

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0988472	<b>(X3) Date Survey Completed</b>  12/08/2021
<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: REPEAT DEFICIENCY 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 Antigen test results as required for 628,519 patients. Findings include: 1. The patient COVID-19 Antigen results performed on November 9, 2021 and November 11, 2021, the OCL laboratory Information System (LIS) lists, the Emergency Use Authorization (EUA) for SARS-CoV-2 Antigen testing, and the laboratory's COVID-19 reporting procedures were reviewed. 2. The OCL-LIS revealed DCL collection sites performed 8,828 COVID-19 antigen tests on November 9, 2021, and 7,653 on November 11, 2021. 3. Under the EUA's "CONDITION OF AUTHORIZATION" for CareStart, INDICAID, Celltrion DiaTrust, and SIENNA-Clarity COVID-19 Antigen tests, the health provide968r is required to report all negative and positive COVID-19 antigen results to the appropriate Public Health Agency. 4. The laboratory failed to include in its COVID-19 reporting procedures, the requirement and process to report the COVID-19 antigen test results performed at the collection sites to the appropriate Public Health agency. 5. The laboratory failed to provide evidence of reporting to the state agency for the</p>

16,481 antigen tests performed on November 9, 2021 and November 11, 2021. 6. Interview with a reporting specialist on November 17, 2021 at 3:20 PM confirmed that negative results for antigen testing are not reported to the state agency. 7. The laboratory reporting specialist was unable to provide evidence of reporting for COVID-19 antigen testing for ten of ten patient specimens requested by the surveyor. 8. Email on November 24, 2021 at 12:10 PM confirmed that upon the start of COVID-19 antigen testing on June 7, 2021, that 628,519 patients have been tested and 605,684 were resulted as negative and 22,835 had been resulted as positive. 9. On a Recertification and Complaint survey conducted on November 17, 2021 at 1:30 PM, the laboratory director and information technology (IT) employee confirmed the above findings. **B. FAILED TO REPORT SARS-CoV-2 PCR RESULTS** Based on record review, lack of documentation, and interview, the laboratory failed to report SARS-CoV-2 PCR-RNA results as required for two out of two days reviewed in the week of November 2021 for 14,262 patients. Findings include: 1. The total final patient reports from the DCL laboratory information system (LIS) collected from November 9 and 11, of 2021, the DCL Laboratory reporting policy and procedures, and DoIT State of Illinois Notification confirmations were reviewed. 2. The DCL-LIS and DoIT notification confirmations revealed the following: \*DCL laboratory reported 8,828 SARS-CoV-2 RNA-PCR tests results on November 9, 2021; 499 of these results were received by DoIT. \*DCL laboratory reported 7653 SARS-CoV-2 RNA-PCR tests results on November 11, 2021, 1720 of these results were received by DoIT. \*The transmission of 14,262 SARS-CoV-2 RNA-PCR tests results failed to be received by DoIT State Agency. 3. The laboratory failed to include in its COVID-19 reporting procedures a process to ensure COVID-19 PCR-RNA results which fail to transmit are identified and retransmitted to the appropriate Public Health Agency. 4. On a Recertification and Complaint survey conducted on November 17, 2021 at 1:30 PM, the laboratory director and information technology (IT) employee confirmed the above findings. **C. FAILED TO REPORT SARS-CoV-2 PCR RESULTS TO STATE PUBLIC HEALTH AUTHORITY** 1. The laboratory failed to report SARS-CoV-2 PCR (SCP) patient test results to the applicable state public health authority for the following states: a) Texas- 4064 SCP patient test results b) Michigan- 6210 SCP patient test results c) Colorado- 14172 SCP patient test results d) Florida- 9699 SCP patient test results e) Ohio- 9750 SCP patient test results f) South Carolina- 356 SCP patient test results g) Arizona- 4669 SCP patient test results h) Massachusetts- 954 SCP patient test results i) Georgia- 46 SCP patient test results j) Indiana- 1194 SCP patient test results k) Washington- 3403 SCP patient test results l) Virginia- 369 SCP patient test results m) Oregon- 7078 SCP patient test results n) Minnesota- 491 SCP patient test results o) California- 190 SCP patient test results p) Missouri- 1597 SCP patient test results q) Maryland- 856 SCP patient test results r) Rhode Island- 154 SCP patient test results s) Arkansas- 369 SCP patient test results t) New York- 126 SCP patient test results 2. The IT employee confirmed the above findings on November 18, 2021 at 12:00 PM.