

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0463292	(X3) Date Survey Completed 01/11/2019
Name of Provider or Supplier Springhill Medical Center	Street Address, City, State 2001 Doctors Drive, Springhill, 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 January 7, 2019 through January 11, 2019 at Springhill Medical Center-Respiratory - CLIA ID # 19D0463292. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>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 failed to have policies and procedures</p>

for: * Performance specifications for Laboratory Instrumentation to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges. b) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges. c) Policies and procedures for when data from the studies for precision, accuracy, reportable and reference ranges fail to meet acceptability criteria. 2. Interview with Personnel 1 and 6 on January 8, 2019 at 11:05 am confirmed the laboratory did not have a complete policy and procedure manual.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview with personnel, the laboratory failed to document the ambient temperature where blood gas testing is performed. Findings: 1. Observation by surveyor during laboratory tour on January 7, 2019 revealed the laboratory utilizes the Abbott iSTAT analyzer for blood gas testing. 2. Review of the laboratory's Refrigerator Log revealed the laboratory did not document the ambient temperature (64-86 degrees fahrenheit) as required for the following two (2) of one hundred two (102) days reviewed: a) August 22, 2017 b) October 19, 2017 3. In interview on January 8, 2019 at 9:37 am, Personnel 1 stated the laboratory has to switch to ambient temperature from the refrigerator temperature on the digital thermometer in use. Personnel 1 confirmed the ambient temperature was not documented for the above dates.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview with personnel, the laboratory failed to document the iSTAT electronic simulator results as required by laboratory policy. Findings: 1. Observation by surveyor during the laboratory tour on January 7, 2019 revealed the laboratory utilized an iSTAT analyzer for Arterial Blood Gas (ABG) testing. 2. Further review of the Refrigerator Log revealed the laboratory did not document electronic simulator for the following four (4) of one hundred two (102) days reviewed: a) February 28, 2017 b) October 19, 2017 c) November 26, 2017 d) September 2, 2018 3. Review of patient records revealed the laboratory performed the

	<p>following three (3) patients for the above mentioned dates: a) Patient 1 - ABG resulted on September 2, 2018 at 10:55 am b) Patient 2 - ABG resulted on September 2, 2018 at 07:42 am c) Patient 3 - ABG resulted on November 26, 2017 at 09:28 am 4. In interview on January 8, 2019 at 09:37 am, Personnel 1 stated the iSTAT analyzer cannot perform patient testing unless the electronic simulator is performed. Personnel 1 confirmed the laboratory did not document the electronic simulator and patients were resulted for the above dates.</p>
<p>D5793</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues. Findings: 1. The laboratory failed to document the ambient temperature where blood gas testing is performed. Refer to D5413. 2. The laboratory failed to document the iSTAT electronic simulator results as required by laboratory policy. Refer to D5431.</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>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.</p> <p>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. Findings: 1. The laboratory failed to document the ambient temperature where blood gas testing is performed. Refer to D5413. 2. The laboratory failed to document the iSTAT electronic simulator results as required by laboratory policy. Refer to D5431.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p>

	<p>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. Refer to D5793.</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>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;</p> <p>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 an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document personnel competency annually. Findings: 1. Review of Laboratory Personnel Report (Form 209) revealed that Personnel 6 serves as Laboratory Director and Technical Consultant. 2. Review of personnel records for the respiratory staff revealed Personnel 1 performed annual competency assessments in 2017 and 2018 for the respiratory staff; However, upon review of the personnel records for Personnel 1, he does not qualify as Technical Consultant. 3. In interview on January 8, 2019 at 09:11 am, Personnel 6 stated he signs the competency assessment forms for each personnel but he does not perform the assessments. Personnel 6 confirmed he did not perform the competency assessments for 2017 and 2018.</p>