Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0707823	02/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Franklin Medical Center - Resp	2106 Loop Road, Winnsboro, 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 Certification Survey was conducted on February 5, 2018 at Franklin Medical Center-CLIA ID # 19D0707823. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard 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 policy and procedure manual and interview with personnel, the laboratory failed to have a policy for Proficiency Testing. Findings: 1. Review of the laboratory policy and procedure manual revealed there was no policy or detailed instructions for Proficiency Testing (PT) to include, but not limited to: *Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) what steps to take if corrective action is needed. h) How to handle PT failures. 2. Interview with Personnel 2 on February 5, 2018 confirmed there was no policy for PT testing.
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 review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to follow the maufacturer's instructions for sample timing for Arterial Blood Gas (ABG) testing. Findings: 1. Review of the policy and procedure manual revealed the laboratory did not have a policy for sample timing. 2. Further review of the manufacturer's instructions under "Sample Timing" revealed "As a common practice, a sample will not need to be iced if it is analyzed within 5 minutes or 15 minutes". 3. Review of a random selection of patients from December 24, 2016 through December 15, 2017 revealed the following eleven (11) of twenty five (25) patients were resulted over the manufacturer's instructions to be analyzed within 15 minutes: a) December 24, 2016 - Patient 2 collected at 600; resulted at 633 - 18 minutes over the manufacturer requirements b) December 25, 2016 - Patient 3 collected at 2248; resulted at 2309 - 6 minutes over the manufacturer requirements c) December 25, 2016 - Patient 4 collected at 2211; resulted at 2231 - 5 minutes over the manufacturer requirements d) March 8, 2017 - Patient 6 collected at 1257; resulted at 1314 - 2 minutes over the manufacturer requirements e) March 11, 2017 - Patient 9 collected at 1237; resulted at 1256 - 4 minutes over the manufacturer requirements f) September 21, 2017 - Patient 11 collected at 1354; resulted at 1436 - 27 minutes over the manufacturer requirements g) November 2, 2017 - Patient 19 collected at 1209; resulted at 1240 - 16 minutes over the manufacturer requirements h) December 14, 2017 - Patient 22 collected at 1012; resulted at 1042 - 15 minutes over the manufacturer requirements i) December 14, 2017 - Patient 23 collected at 2027; resulted at 2059 - 17 minutes over the manufacturer requirements j) December 15, 2017 - Patient 24 collected at 920; resulted at 1000 - 25 minutes over the manufacturer requirements k) December 15, 2017 - Patient 25 collected at 1107; resulted at 1134 - 12 minutes over the manufacturer requirements 4. Interview with Personnel 2 confirmed the above patients were resulted over the 15 minutes required by the manufacturer.
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 record review and interview with personnel, the laboratory failed to verify performance specification studies after moving the analyzer to a new location. Findings: 1. Observation by surveyors on February 5, 2018 revealed the laboratory utilizes the Instrumentation Laboratory GEM Premier 3500 analyzer for Arterial Blood Gas (ABG) testing. 2. Interview with Personnel 2 on February 5, 2018 at 105pm revealed the laboratory moved the analyzer from the Respiratory Department

	located on the second floor to the current location on the first floor on January 19, 2018. 3. Review of a random selection of patients revealed the following five (5) patients were tested and reported without assuring the performance specifications were verified for the Instrumentation Laboratory GEM Premier 3500 ABG analyzer. Findings: a) Patients 21 - 23 on December 14, 2018 b) Patients 24 - 25 on December 15, 2018 4. Interview with Personnel 2 on February 5, 2018 confirmed the laboratory did not verify the accuracy, precision, reportable, and reference ranges prior to patient testing after the relocation of the analyzer. 6. Review of the Task 1 & 3 provided by the laboratory revealed that one thousand six hundred ninety five (1695) Arterial Blood Gas (ABG) tests are performed annually.
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, record review, and interview with personnel, the laboratory failed to to have a complete Individualized Quality Control Plan (IQCP) to reduce of the frequency of quality control (QC) for arterial blood gas testing. Findings: 1. Observation by surveyor during the laboratory tour on February 5, 2018 revealed the laboratory utilizes the Instrumentation Laboratory GEM Premier 3500 analyzer for arterial blood gas (ABG) testing. 2. Review of the laboratory's IQCP binder revealed historic raw data to include maintenance and quality control. The Risk Assessment data included did not identify and evaluate potential failures for Specimen, Test System, Regaent, Environment and Testing Personnel throughout the entire testing process. 3. Further review of the IQCP binder revealed the laboratory did not have thirty (30) consecutive days to support the reduction of ABG QC frequency to monthly. 4. In interview on February 15, 2018, Personnel 2 stated the laboratory followed the IQCP booklet but was unsure how to present the data. Personnel 2 confirmed the laboratory did not have a complete IQCP. 5. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs one thousand six hundred ninety five (1695) arterial blood gas tests annually.
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: Based on observation, record review, and interview with personnel, the laboratory's

	Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems found in the analytic systems as follows: a) The laboratory failed to have a policy for Proficiency Testing. Refer to D5401. b) The laboratory failed to follow the maufacturer's instructions for sample timing for Arterial Blood Gas (ABG) testing. Refer to D5411. c) The laboratory failed to verify performance specification studies after moving the analyzer to a new location. Refer to D5421. d) The laboratory failed to to have a complete Individualized Quality Control Plan (IQCP) to reduce of the frequency of quality control (QC) for arterial blood gas testing. Refer to D5445.
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 laboratory 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, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5411.
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, record review, and interview with personnel, the Laboratory Director failed to ensure the quality control program was maintained to assure quality laboratory services were provided. Refer to D5445.
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, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5791.
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 responsible for any aspect of the testing process. Refer to D5401.