

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2190954	<b>(X3) Date Survey Completed</b>  02/05/2021
<b>Name of Provider or Supplier</b>  Lung Bioengineering Inc (Lb2)	<b>Street Address, City, State</b>  14221 Kendall Hench Circle, 1st Floor, Jacksonville, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial survey was conducted on 1/5/21-2/5/21. Lung Bioengineering Inc was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D6076</b>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory director failed to provide oversight of the laboratory by ensuring all staff met the qualifications of high complexity testing. See D6102</p>
<b>D6102</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must 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.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview, review of the CMS form 209, testing log, and personnel college transcripts, it was determined the Laboratory Director failed to ensure 3 (#B, C, E) of five (#A - #E) testing persons were qualified to perform high complexity</p>

testing prior to reporting results. The testing performed was pH, pCO<sub>2</sub>, pO<sub>2</sub>, Glucose, and Lactate. Findings include: The CMS form 209, Laboratory Personnel Report (CLIA), signed and dated by the director on 1/1/21, indicated there were five employees (#A-E) who performed high complexity testing. Interview with the Quality Assurance Manager on 1/5/21 at 10:00am revealed that testing person #A has a Masters degree in Biomedical Science, #B & #C have an Associates Degree in Surgical Technology, #D has an Associates Degree in Nursing, and testing person #E has a Bachelors Degree in Nuclear Engineering. After review of the college transcripts provided on 1/27/21, it was determined that testing persons #B, C, and E do not meet the requirements of 42 CFR 493.1489(b)(2)(ii). The review of the testing logs dated 12/2/20, 12/30/20, 1/1/21, and 1/12/21 indicated testing persons #B & #C performed sample testing of pH, pCO<sub>2</sub>, pO<sub>2</sub>, Glucose, and Lactate.

**D6168**

**TESTING PERSONNEL**  
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:  
Based on staff interview, review of the CMS form 209 Laboratory Personnel Report (CLIA), and personnel college transcripts, the laboratory failed to ensure three (#B, #C, #E) of five (#A - E) testing persons met the required qualifications for high complexity testing. (See D6171).

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training

program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on staff interview and review of the CMS form 209 and personnel college transcripts, it was determined the laboratory failed to ensure 3 (#B, C, E) of five (#A - #E) testing persons were qualified to perform high complexity testing. The testing performed was pH, pCO<sub>2</sub>, pO<sub>2</sub>, Glucose, and Lactate Findings include: The CMS form 209, Laboratory Personnel Report (CLIA), signed and dated by the director on 1/1/21, indicated there were five employees (#A-E) who performed high complexity testing. Interview with the Quality Assurance Manager on 1/5/21 at 10:00am revealed that testing person #A has a Masters degree in Biomedical Science, #B & #C have an Associates Degree in Surgical Technology, #D has an Associates Degree in Nursing, and testing person #E has a Bachelors Degree in Nuclear Engineering. After review of the college transcripts provided on 1/27/21, it was determined that testing persons #B, C, and E do not meet the requirements of 42 CFR 493.1489(b)(2)(ii). 42 CFR 1489(b)(2)(i) states "Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or--Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes--(b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either--(b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include--(b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1)

Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing."