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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0498452 | (X3) Date Survey Completed 09/07/2021 |
| Name of Provider or Supplier Baylor Scott & White-The Brenham Clinic | Street Address, City, State 600 North Park Street, Brenham, 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 |
|---------------------------|---|
| 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 cobas Liat SARS-COV-2 & Influenza A/B nucleic acid test for 545 patients tested between August 1, 2021 and September 7, 2021. The findings included: 1. Review of the manufacturer's instructions found under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories using the cobas Liat SARS-COV-2 & Influenza A/B nucleic acid test 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 three of three patient reports reviewed. 3. Interview of one of the clinic providers conducted September 7, 2021 at 12:07 PM confirmed he did not receive the authorized fact sheets as part of the final report for recently tested patients. Interview of the Technical Consultants listed on the CMS report 209 Laboratory Personnel Report conducted on September 7, 2021, at 12:17 PM confirmed that the Fact Sheets were not included with the patient test results for SARS COV-2 testing .</p> |