

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2252174	(X3) Date Survey Completed 02/18/2022
Name of Provider or Supplier Rapid Screening Llc	Street Address, City, State 1245 N Roselle Rd, Schaumburg, IL	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on direct observations, record review, and interview, the laboratory failed to follow and document the manufacturer's instructions for the Emergency Use Authorization (EUA) for the SARS testing performed in the laboratory, affecting 17,307 patients. Findings. 1. The Celltron DiaTrust COVID-19 Antigen Test Information for Use (IFU) and EUA were reviewed. 2. On February 18, 2022 at 12:50 PM, the surveyor observed that the facility used the DiaTrust COVID-19 test to perform COVID-19 antigen testing. 3. Review of the IFU and EUA revealed the following: *All operators using the product must be appropriately trained in performing and interpreting the results of your product. *Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. 4. The laboratory failed to document operators' training and failed to ensure each patient tested with DiaTrust COVID-19 received Authorized FACT SHEETS. 5. The laboratory performed 17,307 COVID-19 tests since the facility began testing. 6. On February 18, 2022 at 2:30 PM, owner confirmed the above findings.</p>
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>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>

This CONDITION is not met as evidenced by:

Based on direct observation, record review, and interview, the laboratory failed to report COVID-19 Antigen test results as required by the manufacturer's instructions for the Emergency Use Authorization (EUA), affecting 17,307 patients' tests. Findings include: 1. Rapid Screening and Medstar Laboratory agreement and procedure manual were reviewed. 2. On February 18, 2022 at 1:06 PM, the surveyor observed Staff-A1 perform the following activities: *Tested patients using the DiaTrust COVID-19 Antigen test kit, *Collected patients' nasopharyngeal swabs for SARS-CoV-2 RT-PCR testing; and *Generated the patient's requisition in the Medstar's electronic medical records. 3. On February 18, 2022 at 1:35 PM, the surveyor ask the owner /manager to provide the laboratory's procedure for reporting the COVID-19 antigen results to the Health Department. The owner stated that he does not report results to the health departments because it was the responsibility of Medstar laboratory. 4. Review of the Medstar agreement signed on 12/01/2020 revealed the reporting responsibility of patients' results to the Health department was not included. 5. The laboratory performed 17,307 COVID-19 tests since the facility began testing. 6. On a Complaint investigation conducted on 02/18/2022 at 2:00 PM, the owner confirmed the above findings.