

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1000973	(X3) Date Survey Completed 01/20/2021
Name of Provider or Supplier Family Medicine Clinic Pa	Street Address, City, State 704 E Wonsley Drive, Suite 100, Austin, 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
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 Ecotest COVID-19 IgG/IgM Rapid test instructions for use, patient records, and interview with facility personnel, the laboratory failed to report SARS-COV-2 test results as required for 15 of 15 days reviewed between October 1, 2020 and December 14, 2020. The findings included: 1. Based on review of the Ecotest COVID-19 IgG/IgM Rapid test instructions for use (Number 1110032033, REV 1.4 Effective date: 2020-09-22), under Condition of Authorization for the Laboratory on page 2 of 3, the instructions state "4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. 2. Based on review of patient records, the laboratory performed patient tests on 7 days in October 2020 5 days in November 2020, and 3 day in December 2020. a. Eight patient tests in October 2020. Eight of eight patients were recorded to have negative results to the Ecotest COVID-19 IgG/IgM Rapid test. b. Seven patient tests were performed in November 2020. Five of seven patients were recorded to have negative results to the Ecotest COVID-19 IgG/IgM Rapid test. Two of seven patients were recorded to have positive results to the Ecotest COVID-19 IgG/IgM Rapid test. c. Five patients were</p>

test in December 2020. Four of five patients were recorded to have negative results to the Ecotest COVID-19 IgG/IgM Rapid test. One of five patients were recorded to have positive results to the Ecotest COVID-19 IgG/IgM Rapid test. 3. In an interview on January 19, 2021 at 11:52 hours in the laboratory, the Technical Consultant stated the laboratory had not reported both positive and negative COVID-19 tests results to HHS.