

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1015547	(X3) Date Survey Completed 10/12/2022
Name of Provider or Supplier Devito And Alvarado Pediatric Associates Pllc	Street Address, City, State 3142 Victory Boulevard, Staten Island, NY	
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
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 Covid-19 Antigen testing records's and an interview with the laboratory director, at the time of this survey, that the laboratory failed to report the positive and negative Sars-Cov-2 patient results to New York State Electronic Clinical Laboratory Reporting System (ECLRS) from December 13, 2021 through survey date. FINDINGS: The laboratory failed to enroll in the ECLRS program when Covid -19 Antigen testing was implemented on December 13, 2021 through survey date. a. The laboratory is performing Sars-Cov-2 testing on the Quidel Sofia Rapid test cassette. b. Approximately 1,000 patients were tested and result from December 13, 2022 through survey date.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:

Based on review of the twice per year verification records and an interview with the laboratory director, the laboratory failed to verify the accuracy of interpretation of urine colony counts at least twice per year in calendar years 2020 and 2021.

FINDINGS: The laboratory director confirmed on October 12, 2021 at approximately 2:00 PM, the surveyor's findings that the laboratory failed to verify the accuracy of interpretation of urine colony counts at least twice per year in calendar years 2020 and 2021. a. Approximately 140 patient samples were tested for urine colony counts for the calendar years 2020 and 2021.