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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>16D0384448      | <b>(X3) Date Survey Completed</b><br><br>08/21/2025 |
| <b>Name of Provider or Supplier</b><br><br>Van Diest Medical Center  | <b>Street Address, City, State</b><br><br>2350 Hospital Drive, Webster City, IA |   |
| 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>D5449</b>              | <p>CONTROL PROCEDURES<br/>CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the Clostridium difficile Individualized Quality Control Plan (IQCP) and quality control (QC) records and confirmed by interview with the General Supervisor (GS) at 12:27 pm on 8/21/2025, the laboratory failed to perform a positive and negative control for one out of one new lot numbers of Clostridium difficile test kits in March 2025 . The findings include: 1. The Clostridium difficile IQCP stated that positive and negative QC would be performed with each new lot number and shipment of test kits. 2. On 3/2/2025, Patient A had Clostridium difficile testing performed using test kit lot number 0824258, expiration date 6/1/2026. 3. The General Supervisor confirmed at the time of the survey, the laboratory did not perform QC for lot number 0824258, expiration date 6/1/2026 of Clostridium difficile test kit.</p> |