Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1015749	06/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Acadia-St Landry Hospital	810 South Broadway St, Church Point, 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 on June 21, 2021 through June 25, 2021 at Acadia St. Landry Hospital-Respiratory, CLIA ID # 19D1015749. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 validation records, test menu, and interview with personnel, the laboratory failed to have complete performance verification studies for the Nova Biomedical Stat Profile Prime blood gas analyzer. Findings: 1. Observation by surveyor during laboratory tour on June 21, 2021 at 11:08 am revealed the laboratory utilizes the Nova Biomedical Stat Profile Prime analyzer for blood gas testing. 2. In interview on June 21, 2021 at 10:40 am, the Respiratory Manager stated the laboratory has utilized the Nova Biomedical Stat Profile prime instrument for blood gas testing for patient testing since June 2020. The Laboratory Director reviewed/approved the "Verification of Performance Specifications" studies on June 3, 2020. 3. Review of the laboratory's summary page, received on June 21, 2021, for the verification of performance specifications (validation) revealed the following: a) " Accuracy was verified by testing quality control materials over time (minimum 20 days)." b) "Precision was verified by day to day (minimum 20 samples

	of each level of external and internal quality control material analyzed once per day) and within day (10 samples of each level of quality control material analyzed in one day) quality control analysis. 4. Review of the laboratory's validation summary page received on June 23, 2021, which differed from the summary presented to surveyor on June 21, 2021, revealed the following: a) "Accuracy was verified by testing quality control materials over time (minimum 20 days)." b) "Precision was verified by day to day (minimum 20 samples of each level of external and internal quality control material analyzed once per day) and within day (5 samples of each level of quality control material analyzed in one day) quality control analysis." 5. Review of the laboratory's validation studies revealed the the laboratory did not include the following: a) Accuracy: raw data to include the minimum number of samples /frequency indicated in the laboratory's summary b) Precision (including run to run, day to day, within run, operator variance): raw data to include the minimum number of samples/frequency indicated in the laboratory's summary The raw data presented to surveyor did not match either of the laboratory's validation summary procedures. 6. In interview on June 23, 2021 at 10:00 am the Technical Consultant stated via telephone that there may have been an error in the number of samples used for the accuracy and precision studies. The Technical Consultant further stated there should have been a spreadsheet included. 7. Review of the laboratory's test menu revealed the laboratory performs 159 blood gas tests 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 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) for blood gas testing. Findings: 1. In interview on June 21, 2021 at 10:40 am, the Respiratory Manager stated the laboratory has utilized the Nova Biomedical Stat Profile prime instrument for blood gas testing for patient testing since June 2020. 2. Review of the laboratory's IQCP documents revealed the laboratory did not include the following: a) Quality Assessment Plan specific to the laboratory's location and frequency of review 3. Further review of the laboratory's IQCP Quality Assessment Plan revealed the plan was for a hospital in a neighboring city, not the laboratory's respiratory department. 4. In interview on June 23, 2021 at 10:00 am the Respiratory Manager confirmed the laboratory's IQCP Quality Assessment Plan did not include frequency of review and not specific to their laboratory. 5. Review of the laboratory's test menu revealed the laboratory performs 159 blood gas tests annually.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of policies, manufacturer instructions, temperature/humidity logs, and interview with personnel, the laboratory failed to perform and document corrective actions when the room humidity was not maintained within acceptable range for nine (9) of twenty eight (28) days in February 2021. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a policy related to corrective actions for unacceptable room temperature/humidity readings. 2. Review of the laboratory's temperature/humidity log revealed the following acceptable humidity range: "20-85 % without condensation." 3. Review of the manufacturer's instructions for the Nova Biomedical Stat Profile Prime blood gas analyzer revealed the following: "Operate at humidity 20-85 % without condensation." 4. Review of the laboratory's temperature/humidity log for February 2021 revealed the room humidity was documented as outside of acceptable limits without corrective actions performed for the following nine (9) dates: a) February 2, 2021: documented room humidity 19 % b) February 3, 2021: documented room humidity 19 % c) February 14, 2021: documented room humidity 17 % d) February 15, 2021: documented room humidity 17 % e) February 16, 2021: documented room humidity 10 % f) February 17, 2021: documented room humidity 16 % g) February 18, 2021: documented room humidity 18 % h) February 19, 2021: documented room humidity 18% i) February 20, 2021: documented room humidity 17 % 5. In interview on June 21, 2021 at 11:15 am, the Respiratory Manager confirmed the laboratory did not perform corrective action for the identified dates.
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 by surveyor, review of the laboratory's policies, validation records, temperature/humidity logs, quality assurance records, and interview with personnel, the laboratory failed to follow and maintain their established quality assurance (QA) plan to identify issues within the analytic system. Findings: 1. Review of the laboratory's "Quality Assessment" polices revealed the following: "Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the other non-laboratory areas or departments of the facility of which it is a part." 2. Further review of the laboratory's "Quality Assessment" polices revealed the following forms: a) "Specimen Collection/Requisition Deficiency Report" b) "Effectiveness of Corrective Actions Form Pre-Analytical" c) " Quality Control Outliers Form" d)" Effectiveness of Corrective Actions Form Analytical" e) "Corrected Laboratory Report Form" f)" Effectiveness of Corrective Actions Form Post-Analytical" g) "Quality Assessment

	Sheet" that included "Pre-analytic, Analytic, and Post-Analytic" sections, which included the following monitors: specimen handling, requisition deficiency, effectiveness of corrective action, specimen and reagent storage, maintenance, quality control, effectiveness of corrective action, accuracy of test report, panic values, TAT, effectiveness of corrective action 3. Review of the laboratory's 2020 and 2021 QA records revealed the laboratory utilized a "Monthly Review of Respiratory Department by the Technical Consultant" form, not the "Quality Assessment" related forms identified with the policy. 4. Further review of the "Monthly Review of Respiratory Department by the Technical Consultant" form revealed the following monitors were included: a) Instrument Maintenance and Reagent Storage b) Quality Control Review c) Patient Testing Review d) Personnel Competency Assessment & Licensure Review e) Calibration Verification Review f) Proficiency Testing Review g) Policy and Procedure Review 5. Further review of the "Monthly Review of Respiratory Department by the Technical Consultant" forms revealed the laboratory did not have documentation of QA review for January through July 2020 and January 2021. 6. In interview on June 22, 2021 at 10:06 am the Respiratory Manager stated the Technical Consultant was not allowed into the hospital January through July 2020. The Respiratory Manager stated the Technical Consultant may have been out on leave during January 2021. The Respiratory Manager further stated the "Monthly Review of Respiratory Department by the Technical Consultant" form is the only QA review that she knows is done, not the previously identified forms included with the laboratory's policy. 7. Observation by surveyor, review of the laboratory's policies, validation records, temperature/humidity logs, quality assurance records revealed the laboratory did not identify the following issues within the analytic system: a) The laboratory failed to have complete performance verification studies for the Nova Biomedical Stat Profile Prime blood gas analyzer. Refer to D5421. b) The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Refer to D5445. c) The laboratory failed to perform and document corrective actions when the room humidity was not maintained within acceptable range for nine (9) of twenty eight (28) days in February 2021. Refer to D5785.
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.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established 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, 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.
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 D5785.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Refer to D5445.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on observation, 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 D5785.