

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382617	(X3) Date Survey Completed 03/22/2023
Name of Provider or Supplier Audubon County Memorial Hospital	Street Address, City, State 515 Pacific Avenue, Audubon, IA	
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 lack of MTS-dispenser volume check records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 3/22/2023, the laboratory failed to define the frequency for performing volume checks on the MTS-dispenser used for blood bank testing. Additionally, the laboratory failed to perform MTS-dispenser volume checks from 1/1/2021 - 3/24/2023.</p>
D6055	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.</p>

This STANDARD is not met as evidenced by:

Based on review of personnel training and competency records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), at approximately 9:30 am on 3/22/2023, the technical consultant failed to document training for the Sysmex XN-L 450 and Qiasat test systems prior to reporting patient test results for two out of two testing personnel (identifiers #1 and #2). The findings include: 1. The laboratory began using the Sysmex XN-L 450 hematology analyzer in October of 2021. 2. The laboratory began using the Qiasat test system in March of 2021. 3. At the time of the survey, the laboratory did not have training records for testing personnel identifiers #1 and #2.