| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 19D0694058 | 09/09/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ncmc Medical & Surgical | 815 South Pine Street, Vivian, LA | |

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 Recertification survey was performed on September 9, 2021 at North Caddo Medical and Surgical Clinic, CLIA ID # 19D0694050. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, review of manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to providers or patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Observation by surveyor during laboratory tour on September 9, 2021 at 10:00 am revealed the laboratory utilizes the Abbott BinaxNow Covid-19 Antigen test kit for SARS CoV-2 testing. 2. Review of the manufacturer's instructions for use under the "Conditions of Authorization for Laboratory and Patient Care Settings" section revealed "Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. In interview on September 9, 2021 at 12:10 pm, the Laboratory Director stated that patients and providers are directed to the hospital website to obtain information about testing but there is not a policy available to laboratory personnel. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a) |

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| | A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: a) Reporting of SARS COV-2 test results to state public health agency, to include but not limited to frequency and who is responsible. 2. In interview on September 9, 2021 at 12:10 pm, the Laboratory Director stated he was unaware the laboratory needed a policy for SARS CoV-2 reporting of test results. The Laboratory Director confirmed the laboratory did not have the identified policy. |
| **D6031** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(13)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5401. |