am, the Respiratory Manager confirmed the identified item was 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 comparison studies for the cartridge change, and interview with personnel, the laboratory failed to perform complete performance verification studies for the EG6+ cartridges utilized with the i-Stat analyzers for blood gas testing. Findings: 1. Observation by surveyor during the laboratory tour on January 11, 2022 at 9:40 am revealed the laboratory utilizes two (2) i-Stat 1 analyzers with EG6 + cartridges for blood gas testing. 2. In interview on January 11, 2022 at 9:44 am , the Respiratory Manager stated the laboratory changed from G3 + to EG6 + cartridges last year and performed a comparison using calibration verification controls January 22, 2020. 3. Review of the comparison data revealed the following: a) Note stating "Comparison Study for EG6+ & G3+ using cal. ver. control done 1/22/2020" b) Raw data for five (5) levels of controls for EG6+ and G3+ c) Manufacturer's insert for the Tri-Controls Calibration Verification Set 4. Review of the comparison data revealed the laboratory did not include the following: a) Precision studies, to include, but not limited to day-to-day, run-to-run, within-run, operator variance b) Reference range c) Acceptability Criteria d) Review/approval by Laboratory Director 4. In further interview on January 11, 2022 at 12:30 pm, the

	Respiratory Manager confirmed the laboratory did not include documentation of the identified items.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's Individualized Quality Control Plan (IQCP), and interview with personnel, the laboratory failed to re-evaluate the risk and quality assessments after a change in cartridge type for blood gas testing on the i-Stat. Findings: 1. Observation by surveyor during the laboratory tour on January 11, 2022 at 9:40 am revealed the laboratory utilizes two (2) i-Stat 1 analyzers with EG6 + cartridges for blood gas testing. 2. In interview on January 11, 2022 at 9:44 am , the Respiratory Manager stated the laboratory changed from G3 + to EG6 + cartridges last year and performed a comparison using calibration verification controls January 22, 2020. 3. Review of the laboratory's IQCP revealed the laboratory did not re-evaluate the risk assessment, which includes reagents, or quality assessment, since the change to the EG6+ cartridges. The Laboratory Director reviewed/approved the IQCP on December 19, 2015. 4. In interview on January 11, 2022 at 12:30 pm, the Respiratory Manager confirmed the laboratory's IQCP was not re-evaluated by the Laboratory Director since the change in cartridges for blood gas testing.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: I. Based on review of monthly quality assessment (QA) documents and interview with personnel, the laboratory failed to ensure the Laboratory Director performed a review per policy. Findings: 1. Review of the laboratory's QA documents for 2020 and 2021 revealed the laboratory utilizes a "Quality and Appropriateness Review Quality Assurance Outcome Summary" form and "ABG Daily Log Quality Assessment" form. 2. Further review of the QA documents revealed the following: a) "Quality and Appropriateness Review Quality Assurance Outcome Summary" form did not indicate who performed the review or date it was performed. b) "ABG Daily Log Quality Assessment" form included a signature line for the Laboratory Director; however, no documentation that the Laboratory Director performed a review 3. In interview on

	January 11, 2022 at 2:40 pm, the Respiratory Manager stated the previous Respiratory Manager performed the reviews and the Laboratory Director does not review. II. Based on observation by surveyor, review of records, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to establish complete written policies to assess competency for testing personnel. Refer to D5209. 2. The laboratory failed to ensure the Laboratory Director reviewed the proficiency testing performance evaluation results for five (5) of six (6) events reviewed. Refer to D5211. 3. The laboratory failed to establish a complete temperature monitoring policy. Refer to D5401. 4. The laboratory failed to ensure supplies did not exceed expiration date. Refer to D5417. 5. The laboratory failed to include complete performance verification studies for the EG6+ cartridges utilized with the i-Stat analyzers for blood gas testing. Refer to D5421. 6. The laboratory failed re-evaluate the risk and quality assessments after a change in cartridge type for blood gas testing on the i-Stat. Refer to D5445.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance verification studies were complete. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to 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. Refer to D6018. 4. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 5. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 6. The Laboratory Director failed to ensure complete policies and procedures for assessing personnel competency were established. Refer to D6030.
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 by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. 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 by surveyor 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 with personnel, the Laboratory Director failed to 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. Refer to D5211.
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 by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D5445.

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 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 D5791.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) 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 complete policies and procedures were available to laboratory personnel. Findings: 1. The laboratory failed to establish complete written policies to assess competency for testing personnel. Refer to D5209. 2. The laboratory failed to establish a complete temperature monitoring policy. Refer to D5401.