Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0873698	06/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pointe Coupee General Hospital	2202 False River Drive, New Roads, 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 Validation survey was performed at Pointe Coupee General Hospital (Respiratory), CLIA ID 19D0873698, on June 24, 2024 through June 27, 2024. 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 review of the laboratory's policies and interview with personnel, the laboratory failed to have a written corrective action policy for temperatures that were outside of the established acceptable limits. Findings: 1. Review of the laboratory's policies revealed the laboratory did not include corrective action procedures for temperatures outside of acceptable limits. 2. In interview on June 25, 2024 at 9:55 am, the Respiratory Manager stated the laboratory performs corrective actions when temperatures are within a few degrees of being outside of the acceptable limits; however, there is not a written policy.
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 by surveyor, review of policies, random selection of patient reports, and interview with personnel, the laboratory failed to test blood gas samples within thirty (30) minutes of collection per manufacturer requirements for four (4) of ten (10) patients. Findings: 1. Observation by surveyor during the laboratory tour on June 24, 2024 at 1:23 pm revealed the laboratory utilizes the EPOC for blood gas testing. 2. In interview on June 24, 2024 at 1:32 pm, the Respiratory Manager, stated the blood gas instrument does not leave the respiratory department. The testing is performed in the blood gas laboratory. 3. Review of the laboratory's "Cardiopulmonary Services" policy and manufacturer's instructions revealed under the "Sample Collection Details" section for non-capillary tubes "test in less than 30 minutes." 4. Review of a random selection of patient final reports revealed the following patients exceeded the manufacturer's thirty (30) minutes test requirement: March 4, 2024 Patient 9035728 ordered: 11:57; resulted: 12:58 March 9, 2024 Patient 9079565 ordered 18:20; resulted: 19:07 March 9, 2024 Patient 9033410 ordered 18: 57; resulted: 19:50 April 28, 2024 Patient 9078172 ordered: 18:37; resulted: 19:14 5. In interview on June 24, 2024 at 3:52 pm, the Respiratory Manager, stated the laboratory does not document the actual time of collection. The laboratory utilized the result time for the collection and receive times. The Respiratory Manager stated the laboratory monitors the order time and result time to ensure the result is reported in less than sixty (60) minutes. The Respiratory Manager stated the time of collection to test time is not monitored.
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 review of the laboratory's quality assessment monitors and interview with personnel, the laboratory failed to ensure their monitors identified issues within the analytic system. Findings: 1. Review of the laboratory's "Performance Improvement" form revealed the laboratory monitors the following items monthly: a) Total number of arterial blood gas (ABG) samples b) Number of critical ABG's reported c) Turn-around time (Time ordered- time out of machine) d) Number of critical test results not reported in fifteen (15) minutes e) ABG not performed in 60 minutes f) Number critical test results without documentation g) Number of Allen tests not documented h) Complete audit of ABG reports i) Number of temperature and humidity corrective actions reported j) Proficiency Testing k) Number of annual competencies completed 2. Further review of the laboratory's "Performance Improvement" form revealed the laboratory's monitors did not identify the following issue within the analytic system: The laboratory failed to test blood gas samples within thirty (30) minutes of collection per manufacturer requirements for four (4) of ten (10) patients. Refer to D5411. 3. In interview on June 24, 2024 at 3:52 pm, the Respiratory Manager stated the laboratory

	monitors the order time and result time to ensure the result is reported in less than sixty (60) minutes. The Respiratory Manager stated the time of collection to test time is not monitored.
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, record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5411.
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 personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.

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 have a written corrective action policy for temperatures that were outside of the established acceptable limits. Refer to D5401. 2. The laboratory failed to test blood gas samples within thirty (30) minutes of collection per manufacturer requirements for four (4) of ten (10) patients. Refer to D5411.