

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D1034518	(X3) Date Survey Completed 06/29/2022
Name of Provider or Supplier North Idaho Direct Primary Care	Street Address, City, State 8880 N Hess St #1, Hayden, 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 a phone interview with a staff physician on 06/27/2022 and an emailed letter from the laboratory director on 06/27/2022, the laboratory failed to provide documentation that they followed their procedure or policy to report SARS-CoV-2 test results per the manufacturer's instruction for use (IFU) since testing began on 08/20/2021. The findings include: 1. A phone interview with a staff physician on 06/27/2022 found that the laboratory could not confirm following the IFU or their written procedure to report SARS-CoV-2 results to the Public Health Department or the State of Idaho 2. The Laboratory Director confirmed via email on 06/27/2022 that the laboratory could not confirm following the IFU or their written procedure to report SARS-CoV-2 results to the Public Health Department or the State of Idaho 3. The laboratory initiated patient SARSCoV 2 testing on 08/20/2021</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 timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on a phone interview with a staff physician on 06/27/2022 and an emailed letter from the laboratory director on 06/27/2022, the laboratory failed to provide documentation of reporting of SARS-CoV-2 test results since testing began on 08/20/2021. The findings include: 1. A phone interview with a staff physician on 06/27/2022 found that the laboratory went to a new EMR system and are unable to provide documentation of patient testing. 2. The laboratory was unable to provide documentation of submission of patient test results to the local health department 3. The laboratory initiated patient SARS-CoV 2 testing on 08/20/2021 4. The Laboratory Director confirmed via email on 06/27/2022 that the laboratory could not confirm reporting SARS-CoV-2 since testing began on 08/20/2021.