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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2025792 | (X3) Date Survey Completed 11/15/2023 |
| Name of Provider or Supplier Creative Testing Solutions | Street Address, City, State 201 Carlson Circle, San Marcos, TX | |
| 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 |
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| D0000 | The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. |
| D5211 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview, the laboratory failed to review four of 18 PT events in Chemistry and General Immunology from 2022 and 2023. Findings follow. A. Review of the American Association of Bioanalysts (AAB) proficiency testing records for 2022 and 2023 (three testing events per year) found that the laboratory failed to review three of six proficiency testing events in Chemistry in 2023 (3 events) for Total Protein and Alanine Aminotransferase. Random review of the College of American Pathologists (CAP) proficiency testing records from 2022 and 2023 (three testing events per year) found that the laboratory failed to review one of 12 proficiency testing events for General Immunology in 2023. VM-B, the 2nd event for Viral Markers, was not reviewed prior to the request of documents on 11/14/2023. B. Interview with Laboratory Quality Assurance (QA) Manager on November 14, 2023 at 1130 hours acknowledged they had the 3rd event, but did not have the 2nd event for the Viral Markers, so printed and were signing today. Further interview with the Laboratory QA Manager on November 14, 2023 at 1445 hours acknowledged they never received the AAB results, and were printing the documents today, and just learned AAB stopped mailing copies of the evaluations. She confirmed the PT had not been reviewed.</p> |