| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 14D2132371 | 06/08/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Advanced Urgent Care | 5907 W 63rd Street, Chicago, 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 |
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| **D0000** | The laboratory was found to be in substantial compliance with CLIA regulations (42 CFR Part 493, effective April 24, 2003). No deficiencies were cited. |
| **D3000** | FACILITY ADMINISTRATION<br>CFR(s): 493.1100<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to report 19 of 19 positive SARS-CoV-2 test results as required for the 32 days reviewed from September 2020 through December 2020 and March 2022 through June 2022. Findings include: 1. The COVID-19 Test logs were reviewed from July 2020 through November 2020 and March 2022 through June 2022. 2. Test results reporting documentation was reviewed from September 4, 2020 through December 8, 2020 and March 17, 2022 through June 06, 2022. 3. 19 of 77 patients' tested were positive during the time period reviewed. 4. Documentation revealed that 19 positive SARS-CoV-2 test results were not reported to the Health Department as required for patient testing. 5. The laboratory director confirmed the findings on June 8, 2022 at 12:08 PM. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b) |

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| | The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to establish procedures to report positive SARS-CoV-2 results to the Health Department as required, affecting 19 of 19 positive patients results. Findings include: 1. The laboratory's procedures manual, COVID-19 Test logs September 4, 2020 through December 08, 2020 and March 17, 2022 through June 6, 2022 were reviewed. 2. The laboratory failed to report 19 positive SARS-CoV-2 results. See D3000. 3. The procedures manual revealed that the laboratory failed to include a step-by-step process for reporting SARS-Cov-2 results to the Health department and confirming their receipt as required by federal mandate. 4. The laboratory director confirmed the above findings on June 8, 2022 at 12:08 PM. |