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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>28D0679422 | <b>(X3) Date Survey Completed</b><br><br>06/14/2022 |
| <b>Name of Provider or Supplier</b><br><br>Memorial Community Health Inc   | <b>Street Address, City, State</b><br><br>1423 7th Street, Aurora, NE      |   |
| 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>  |
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| <b>D5411</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of manufacturer's instructions for coagulation, lack of documentation, and interview with the laboratory manager, the laboratory failed to follow manufacturer's instructions for coagulation. Findings are: 1. Based on manufacturer's instructions "verification of reference range should be should be followed before new lots are put into use." 2. The laboratory confirmed innovin lot number change to lot #549759. The laboratory did not have documentation of when lot number change occurred. 3. Interview with the lab manager on 6/14/2022 at 1:20 PM confirmed the laboratory had changed innovin lot number and had not verified the reference range before new lot was put into use. 4. Based on the laboratory's list of tests for 2021, the laboratory tested 184 patients.</p> |