| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D0693402 | 04/20/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Cornerstone Medical Group | 914 Vista Drive, Dalton, GA | |

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** | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 20, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following 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 lack of reporting SARS-CoV-2 documents and subsequent staff interview, the laboratory failed to meet the specific requirements for reporting SARS-CoV-2 test results during the Public Health Emergency, to the Secretary. Findings include: 1. Review of SARS-CoV-2 testing logs reveals the lack of documentation for the required reporting of SARS-CoV-2 patient results for the Right Sign COVID-19 IgG/ IgM Rapid Test kit utilized by the lab. 2. Interview with staff #4 (CMS 209 form) on 04/20/21 at approximately 12:15 PM in the back office reception area confirmed the lab was not reporting results to the Secretary. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g) |

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| | Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control (QC) document review and staff interview, the laboratory failed to perform and document external QC on the Right Sign COVID-19 IgG/ IgM Rapid Test kit. Findings include: 1. No QC documents were available to review on the Right Sign COVID-19 IgG/ IgM Rapid Test kit at the time of survey. 2. . Interview with staff #4 (CMS 209 form) on 04/20/21 at approximately 12:15 PM in the back office reception area confirmed the lab was not performing external QC on the aforementioned test kit. |