

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D1043439	<b>(X3) Date Survey Completed</b>  11/09/2021
<b>Name of Provider or Supplier</b>  Southside Community Health Services	<b>Street Address, City, State</b>  324 East 35th Street, Minneapolis, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3000</b>	<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:</p> <p>. Based on record review, interview with laboratory personnel, and email communication, the laboratory failed to report SARS-CoV-2 negative test results for 106 of 168 days reviewed from October 2020 through November 2021. In addition, the laboratory failed to retain documentation of SARS-CoV-2 result reporting for 168 of 168 days reviewed from October 2020 through November 2021. Findings are as follows: 1. The laboratory performed SARS-CoV-2 testing using the Quidel Sofia SARS Antigen FIA test as confirmed by the Laboratory Director during the entrance interview at 1:20 p.m. on 11/02/21. 2. In the interview at 1:20 p.m. on 11/02/21, Testing Personnel 1 (TP1) indicated negative SARS-CoV-2 results had not been reported to the appropriate health authorities from test implementation in June 2020 through 05/20/21. 3. Quidel Sofia2 SARS Antigen FIA (COVID) Test patient testing logs were reviewed on date of survey. A test record spreadsheet, provided by the LD via email on 11/09/21, was also reviewed. The documents included testing dates and the number of positive and/or negative results obtained each day of testing from 10/01/20 - 11/02/21. Days of non-reporting are indicated below. 2020 Days not reported October 21 November 17 December 12 2021 Days not reported January 12 February</p>

10 March 15 April 14 May 7 4. 233 negative SARS-CoV-2 test results were not reported as required from 10/01/20 through 05/20/21 as indicated on the test record spreadsheet. 5. The laboratory performed 256 SARS-CoV-2 tests between 10/01/21 and 05/20/21 as indicated on the test record spreadsheet. 6. Documentation of SARS-CoV-2 result reporting was not found during review of laboratory records. The laboratory was unable to provide this documentation upon request. 7. The laboratory performed 373 SARS-CoV-2 tests on 168 days from 10/01/21 through 11/02/21 as indicated on the test record spreadsheet. 8. In an interview at 3:35 p.m. on 11/02/21, TP1 confirmed the above findings. TP1 indicated all positive results had been reported to the appropriate health authorities but negative results were not reported until after 05/20/21. TP1 also indicated the reported results were sent to the health authorities via fax but the fax confirmation pages had not been retained.