

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D1031453	<b>(X3) Date Survey Completed</b>  12/12/2023
<b>Name of Provider or Supplier</b>  Lung Centre,The	<b>Street Address, City, State</b>  5010 Davis Lant Dr Suite 1, Evansville, IN	
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>	A recertification survey was completed on 12/12/2023. It was determined that the following condition-level deficiency existed: 42 Code of Federal Regulations (CFR) 493.1409: Technical Consultant- Moderate Complexity
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(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-- (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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform two levels of liquid quality control every day of patient testing for six of six test reports (PT#1-PT#6) reviewed and failed to have an IQCP (Individualized Quality Control Plan) in place. Findings include: 1) Medical record review indicated the following patients had quality control performed on a date other than their testing date and no IQCP in place: PT# Test Date QC Date 1 1-3-22 12-17-21 2 3-25-22 3-18-22 3 6-28-22 6-3-22 4 12-19-22 12-1-22 5 2-7-23 1-22-23 6 3-20-23 3-10-23 PT=patient QC=Quality Control 2) Review of policy titled, "Quality Control," approved by the laboratory director on "11-2005," read "...3 Monthly procedures...b. Run Level 1 and Level 3 controls..." 3) In interview on 12/12/23 at 11:28 am, SP-1 (testing person) confirmed the laboratory was only performing two levels of external quality control material monthly and had no IQCP in place. 4) Total Annual Chemistry Tests = 212.</p>

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure one (SP-1) of two personnel performing the duties of technical consultant met the qualifications. SP-1 (testing person) performed annual competency (2023) on two of four personnel reviewed (SP-3 & SP-4) and did not qualify to be a Technical Consultant. Refer to D-6035.

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on record review and interview, SP-1 (testing person) performed annual

competency (2023) on two of four personnel reviewed (SP-3 & SP-4 = testing personnel) and did not qualify to be a Technical Consultant. Findings include: 1) Review of "Critical Skill Evaluation Form" indicated SP-3 and SP-4 competency documentation was signed off by SP-1 on 1/5/23 for SP-3 and 1/6/23 for SP-4. 2) Review of SP-1's education documentation indicated the highest level of education with qualifying science courses was an Associate of Science degree. 3) In interview on 12/12/23 at 12:15 pm, SP-1 confirmed they performed annual competency (2023) on SP-3 and SP-4 and does not qualify to be a Technical Consultant. 4) Total Annual Chemistry tests=212.