

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2232224	(X3) Date Survey Completed 02/01/2022
Name of Provider or Supplier Covid Clinic Inc	Street Address, City, State 784 S Clearwater Loop Ste B, Post Falls, ID	
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: Based on review of laboratory logs, testing instruction for use (IFU) and an interview with the site manager on 2/1/2022, the laboratory failed to follow the manufacturer's instructions for performing COVID-19 and Influenza testing. The findings include: 1. A review of the manufacturer's IFU identified the following test storage requirements: Indicaid COVID-19 antigen rapid test 2-30 C (36-86 F) do not freeze FaStep COVID-19 IgG/IgM rapid test 2-30 C (36-86 F) do not freeze Consult Diagnostic Influenza A&B test 2-30 C (35-86 F) Accula SARS-CoV-2 test 15-30 C (59-86 F) do not refrigerate or freeze 2. A review of the laboratories January 2022 temperature log identified that the laboratory failed to store the test kits above 32 F for 14 of 24 days. 3. An interview with the laboratory manager on 2/1/2022 at 9:25 am confirmed that the am temperatures were below the storage requirements. 4. The CLIA certificate number 13D2232224 for the Covid Clinic Post Falls was hanging on the wall of the 140 N Milwaukee, Boise, Idaho location. It was later confirmed by email with a Covid Clinic project manager that the Boise location is testing under the Post Falls CLIA certificate.</p>
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such</p>

timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:

Based on direct observation, a record review and an interview with the laboratory manager on 2/1/2022, the laboratory failed to report SARS-CoV-2 test results as required since testing began on September 2, 2021. The findings include: 1. It was observed that the laboratory was testing for SARS-CoV-2 using the Accula SARS-CoV-2 test, Indicaid COVID-19 rapid antigen test, and the FaStep COVID-19 IgG /IgM rapid test. 2. The laboratory failed to have documentation of reporting SARS-CoV-2 test results to the state of Idaho from September 2, 2021 to February 1, 2022. 3. An interview with the laboratory manager on 2/1/2022 at 9:16 am confirmed that the laboratory has not reported SARS-CoV-2 test results to the state of Idaho. 4. The CLIA certificate number 13D2232224 for the Covid Clinic Post Falls was hanging on the wall of the 140 N Milwaukee, Boise, Idaho location. It was later confirmed by email with a Covid Clinic project manager that the Boise location is testing under the Post Falls CLIA certificate.