Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1015749	12/06/2018
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 CERTIFICATION SURVEY was performed at Acadia St Landry Hospital - Respiratory - CLIA # 19D1015749 on December 3, 2018 through December 6, 2018. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to label control material for the Abbott iSTAT 1 analyzer with expiration dates for proper use. Findings: 1. Observation by surveyor during the laboratory tour on December 3, 2018 revealed the laboratory utilizes the Abbott iSTAT 1 analyzer with i-STAT Control Levels 1 and 3 stored at 2 to 8 degrees celsius for blood gas testing. 2. Review of the i-STAT package insert for Quality Control under "Storage" revealed "Refrigerated storage at 2 to 8 degrees celsius should be maintained until the printed expiration date on the box and ampule labels. Control solutions may also be stored at room temperature for up to 5 days (18 to 30 degrees celsius)". 3. Further observation by surveyor revealed the laboratory did have Quality Control (QC) ampules placed at room temperature with a date written; However, the laboratory did not label the ampules to specify the date in which QC material was removed from the refrigerator and placed at room temperature for the following controls: i-STAT Level 1 Control Lot # 101104 (2 vials) i-STAT Level 3 Control Lot # 121104 (2 Vials) 4. In interview on December 4, 2018 at 2:28 pm, Personnel 3 stated the date written on the

	ampules was the expiration date but it does not specify when they are taken out of the refrigerator. Personnel 3 confirmed the laboratory did not label the control materials as needed.
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, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5415