

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2134034	(X3) Date Survey Completed 11/02/2022
Name of Provider or Supplier Main Street Family Care	Street Address, City, State 211 Church Street, Tiptonville, TN	
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 Main Street Family Care laboratory was found to be in compliance with the requirements at 42 CFR, Part 493, 'Requirements for Laboratories' as a result of an onsite survey on November 2, 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 observation of the laboratory, review of patient SARS-COV-2 test records and interview with the laboratory director, the laboratory failed to report positive SARS-CoV-2 test results as required for one of four days selected for review in 2022. The findings include: 1. Observation of the laboratory on November 10, 2022 at 8 am revealed the GenBody waived SARS-CoV-2 antigen test in use for patient testing . 2. SARS-CoV-2 patient logs and test reporting documentation was reviewed for the dates of 06/13/22, 07/11/22, 07/13/22 and 08/22/22. 3. Documentation revealed that positive SARS-CoV-2 results were not reported as required on 07/11/22 for three patients. 4. Interview with the laboratory director on 11/02/2022 at 11 am confirmed the laboratory did not report positive SARS-CoV-2 results as required for one of four dates in 2022.</p>