

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2113367	(X3) Date Survey Completed 05/29/2019
Name of Provider or Supplier Cardiovascular Outpatient Center Of Southwest La	Street Address, City, State 401 Dr Michael Debaker Dr, Suite 300, Lake Charles, 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 Cardiovascular Outpatient Center of Southwest Louisiana-CLIA ID # 19D2113367 on May 28, 2019 through May 29, 2019. Cardiovascular Outpatient Center of Southwest Louisiana was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1421 CONDITION: Laboratories performing moderate complexity testing; Testing Personnel
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to perform quality control as required by laboratory policy on the Avoximeter 1000E analyzer. Findings: 1. Observation by surveyor during the laboratory tour on May 29, 2019 revealed the laboratory utilizes the Avoximeter 1000E analyzer for O2 Saturation (O2 Sat) and Hemoglobin (Hgb) testing. 2. In interview on May 29, 2019, the facility representative stated the outpatient surgery center is open on Mondays and Thursday while the outpatient center is open on Tuesday, Wednesday, and Friday. 3. Review of the "Quality Control and Assessment" policy revealed the laboratory "Run the Level 1 and Level 3 (CVCxxxxxx) controls once per month, and Level 2 once per week and after any significant maintenance has been performed". 4. Review of the laboratory's "AVOX Weekly and New Cartridge Lot Control Log" records for January</p>

2018 through May 2019 revealed the laboratory did not perform quality control (QC) as required by laboratory policy for the following: a) January 2018 * Level 2 not performed for weekly requirement on following: January 1, 2018 through January 5, 2018 January 8, 2018 through January 12, 2018 January 15, 2018 through January 19, 2018 January 22, 2018 through January 26, 2018 January 29, 2018 through February 2, 2018 b) February 2018 * Level 1 and Level 3 not performed for monthly requirement * Level 2 not performed for weekly requirement on following: February 5, 2018 through February 9, 2018 February 12, 2018 through February 16, 2018 February 19, 2018 through February 23, 2018 February 26, 2018 through March 2, 2018 c) March 2018 * Level 1 and Level 3 not performed for monthly requirement * Level 2 not performed for weekly requirement on following: March 5, 2018 through March 9, 2018 March 12, 2018 through March 16, 2018 March 19, 2018 through March 23, 2018 March 26, 2018 through March 30, 2018 d) April 2018 * Level 1 and Level 3 not performed for monthly requirement * Level 2 not performed for weekly requirement on following: April 2, 2018 through April 6, 2018 April 9, 2018 through April 13, 2018 April 16, 2018 through April 20, 2018 April 23, 2018 through April 27, 2018 e) May 2018 * Level 2 not performed for weekly requirement on following: April 30, 2018 through May 4, 2018 May 7, 2018 through May 11, 2018 May 14, 2018 through May 18, 2018 May 21, 2018 through May 25, 2018 May 28, 2018 through June 1, 2018 f) June 2018 * Level 2 not performed for weekly requirement on following: June 4, 2018 through June 8, 2018 June 11, 2018 through June 15, 2018 June 18, 2018 through June 22, 2018 June 25, 2018 through June 29, 2018 g) July 2018 * Level 1 and Level 3 not performed for monthly requirement * Level 2 not performed for weekly requirement on following: July 2, 2018 through July 6, 2018 July 9, 2018 through July 13, 2018 July 16, 2018 through July 20, 2018 July 23, 2018 through July 27, 2018 July 30, 2018 through August 3, 2018 h) August 2018 * Level 2 not performed for weekly requirement on following: August 6, 2018 through August 10, 2018 August 13, 2018 through August 17, 2018 August 20, 2018 through August 24, 2018 August 27, 2018 through August 31, 2018 i) September 2018 * Level 2 not performed for weekly requirement on following: September 3, 2018 through September 7, 2018 September 10, 2018 through September 14, 2018 September 17, 2018 through September 21, 2018 September 24, 2018 through September 28, 2018 j) October 2018 * Level 1 and Level 3 not performed for monthly requirement * Level 2 not performed for weekly requirement on following: October 1, 2018 through October 5, 2018 October 8, 2018 through October 12, 2018 October 15, 2018 through October 19, 2018 October 22, 2018 through October 26, 2018 October 29, 2018 through November 2, 2018 k) November 2018 * Level 2 not performed for weekly requirement on following: November 5, 2018 through November 9, 2018 November 12, 2018 through November 16, 2018 November 19, 2018 through November 23, 2018 November 26, 2018 through November 30, 2018 l) December 2018 * Level 1 and Level 3 not performed for monthly requirement * Level 2 not performed for weekly requirement on following: December 3, 2018 through December 7, 2018 December 10, 2018 through December 14, 2018 December 17, 2018 through December 21, 2018 December 24, 2018 through December 28, 2018 m) January 2019 * Level 2 not performed for weekly requirement on following: December 31, 2018 through January 4, 2019 January 7, 2019 through January 11, 2019 January 14, 2019 through January 18, 2019 January 21, 2019 through January 25, 2019 January 28, 2019 through February 1, 2019 n) February 2019 * Level 2 not performed for weekly requirement on following: February 4, 2019 through February 8, 2019 February 11, 2019 through February 15, 2019 February 18, 2019 through February 22, 2019 February 25, 2019 through March 1, 2019 o) March 2019 * Level 2 not performed for weekly requirement on following: March 4, 2019 through March 8, 2019 March 11, 2019 through March 15, 2019 March 18, 2019 through March 22, 2019 March 25,

