Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0701211	05/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northern Louisiana Medical Center Respiratory Care	401 E Vaughn Street, Ruston, 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 conducted at Northern Louisiana Medical Center Respiratory-CLIA ID # 19D0701211 on May 13, 2019. 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 record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory did not have detailed instructions for: a) Downtime Policies and Procedures for when test systems are inoperable. 2. In interview on May 13, 2019 at 13:24 pm, Personnel 4 confirmed the policy and procedure manual was incomplete.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test

	results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate 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 document corrective actions performed when the relative humidity was not maintained at 20 % to 80 %. Findings: 1. Review of the laboratory's "Temperature and Daily ABG Maintenance Log" revealed the acceptable range for relative humidity is 20% to 80%. 2. Further review of the "Temperature and Daily ABG Maintenance Log" revealed the following: "Correction Action: If temperature is out of range, call maintenance and the Respiratory Director and/or Lead Therapist to report issue. If temperature, humidity, or barometric pressure exceeds limits no patient results will be reported until environmental conditions are back in range and instrument working correctly. Document corrective action taken per occurrence on the reverse side of this report." 3. Review of the humidity logs for January 2018 revealed the relative humidity was outside of acceptable limits without corrective action documentation for the following three (3) dates: January 1, 2018: recorded humidity 19% January 2, 2018: recorded humidity 18% January 3, 2018: recorded humidity 18% 4. Review of patient reports for January 1, 2018 through January 3, 2018 revealed the following thirty (30) patients were reported without corrective action being performed: a) Patient 8567457 on January 2, 2018 b) Patient 8567078 on January 2, 2018 c) Patient 8567597 on January 3, 2018 d) Patient 8567563 on January 3, 2018 e) Patient 8567450 on January 2, 2018 f) Patient 8567450 on January 3, 2018 g) Patient 8567516 on January 3, 2018 h) Patient 8567313 on January 2, 2018 i) Patient 8567313 on January 1, 2018 j) Patient 8567503 on January 2, 2018 k) Patient 8564657 on January 1, 2018 l) Patient 8564657 on January 3, 2018 m) Patient 8564657 on January 1, 2018 n) Patient 8566858 on January 2, 2018 o) Patient 8567318 on January 1, 2018 p) Patient 8567484 on January 3, 2018 q) Patient 8567484 on January 2, 2018 r) Patient 8567484 on January 2, 2018 s) Patient 8567484 on January 3, 2018 t) Patient 8566837 on January 2, 2018 u) Patient 8566913 on January 3, 2018 v) Patient 8566913 on January 3, 2018 w) Patient 8566913 on January 3, 2018 x) Patient 8567523 on January 3, 2018 y) Patient 8567291 on January 2, 2018 z) Patient 8567291 on January 2, 2018 aa) Patient 8567291 on January 1, 2018 bb) Patient 8567291 on January 1, 2018 cc) Patient 8567291 on January 1, 2018 dd) Patient 8567291 on January 1, 2018 5. In interview on May 13, 2019 at 02:38 pm, Personnel 4 stated she did not find any documentation that corrective action for relative humidity was performed on the above dates. Personnel 4 confirmed that the corrective action was not performed and the above patients were resulted.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.
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.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5781.