

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1032166	<b>(X3) Date Survey Completed</b>  04/13/2021
<b>Name of Provider or Supplier</b>  Healthykids Of Gardendale	<b>Street Address, City, State</b>  1127 Pecan Avenue, Gardendale, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The surveyor determined this laboratory is in substantial compliance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88).
<b>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> 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 record review and interview, the laboratory failed to report SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) test results for negative Coronavirus Disease 2019 (COVID-19) performed on the Quidel Sofia SARS Antigen FIA test from January 8, 2021 [the date State Surveyors received CMS guidance for surveying on this deficiency] to April 13, 2021. The laboratory failed to report negative results for SARS-CoV-2 for the COVID-19 antigen test results to the Alabama Department of Public Health and positive results were reported to the Report Card for Alabama Department of Public Health (which is not the mechanism to use to report a patient that has a reportable disease). Findings include: 1. A review of SARS-CoV-2 test results revealed patients were tested for SARS-CoV-2 using the Quidel Sofia SARS Antigen FIA test, starting November 29, 2020 through April 13, 2021. A total of 98 test were performed (12 Positives and 86 Negatives) during this time</p>

period. 2. During an interview on April 13, 2021 at 09:00 AM, Testing Personnel #1 stated positive results were reported to the Novel Coronavirus (COVID-19) Report Card to the Alabama Department of Public Health. The Report Card has the following statement "If you are a Laboratorian, reporting on behalf of a laboratory, blood bank, or plasma center, the REPORT Card is not the mechanism you should use to report a patient that has a reportable disease or health condition." Testing Personnel #1 confirmed the laboratory had reported only positives (to the Report Card) but none of the negative SARS-CoV-2 patient test results to the Alabama Department of Public Health.