

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0652694	(X3) Date Survey Completed 09/13/2022
Name of Provider or Supplier Cherry County Hospital	Street Address, City, State 510 North Green Street, Valentine, 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 new instrumentation, lack of documentation, and interview with the technical consultant the laboratory failed to verify precision on the laboratory's handheld blood analyzer. 1. Review of new instrumentation revealed the laboratory started patient testing on 8/19/2021 with the new handheld blood analyzer. 2. Review of the validation of performance specifications for the new handheld blood analyzer revealed no run to run precision studies had been performed. 3. Interview with the technical consultant on 9/13/2021 at 9:00 AM confirmed run to run precision was not performed prior to patient testing.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the</p>

condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of test reports and interview with the technical consultant, the test report dates changed when test report copies were generated at a later time. 1. Review of three chemistry test reports, one blood bank test report, and one hematology test report revealed the report dates changed with subsequent printing of test reports. 2. Interview with the technical consultant on 9/13/2022 confirmed the report dates changed with subsequent printing of test reports.