Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0874986	(X3) Date Survey Completed 08/08/2019
Name of Provider or Supplier St Helena Parish Hospital-Respiratory	**Street Address, City, State** 16874 Hwy 43, Greensburg, 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 performed on August 8, 2019 at St. Helena Parish Hospital-Respiratory, CLIA ID # 19D0874986. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 record review and interview with personnel, the laboratory failed to follow their established competency assessment policy for testing personnel. Findings: 1. Review of the laboratory's "Employee Competency Evaluations" policy "Any new hire respiratory employee will undergo an initial competency as part of department orientation and again with their 90 day evaluation." 2. In interview on August 8, 2019 at 9:49 am, the Respiratory Director stated Testing Personnel 7 was hired in November 2018. 3. Review of personnel records for Testing Personnel 7 revealed the initial assessment was completed February 25, 2019 and the ninety (90) day evaluation was completed February 14, 2019. 4. In interview on August 8, 2019, the Respiratory Director confirmed the 90 day evaluation was performed prior to the initial assessment.
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 have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Findings: 1 Observation by surveyor during the laboratory tour on August 8, 2019 revealed the laboratory utilized the EPOC analyzer for blood gas testing. 2. Review of the laboratory's IQCP Quality Control Plan revealed "Testing of appropriate QC material, level 1 and 3 in duplicate, on each new lot/shipment of test cards before or concurrently placing these materials into use for patient's specimens; and subsequently on the first of every month." 3. Review of the laboratory's IQCP documents revealed the laboratory did not include in-house data to support the reduction in frequency of external QC to monthly. 3. In interview on August 8, 2019 at 9:52 am, the Respiratory Director stated liquid controls level 1 and 3 are tested once a month and new lot/shipment of test cards. 4. In further interview on August 8, 2019, the Respiratory Director confirmed the laboratory did not have in-house QC data to support the QC reduction to monthly. The Respiratory Director stated the laboratory had ten (10) consecutive days of QC data.
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 that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D5445.
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 policies and procedures for assessing personnel competency were maintained. Refer to D5209.