

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2002212	(X3) Date Survey Completed 07/28/2022
Name of Provider or Supplier Valley Day And Night Clinic	Street Address, City, State 1214 Dixieland Rd Ste 8, Harlingen, TX	
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	The laboratory was surveyed for recertification and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended. NO DEFICIENCIES were cited.
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results 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 review of the laboratory's test menu, review of manufacturer's instructions, patient test records, and staff interview, the laboratory failed to have documentation of reporting 70 SARS-CoV-2 antigen positive results from April 1, 2022 to June 3, 2022 and 335 SARS-CoV-2 antigen positive results from June 15, 2022 to July 27, 2022 as required. The findings included: 1. A review of the laboratory's test menu found the laboratory utilized the Quidel QuickVue antigen SARS-CoV-2 kit for patient testing. 2. A review of the manufacturer's instructions for use for the Quidel Quick-Vue antigen SARS-CoV-2 antigen assay under the section titled "Conditions for Authorization for the Laboratory and Patient Care Settings" stated, "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. A review of laboratory policies found no documentation of a policy or procedure related</p>

to SARS-CoV-2 test reporting to public health authorities. 4. Review of patient test records found the following SARS-CoV-2 antigen positive results were not reported to any public health authority (patient alias list provided to technical consultant on July 28, 2022). April 2, 2022 - June 3, 2022: 70 positive antigen results not reported June 15, 2022 - July 27, 2022: 335 positive antigen results not reported 5. An interview with the office clerk on July 29, 2022 at 10:05 hours in the front office confirmed the findings.