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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>39D2205057 | <b>(X3) Date Survey Completed</b><br><br>03/24/2021 |
| <b>Name of Provider or Supplier</b><br><br>Whitehall Pharmacy  | <b>Street Address, City, State</b><br><br>4117 Main St, Whitehall, PA      |   |
| 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>D1001</b>              | <p>CERTIFICATE OF WAIVER TESTS<br/>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:<br/>Based on review of the laboratory procedures and interview with the Testing Personnel, the laboratory failed to establish a procedure for reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as required from January 16, 2021 through the day of survey. Findings include: 1. On the day of survey, 03/24/2021, the laboratory could not provide a procedure for reporting positive and negative SARS-CoV-2 testing to the appropriate health agencies as required from 01/16/2021 to 03/2021. 2. 377 Access Bio CareStart COVID -19 Antigen specimens were analyzed for SARS-CoV-2 from 01/16/2021 to 03/24/2021. 3. The Testing personnel confirmed the findings above on 3/24/2021 around 8:45 a.m.</p> |