

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2163038	(X3) Date Survey Completed 01/12/2021
Name of Provider or Supplier Dominion Family Care, Llc	Street Address, City, State 4101 Dominion Blvd, Suite 300, Glen Allen, VA	
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	An unannounced Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00050411) was conducted at Dominion Family Care, doing business as (dba) American Family Care on January 12, 2021 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The laboratory holds a Certificate of Waiver and operates under CLIA # 49D2163038. Based on a tour, review of documents and interviews, the inspector found that the laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulations: D1002- 42 CFR. 493.41 Condition: Reporting of SARS-CoV-2 test results.
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>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 a laboratory tour, review of written protocols, patient log sheet records and interviews, the laboratory failed to report SARS-CoV-2 negative test results as required for ninety (90) days reviewed (timeframe of October 1, 2020 to the date of the survey, January 12, 2021). Findings include: 1. During a tour on 1/12/21, at approximately 12:00 PM, the inspector noted that the laboratory utilized two (2) Sofia analyzers (Serial numbers 29018772 and 29018753) for rapid SARS-CoV-2 patient testing. The inspector requested to review the test procedures and evidence of results reporting to state agency. The testing personnel stated at approximately 12:30 PM: "We send the positive results on the Virginia Department of Health (VDH) website." The administrator stated concurrently: "We started testing the first of April last year. We manually submit results to VDH on their website". 2. Review the laboratory's</p>

patient Sofia COVID-19 Test Log documentation and reporting protocols from 10/1/20 to 1/12/21 revealed two thousand four hundred ninety (2,490) rapid SARS-CoV-2 patient tests were analyzed: One hundred eighty seven (187) positive SARS-CoV-2 results were assayed/resulted and reported to VDH. Two thousand three hundred three (2,303) negative SARS-CoV-2 results were assayed/resulted but were not reported as required. The practice manager stated on 1/12/21 at approximately 1:00 PM "We were not aware that we were to send negatives as well as positives." 3. The practice manager confirmed the above findings on 1/12/21 at approximately 1:30 PM.