

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0881447	(X3) Date Survey Completed 12/07/2018
Name of Provider or Supplier Leonard J Chabert Medical Center Respiratory	Street Address, City, State 1978 Industrial Boulevard, Houma, 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 performed at Leonard J. Chabert Medical Center, Respiratory-CLIA # 19D0881447 on December 3 through 7, 2018. Leonard J. Chabert Medical Center, Respiratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1421: Laboratories performing moderate complexity testing; Testing Personnel
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director signed the attestation statement for one (1) of five (5) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's College of American Pathologists (CAP) proficiency records for 2017 and 2018 revealed the Laboratory Director did not sign the attestation statement for the following event: 2018 Blood Oximetry 1st Event SO-A 2. In interview on December 5, 2018 at approximately 1:00 pm, Personnel 2 stated it was an oversight that the Laboratory Director did not sign the identified attestation statement.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the laboratory failed to document the review of the performance evaluation for proficiency testing. Findings: 1. Review of the laboratory's College of American Pathologists (CAP) proficiency records for 2017 and 2018 revealed the laboratory did not have documentation of a performance evaluation by the Laboratory Director for the following event: 2018 Blood Oximetry SO-B. 2. In interview on December 5, 2018 at approximately 1:00 pm, Personnel 2 stated it was an oversight that the Laboratory Director did not sign the identified evaluation form.

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, record review, and interview with personnel, the laboratory failed to perform complete reference range studies for the GEM 4000 Premier analyzers. Findings: 1. Observation by surveyor during laboratory tour on December 3 revealed the laboratory utilizes two (2) GEM 4000 Premier analyzers for blood gas testing. 2. In interview on December 5, 2018 at 3:30 pm, Personnel 2 stated the reference ranges in use were from a study previously performed and utilized with previous analyzer. 3. Review of the laboratory's performance verification studies revealed the reference range studies did not include documentation of verification of the normal values for use with the GEM 4000 Premier analyzers. 4. In further interview on December 5, 2018 at 3:30 pm, Personnel 2 stated the laboratory did not perform any further studies before putting the previous reference ranges into use.

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 December 3, 2018 revealed the laboratory utilized two (2) GEM 4000 Premier analyzers for blood gas testing. 2. 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. 3. Further review of the laboratory's IQCP Quality Assessment Plan revealed "The IQCP will be reviewed annually for new occurrences, frequency of occurrences, and changes of severity;" however, there was not documentation of performance of an annual review. 4. In interview on December 3, 2018 at 1:39 pm, Personnel 2 stated the laboratory runs external QC, CVP solutions, when cartridge is changed, approximately every twenty eight (28) days. 5. In further interview on December 5, 2018, Personnel 2 stated the laboratory only tests the external QC with cartridge changes. 6. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 10, 632 blood gas tests annually.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D6018. 3. The Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D6020.

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, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. The laboratory failed to ensure the Laboratory Director signed the attestation statement for one (1) of five (5) proficiency testing (PT) events reviewed. Refer to D2009. 2. The laboratory failed to document the review of the performance evaluation for proficiency testing. Refer to D5211.

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 the quality control was maintained to assure quality laboratory services were provided. Refer to D5445.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure testing personnel performing moderate complexity testing met educational requirements. Refer to D6065.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to provide documentation of individuals who meet the qualification requirements to perform the functions specified in a lab of moderate complexity. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for five (5) of twenty four (24) testing personnel. Findings: 1. Review of personnel records on December 5, 2018 revealed the laboratory failed to maintain documentation of at least a High School Diploma or equivalent for the following five (5) personnel: Personnel 3 Personnel 4 Personnel 5 Personnel 6 Personnel 7 2. Review of the laboratory's "Blood Gas Procedure Arterial Puncture Approval" policy revealed "personnel must hold a High School Diploma." 3. In interview on December 5, 2018 at 12:52 pm, Personnel 2 stated for respiratory therapist who studied in the '80's and early '90's a certificate was issued. Personnel 2 further stated their accreditation organization informed the laboratory that certificates alone were not acceptable to include the transcript to show classes taken.