

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0455463	(X3) Date Survey Completed 06/18/2024
Name of Provider or Supplier Annie Jeffrey Memorial County Health Center	Street Address, City, State 531 Beebe Street, Osceola, NE	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Ortho immunohematology performance specification records, immunohematology procedures, and confirmed by the laboratory manager at 12:45 PM on 06/18/2024, the laboratory failed to establish a function check policy for the Ortho immunohematology dispenser, including the frequency for performing volume checks. The laboratory also failed to perform a volume check on the Ortho dispenser from 07/15/2023- 06/18/2024. Findings are: 1. The laboratory uses the Ortho dispenser to deliver specific volumes of diluent when performing immunohematology procedures. 2. Review of the Ortho immunohematology log indicated that the dispenser volume checks are to be performed every six months. 3. At the time of the survey, the laboratory did not have a policy for performing volume checks on the Ortho dispenser. In addition, the laboratory had not performed a volume check on the dispenser from 07/15/2023- 06/18/2024.</p>