	<p>2019 through March 29, 2019 p) April 2019 * Level 1 and Level 3 not performed for monthly requirement * Level 2 not performed for weekly requirement on following: April 1, 2019 through April 5, 2019 April 8, 2019 through April 12, 2019 April 15, 2019 through April 19, 2019 April 22, 2019 through April 26, 2019 April 29, 2019 thorough May 3, 2019 q) May 2019 * Level 2 not performed for weekly requirement on following: May 6, 2019 through May 10, 2019 May 13, 2019 through May 17, 2019 May 20, 2019 through May 24, 2019 May 27, 2019 through May 31, 2019 5. In interview on May 29, 2019 at 11:54 am, the facility representative stated the facility shares the Avoximeter 1000E analyzer with the outpatient clinic which operates on different days. The facility representative further stated the QC was performed but not as required for each facility. 6. In interview on May 29, 2019, the facility representative confirmed QC was not performed as required by laboratory policy. 7. Review of the Task 1 & 3 forms provided to surveyors revealed the laboratory performs 120 O2 Sat/Hgb tests annually.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>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 the quality control program was maintained to assure quality laboratory services were provided. Refer to D6014. 2. The Laboratory Director failed to ensure laboratory personnel performing moderate complexity testing met state of Louisiana licensure and educational requirements. Refer to D6029.</p>
<p>D6020</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 the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the quality control program was maintained to assure quality laboratory services were provided. Refer to D5447.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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</p>

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 laboratory personnel performing moderate complexity testing met state of Louisiana licensure and educational requirements. Findings: 1. The laboratory failed to ensure five (5) of five (5) testing personnel met the state of Louisiana licensure requirement. Refer to D6064. 2. The laboratory failed to provide documentation that one (1) of five (5) testing personnel reviewed met the educational qualifications for performing moderate complexity testing. 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 the laboratory failed to provide documentation of current state licenses and education for individuals performing moderate complex testing. Findings: 1. The laboratory failed to ensure five (5) of five (5) testing personnel met the state of Louisiana licensure requirement. Refer to D6064. 2. The laboratory failed to provide documentation that one (1) of five (5) testing personnel reviewed met the educational qualifications for performing moderate complexity testing. Refer to D6065.

D6064

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the laboratory failed to ensure five (5) of five (5) testing personnel met the state of Louisiana licensure requirement. Findings: 1. Review of personnel records revealed the following personnel did not meet the State of Louisiana (R. S. 37:131 -1329 "Louisiana Clinical Laboratory Personnel Law" requirement: Personnel 2: no documentation of issued license Personnel 3: no documentation of issued license Personnel 4: no documentation of issued license Personnel 5: no documentation of issued license Personnel 6: no documentation of issued license 2. In interview on May 28, 2019 at 9:51 am, the facility representative confirmed the above personnel did not have a state of Louisiana license for laboratory testing.

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 one (1) of five (5) testing personnel reviewed met the educational qualifications for performing moderate complexity testing. Findings: 1. Review of personnel records on May 28, 2019 revealed the laboratory did not maintain documentation of at least a High School Diploma or equivalent for the following personnel: Personnel 5 2. In interview on May 28, 2019 at 9:51 am, the facility representative confirmed the laboratory did not maintain documentation of education for Personnel 5.