Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1034436	07/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pharr Kids Clinic	832 Del Oro Ste #2, Pharr, 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	Entrance and exit conferences were held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. The laboratory was found to be in compliance for the specialties/subspecialties for which it was surveyed. NO DEFICIENCIES were cited.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 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. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, review of patient test records from March 2021 - July 2021 and staff interview, it was revealed the laboratory failed to report 67 SARS negative Antigen test results as required by 400.200 for 51 of 51 days reviewed. Findings include: 1. Review of the Instructions for Use for the Quidel QuickVue SARS Antigen test (1461700 12/20) under the section titled "Intended Use" revealed: "Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities." 2. Review of the laboratory test records from 2021 revealed the laboratory started SARS Antigen patient testing utilizing the Quidel QuickVue cassette March 2021. 3. Review of the laboratory policies available revealed no documentation of a policy/procedure related

	to SARS test result reporting. 4. Review of the laboratory SARS Antigen patient test records from March 2021 to June 2021, 2021 revealed no documentation the laboratory reported 67 of 67 patient negative test records for 51 of 51 days of testing. Refer to SARS Antigen Patient Alias list. a) March 2021 19 negative results not reported 11 test days b) April 2021 21 negative results not reported 14 test days c) May 2021 17 negative results not reported 13 test days d) June 2021 20 negative results not reported 13 test days 5. An interview with the testing personnel number 1 (as listed on Form CMS 209) on 07/06/202 1130 hours in the laboratory revealed the facility reported positive results to State authorities, but did not report negative results. She stated the facility was unaware of the need to report negative results. This confirmed the findings.