

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2205969	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier Refill Pharmacy	Street Address, City, State 8536 Del Webb Blvd, Las Vegas, NV	
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
D0000	<p>This Statement of Deficiencies was created as a result of an off-site CLIA special focused survey of laboratories with a Certificate of Waiver (CoW) for the purpose of determining compliance with the new CLIA Condition-level regulation (42 CFR 493.41) pertaining to COVID-19 reporting requirements on May 25, 2022. The findings and conclusions of any investigations by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions, or other claims for relief that may be available to any party under applicable federal, state, or local laws.</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: Based on a telephone interview with the laboratory director on May 18, 2022, and review of submitted documents on May 25, 2022, the laboratory failed to ensure that, prior to April 4, 2022, all positive and negative waived SARS-CoV-2 antigen and SARS-CoV-2 PCR test results, and after April 4, 2022, all positive waived SARS-CoV-2 antigen and SARS-CoV-2 PCR test results were reported to the public health authorities, as required. Findings include: 1. The laboratory director stated during a telephone interview on May 18, 2022 at approximately 3:15 PM that the laboratory did not report all positive and negative waived SARS-CoV-2 antigen and SARS-CoV-2 PCR test results to State of Nevada as required prior to April 4, 2022, and did not report all positive waived SARS-CoV-2 antigen and SARS-CoV-2 PCR test results to the State of Nevada after April 4, 2022. The laboratory director stated that laboratory was not certain of the need to report the results, and did not know where the results</p>

were to be reported until contacted for the survey. 2. A review of the Standard Operating Procedure (SOP) dated December 16, 2020, entitled "COVID-19 Testing Standard Operating Procedure" did not include reference to reporting positive and negative SARS-CoV-2 results to the State of Nevada as required. The laboratory has performed approximately 900 tests since January 11, 2021.