

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1012189	(X3) Date Survey Completed 01/22/2021
Name of Provider or Supplier Novant Health Twin City Pediatrics	Street Address, City, State 2821 Maplewood Avenue, Winston-Salem, NC	
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 Novant Health Twin City Pediatrics - Winston Salem laboratory was found in compliance with 42 CFR Part 493 Requirements for Laboratories as a result of an off-site survey performed on January 22, 2021.
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 instrument printouts and review of reported SARS-CoV-2 results 3/2/21-3/5/21, and email from the TC (technical consultant) 2/24/21, the laboratory failed to report SARS-CoV-2 test results as required on 3 of 3 random days (12/10/20, 1/6/21, 1/29/21) reviewed. Findings: 1. Review of instrument printouts from the Abbott ID NOW and reported results from the laboratory's data system 3/2/21-3/5/21 revealed: a. The laboratory tested 13 patients for SARS-CoV-2 on 12/10/20. 2 of 13 patient results were not reported as required on 12/10/20. b. The laboratory tested 9 patients for SARS-CoV-2 on 1/6/21. 1 of 9 patient results was not reported as required on 1/6/21. c. The laboratory tested 16 patients for SARS-CoV-2 on 1/29/21. 1 of 16 results was not reported as required on 1/29/21. 2. In an email on 2/24/21 at 5:44 p.m., the TC stated that some of the laboratory's SARS-CoV-2 results were not reported. She stated the results were not entered in the laboratory's electronic medical records</p>

system, so they were not included in the data reported electronically each day to the state authorities.