

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0282958	(X3) Date Survey Completed 04/26/2022
Name of Provider or Supplier Westchester Pediatric Llc	Street Address, City, State 10300 Sunset Dr Ste 351, Miami, FL	
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	Westchester Pediatrics LLC clinical laboratory is in compliance with the 42 CFR Part 493, Requirements for Laboratories. A CLIA recertification survey was conducted 04/26/2022.
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 record review and interview, the laboratory failed to report SARS-Co-V-2 test results as required since testing began on 11/03/2021. Findings Included: During a tour of the laboratory on 04/26/22 at 10:00 AM revealed the laboratory was using Becton, Dickinson and Company BD Veritor System for Rapid Detection of SARS-CoV-2 (Lot# 2007152 Expiration 10/16/2022) antigen testing. Review of the SARS-COV-2 log revealed that there were 333 test performed since testing started on 11/03/2021. There were 26 positive tests performed on 04/25/22, 04/18/22, 04/19/22, 04/07/22, 03/01/22, 01/28/22, 01/24/22, 01/19/22 (2 Patients), 01/12/22, 01/07/22, 01/05/22 (3 Patients), 12/30/21, 12/28/21, 12/27/21, 12/23/21 (3 Patients), 12/21/21, 12/17/21 (4 Patients), and 12/16/21. Interview on 04/26/22 at 11:55 AM the Office Manager confirmed that no SARS-Cov-2 results to the Department of Health.</p>