Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D1107278	09/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Growing Kids Pediatrics, Llc	3321 Ballard Lane, New Albany, IN	

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 found to be in substantial compliance with CLIA regulations(42 CFR 493, effective April 24, 2003). 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 document review and interview, the laboratory failed to report SARS-Co-V-2 test results as required for 269 of 269 test results and 139 days reviewed from December 2020 through September 28, 2021. Findings included: 1. SARS-Co-V-2 testing documentation "Rapid Antibody Testing" logs were reviewed from December 2020 through September 28, 2021. 2. SARS-Co-V-2 "Rapid Antibody Test" result reporting documentation was reviewed from December 2020 to date of survey. 3. Documentation revealed that SARS-CoV-2 test results were not reported as required for: Year/Month # Days tested # Positive #Negative 2020 December 20 18 38 2021 January 29 6 40 Year/Month # Days tested # Positive # Negative 2021 February 14 2 14 March 4 0 7 April 12 1 13 May 5 0 5 June 2 1 1 July 4 1 5 August 30 9 62 September 19 5 42 Total tests performed since 12/20: 269 Total tests reported: 0 4. 269 test results were not reported as required during the period of review. 5. The laboratory performed 269 SARS-Co-V-2 tests during the period of review. 6. In

	interview on 9/28/21 at 12:10 p.m., SP1, Nurse Practitioner, confirmed SARS-Co-V-2 test results were not reported as required between December 2020 and September 28, 2021.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to have a written procedure for reporting positive and negative SARS-Co-V-2 patient test results to the State. Finding(s) included: 1. During a tour of the laboratory on 9/28/2021 at 11:45 am, the laboratory had the "Fastep COVID-19 IgG/IgM Rapid Test Device" available for SARS-Co-V-2 testing. 2. Upon request for apolicy and procedure to report SARS Co-V-2 test results to the State, on 9/28/2021 at 1:00 pm, SP#1 (Nurse Practitioner), acknowledged there was no written policy or procedure to report to the state.