

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408659	(X3) Date Survey Completed 10/05/2022
Name of Provider or Supplier Towner County Medical Center	Street Address, City, State 228 1st Ave, Cando, ND	
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 record review, staff interview, and policy review, the laboratory failed to verify the accuracy for 1 of 1 new immunology test method (qualitative rheumatoid factor) in 2021 before reporting patient results. The laboratory performed approximately twenty patient tests with the new test kit since implementation. Findings include: 1. Reviewed at 5:20 p.m. on 10/04/22, the laboratory's 2021 records for a new qualitative rheumatoid factor test kit started 11/15/21 lacked evidence the laboratory verified the accuracy performance specifications. Upon request the laboratory failed to provide evidence of accuracy verification for the new qualitative rheumatoid factor test kit. 2. During interview at 8:00 a.m. on 10/05/22, the laboratory supervisor (#1) confirmed the laboratory began patient testing using a new qualitative rheumatoid factor test kit (Cardinal Health RF [rheumatoid factor]) on 11/15/21, and the laboratory did not verify the performance specification for accuracy. 3. Reviewed at 11:45 a.m. on 10/05/22, the policy "Adopting New Test Procedure," dated 09/2014, stated, ". . . Purpose: To provide guidelines to follow when adopting a new test procedure. . . . Procedure: . . . 11. . . the following studies need to be performed: A. Analytical accuracy is established by comparing results to a definitive or reference method, or may be verified by comparing results to an established comparative method. . . . 12. Review the above data with the pathologist responsible for the</p>

section. When all required preliminary testing has been completed and no additional studies are felt to be needed, proceed with preparation of test procedure and personnel training. . . ." 4. Reviewed at 11:45 a.m. on 10/05/22, the policy "Test Implementation for Towner County Medical Center," dated 11/2015, stated, ". . . New Method Data: . . . Qualitative Testing . . . : 1) Approximately 5 patient correlations between testing methods. 2) Approximately 5 control correlations between new and old lots. . . ."