

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0988472	<b>(X3) Date Survey Completed</b>  09/29/2021
<b>Name of Provider or Supplier</b>  Doctors Clinical Laboratory	<b>Street Address, City, State</b>  1685 Winnetka Circle, Rolling Meadows, IL	
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:                      A. FAILED TO REPORT SARS-CoV-2 RAPID ANTIGEN RESULTS Based on record review, lack of documentation, and interview, the laboratory failed to report SARS-CoV-2 test results as required for four out of four days reviewed in the week of August 2021 for 4120 patients. Findings include: 1. 20 final reports of selected patients from the Doctors Clinical laboratory (DCL) laboratory information system (LIS) collected from August 10, 2021 through August 13, 2021, the DCL Laboratory Accession GUIDE User manual, and DoIT State of Illinois Notification confirmations were reviewed. 2. The employees at the collection sites performed the following duties: *Tested patients using the SARS-CoV-2 Rapid test, *Collected patients' nasopharyngeal swabs for SARS-CoV-2 RT-PCR testing; and *Generated the patient's requisition in the DCL-LIS. 3. The LIS User manual failed to include instructions on entering Rapid results or provide a 'field' or space for the result to be documented for each patient at the collection sites. 4. 20 final laboratory reports were reviewed and found to have not had COVID testing results reported as required. 5. DoIT confirmations were also reviewed for a period of two out of four days and investigation revealed that 4110 Rapid COVID test results from August 10 to 11,</p>

2021 also were not reported as required. 6. The laboratory director confirmed the above findings on 09/29/2021 at 3:15PM. B. FAILED TO REPORT SARS-CoV-2 PCR RESULTS Based on record review and interview, the laboratory failed to report SARS-CoV-2 test results as required for two out of four days reviewed in the week of August 2021 for 4110 patients. Findings include: 1. The 20 final reports of selected patients from the DCL laboratory information system (LIS) collected from August 10, 2021 through August 13, 2021, the DCL Laboratory Accession GUIDE User manual, and DoIT State of Illinois Notification confirmations were reviewed. Findings include: 2. 10 out of 20 final reports were reviewed and found to have not had SARS-CoV-2 PCR test results reported as required for two (August 10 and 11, 2021) out of four days. 3. DoIT confirmations were also reviewed for August 10 and August 11, 2021 and investigation revealed that 4110 SARS-CoV-2 test results also were not reported as required. 4. The laboratory director confirmed the above findings on 09/15/2021 at 6:46PM.