

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0697020	(X3) Date Survey Completed 09/25/2024
Name of Provider or Supplier Gordon Memorial Hospital	Street Address, City, State 300 East 8th Street, Gordon, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of list of tests performed, interview with the laboratory manager, and lack of documentation the laboratory failed to verify performance specifications on three out of three new moderate complexity test kits. 1. Review of the list of tests performed, presented by the laboratory, included three new moderate complexity test kits. The three new moderate complexity test kits include: Test kit #1 clostridium difficile Test kit #2 chlamydia trachomatis and neisseria gonorrhoeae Test kit #3 SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus 2. Interview with the laboratory manager on 9/25/2024 at 2:45 PM confirmed patient testing began in 2023 for test kit #1 clostridium difficile, test kit #2 chlamydia trachomatis and neisseria gonorrhoeae, and test kit #3 SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus. 3. Interview with the laboratory manager on 9/25/2024 at 2:54 PM confirmed the laboratory was unable to find the performance specifications for three out of three new moderate complexity test kits. 4. No documentation of verification of performance specifications was found during the survey.</p>
D6151	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4)</p>

(3) The director or technical supervisor may delegate to the general supervisor the responsibility for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

This STANDARD is not met as evidenced by:

Based on review of testing personnel competency records and interview with the laboratory manager, the laboratory failed to ensure that 2023 competency evaluations were completed for three out of four testing personnel (Testing personnel #1, #2, and #4 as listed on the CMS-209 form). 1. Review of testing personnel competency records revealed no 2023 competency evaluations for three out of four testing personnel. 2. Interview with the laboratory manager on 9/25/2024 at 11:17 AM confirmed no 2023 competency evaluations were completed for three out of four testing personnel.