

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D0872524	(X3) Date Survey Completed 08/05/2021
Name of Provider or Supplier Jerry Schwartz Md	Street Address, City, State 7395 S Pecos Rd Ste 102, 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 August 5, 2021. 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 the laboratory Inservice Record Sheet dated June 25, 2021 that stated to report positive SARS-CoV-2 antigen test results to the Southern Nevada Health District (SNHD), a review of laboratory test logs for the Sofia SARS-CoV-2 antigen test between the dates of April 30, 2021 and August 4, 2021, a review of five submitted State of Nevada Confidential Morbidity Report Forms that were completed between the dates of June 28, 2021 and August 4, 2021, and email correspondence and a telephone conversation with the Lead Medical Assistant on August 5, 2021, the laboratory failed to report positive and negative SARS-CoV-2 antigen results as required between the dates of August 25, 2020 and August 4, 2021. Findings include: 1. A review of the document entitled, "Inservice Record Sheet" dated June 25, 2021, which listed the subject of the inservice as "SARS/COVID-19 (In House Testing)" stated, "In house testing for rapid COVID-19 test (antigen)-all test results are logged</p>

in to our log data. Any positive results must be reported to Public Health by completing morbidity report form and faxing to Clark County Public Health." 2. A review of five submitted State of Nevada Confidential Morbidity Report Forms completed between the dates of June 28, 2021 and August 4, 2021 revealed that the completed forms corresponded with the positive patient results listed on the test log between the dates of April 20, 2021 and August 4, 2021. 3. There was no documentation indicating the reporting of the negative SARS-CoV-2 antigen test results to the SNHD. 4. The findings were confirmed via email correspondence and a telephone conversation with the Lead Medical Assistant on August 5, 2021 at approximately 3:30 PM. The laboratory has performed approximately 480 Quidel Sofia SARS-CoV-2 antigen tests between the dates of August 25, 2020 and August 4, 2021.