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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>45D1004799         | <b>(X3) Date Survey Completed</b><br>09/25/2024 |
| <b>Name of Provider or Supplier</b><br>Lakeland Medical Associates   | <b>Street Address, City, State</b><br>170 Municipal Drive, Gun Barrel City, TX |   |
| 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>  |
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| <b>D0000</b>              | An onsite survey conducted 09/25/2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.   |
| <b>D6055</b>              | <p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b><br/>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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory documents, instrument implementation, personnel competency assessments, and confirmed in interview, the technical consultant failed to ensure that seven of seven testing personnel (TP) were evaluated and competent in the use of a new hematology analyzer put into use for patient testing in July 2024. The findings included: 1. Review of laboratory documents included the implementation of the following new hematology analyzer: Sysmex XN-450, SN 12078, put into use for patient testing July 2024 2. Review of testing personnel files included training, but no competence evaluation by the technical consultant to include the new hematology instrumentation for the following testing personnel: TP1, TP2, TP3, TP4, TP5, TP6, TP7 3. In an interview on 9/25/2024 at 09:35 hours, in the conference room, testing personnel (TP)1 confirmed that the technical consultant had not reevaluated the competency of personnel performing testing to include the new Sysmex XN-450 hematology analyzer.</p> |