

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2182592	<b>(X3) Date Survey Completed</b>  11/23/2021
<b>Name of Provider or Supplier</b>  Mriglobal Clinical Laboratories	<b>Street Address, City, State</b>  65 Watkins Mill Rd, Gaithersburg, MD	
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: Based on record review and email communication with the quality assurance (QA) officer the laboratory failed to report SARS-Co-V-2 test results as required for 24 of 24 days reviewed from August 2021 through October 2021. Findings: 1. SARS-CoV-2 testing documentation from the laboratory's LIMS (Laboratory information management) system was reviewed from August 1, 2021 through October 31, 2021. Data was provided in an email from the QA officer on 11/23/2021. 2. During an interview during the initial laboratory survey on 11/10/2021 the QA officer stated that the laboratory had not reported any SARS-CoV-2 test results since they began testing January 2021. 3. Documentation revealed that SARS-CoV-2 test results were not reported as required for 14 days in August 2021, 8 days in September 2021, and 2 days in October 2021. 4. 690 test results were not reported as required during the period of review. 5. The laboratory performed 690 SARS-CoV-2 tests during the period of review. 6. The quality assurance officer confirmed the findings in an email on 11/23/2021.</p>