

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  32D0537459	<b>(X3) Date Survey Completed</b>  12/04/2024
<b>Name of Provider or Supplier</b>  Rio Pecos Medical Associates	<b>Street Address, City, State</b>  305 W Country Club Road, Roswell, NM	
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 onsite initial survey conducted on December 4, 2024, at Rio Pecos Medical Associates found the laboratory to be not in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Rio Pecos Medical Associates LTD Laboratory Services policy and interview with the Technical Consultant, the laboratory director failed to approve, sign off, and date the policy in December of 2024. Findings included: 1. Review of the Rio Pecos Medical Associates LTD Laboratory Services policy created 12/01/2024 revealed the laboratory director did not sign or date policy before it was put in use. 2. Interview on 12/04/2024 at 11:00 am with the Technical Consultant confirmed the above findings. 3. The laboratory reported performing 9,000 hematology tests and 100 direct wet mount preparations annually.</p>
<b>D6029</b>	<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 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</p>

perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid personnel form (CMS 209 form), training records, and interview with the Technical Consultant, the laboratory director failed to ensure that two of three testing personnel (TP) performing direct wet mount preparations had appropriate training since the laboratory began testing under a certificate of compliance in 2024. Findings included: 1. Review of CMS 209 form listed TP1 and TP2 as performing direct wet mount preparations. 2. Review of training records revealed missing initial training records for performing direct wet mount preparations for TP1 and TP2. A request was made for the laboratory to provide initial training records. Laboratory failed to provide records. 3. Interview on 12/04/2023 at 11:30 am with the Technical Consultant confirmed the above findings. 4. The laboratory reported performing 100 direct wet mount preparations annually.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, and interview with the Technical Consultant, the laboratory director failed to ensure that a policy for completing initial trainings and competency assessments for testing personnel (TP) performing direct wet mount preparations was in place since the laboratory began testing under a certificate of compliance in 2024. Finding included: 1. Review of the facility's policies and procedures revealed the laboratory did not have a policy in place for initial trainings and competency assessments for testing personnel performing direct wet mount preparations. 2. Interview on 12/04/2023 at 11:30 am with the Technical Consultant confirmed the above findings. 3. The laboratory reported performing 100 direct wet mount preparations annually.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid personnel form (CMS 209

form), competency records, and interview with the Technical Consultant, the technical consultant failed to ensure that two of three testing personnel (TP) performing direct wet mount preparations had 6 month competency assessments completed since the laboratory began testing under a certificate of compliance in 2024. Findings included:

1. Review of CMS 209 form listed TP1 and TP2 as performing direct wet mount preparations.
2. Review of competence assessment records revealed missing 6 month competency assessments for performing direct wet mount preparations for TP1 and TP2. A request was made for the laboratory to provide competency assessment records. Laboratory failed to provide records.
3. Interview on 12/04/2023 at 11:30 am with the Technical Consultant confirmed the above findings.
4. The laboratory reported performing 100 direct wet mount preparations annually.