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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0952507 | (X3) Date Survey Completed 09/10/2021 |
| Name of Provider or Supplier University Pediatrics | Street Address, City, State 615 East University Drive, Edinburg, 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 participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended. |
| D1001 | <p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Review of manufacturer's instructions, patient final reports and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions when using the QuickVue SARS Antigen test for 5 of 5 patients tested in September 2021. The findings included: 1. Review of the manufacturer's instructions found under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY "Authorized laboratories using your product must include with the test result reports, all authorized Fact Sheets." 2. Review of patient results found no fact sheets included with the final report for five of five patient reports reviewed. 3. Interview with Testing Personnel #1 (as listed on Form CMS-209) on September 10, 2021 at 09:35 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services</p> |