

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  35D0408575	<b>(X3) Date Survey Completed</b>  11/09/2021
<b>Name of Provider or Supplier</b>  Unity Medical Center	<b>Street Address, City, State</b>  164 W 13th St, Grafton, ND	
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>
<b>D5507</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.1261(b)(c)</p> <p>(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to perform quality control (QC) each day for antimicrobial susceptibility testing (AST) for 16 of 18 patient testing days reviewed in October 2021 (October 2, 3, 6, 8, 9, 10, 13, 14, 16, 17, 19, 20, 24, 27, 28, and 31). Findings include: 1. Reviewed on 11/09/21, the October 2021 AST QC and patient testing log lacked evidence of QC performance on the following patient testing days: October 2, 3, 6, 8, 9, 10, 13, 14, 16, 17, 19, 20, 24, 27, 28, and 31. 2. During interview at 10:00 a.m. on 11/09/21, a technical supervisor (Personnel #1), confirmed the laboratory did not perform QC for AST each day of patient testing in October 2021. Personnel #1 stated in August 2020, the laboratory had changed from performing AST QC each day of patient testing to weekly, and the laboratory had not implemented an Individualized Quality Control Plan (IQCP) to reduce the frequency of AST QC performance. 3. Reviewed on 11/09/21, the policy "Antimicrobial Susceptibility Testing (AST), dated 08/17/20, stated, ". . . X. Quality Control . . . Frequency of Testing: AST - Once in seven days . . ." The policy failed to require AST QC performance each day of patient testing.</p>