

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2164901	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier Well Care Services-W Charleston Blvd	Street Address, City, State 3312 W Charleston 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 lead medical assistant on May 19, 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 test results, and after April 4, 2022, all positive waived SARS-CoV-2 antigen test results were reported to the public health authorities, as required. Findings include: 1. The lead medical assistant stated during a telephone interview on May 19, 2022 at approximately 10:00 AM that the laboratory did not report all positive and negative waived SARS-CoV-2 antigen test results to State of Nevada as required prior to April 4, 2022, and added that the laboratory was not aware that all positive and negative SARS-CoV-2 antigen results were required to be reported prior to April 4, 2022. The statement that only positive results were reported to the State of Nevada prior to April 4, 2022 was confirmed in an email received on May 25, 2022 from the office</p>

manager. 2. A review of the undated Standard Operating Procedure (SOP) entitled "Protocol For Infectious Disease Reporting - In Clinic Testing," stated that "all positive results for SARS-CoV-2 antigen is reportable to the local Health Authority." The laboratory has performed approximately 121 SARS-CoV-2 antigen tests since April 8, 2021.