

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408659	(X3) Date Survey Completed 04/21/2021
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to enroll in proficiency testing for 2 of 2 regulated chemistry tests (magnesium and lactate dehydrogenase [LD]) started in May 2019. The laboratory performed approximately 200 magnesium and LD patient tests in May 2019 through April 21, 2021. Findings include: 1. Reviewed at 1:00 p.m. on 04/20/21, the laboratory's test menu listed magnesium and LD available for patient testing. 2. Reviewed at 1:10 p.m. on 04/20/21, the third event 2019, first-third events 2020, and first event 2021 proficiency testing records indicated the laboratory did not participate in proficiency testing for magnesium and LD. 4. During interview at 9:30 a.m. on 04/21/21, the laboratory supervisor (Personnel #1) confirmed the laboratory started performing magnesium and LD patient testing in May 2019 when the laboratory began using a new chemistry analyzer and did not enroll in proficiency testing since the start of magnesium and LD testing. 5. Reviewed at 10:00 a.m. on 04/21/21, the policy "Laboratory Proficiency Testing Policy," dated 11/2015, stated, ". . . Standards: 1. Proficiency testing must be performed for all regulated laboratory tests. . . ."</p>
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review, staff interview, and policy review, the laboratory failed to twice annually verify the accuracy of 4 of 19 non-regulated analytes (phosphorus, sperm absence/presence, direct bilirubin, and potassium hydroxide preparation [KOH prep]) in 2020. The laboratory performed approximately 40 phosphorus, one sperm absence/presence, 90 direct bilirubin, and 30 KOH prep patient tests in 2020. Findings include: 1. Reviewed at 1:00 p.m. on 04/20/21, the laboratory's test menu listed phosphorus, sperm absence/presence, direct bilirubin, and KOH prep available for patient testing. 2. Reviewed at 1:10 p.m. on 04/20/21, the 2020 proficiency testing records indicated the laboratory did not participate in proficiency testing for phosphorus, sperm absence/presence, direct bilirubin, and KOH prep. 3. Reviewed at 9:20 a.m. on 04/21/21, the laboratory's 2020 twice annual comparison records failed to provide evidence of twice annual accuracy verification for phosphorus and sperm absence/presence in 2020. These records indicated the laboratory verified the accuracy of direct bilirubin and KOH prep once in 2020. 4. During interview at 9:30 a.m. on 04/21/21, the laboratory supervisor (Personnel #1) confirmed the laboratory performed phosphorus, sperm absence/presence, direct bilirubin, and KOH prep patient testing in 2020 and did not twice annually verify the accuracy of these tests in 2020. 5. Reviewed at 10:00 a.m. on 04/21/21, the policy "Laboratory Proficiency Testing Policy," dated 11/2015, stated, ". . . Standards: 1. . . . Unregulated analytes must have one of the following: Proficiency Testing, Biannual in house comparison testing or Biannual comparison testing with another approved laboratory. . . ."

D6087

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on record review, manufacturer's instructions review, observation, staff interview, and procedure review, the laboratory failed to use the correct ISI (International Sensitivity Index) and mean normal protime (PT) value for calculating International Normalized Ratios (INRs) for 20 of 20 weeks (December 1, 2020 through April 20, 2021) since the laboratory began using a new lot number of Innovin (thromboplastin) reagent on their coagulation analyzer. The laboratory performed approximately 200 tests during this timeframe. Findings include: 1. Reviewed at 10:55 a.m. on 04/21/21, the 2018-2020 coagulation lot number change records failed to include data to determine the mean normal PT for Innovin lot number 549730. 2. Reviewed at 11:00 a.m. on 04/21/21, the Siemens Dade Innovin package insert for lot number 549730, dated 07/2018, stated the BFTII analyzer ISI as 0.89. 3. Observation of the BFT II coagulation analyzer at 11:30 a.m. on 04/21/21 revealed an ISI of 0.88 and a mean normal PT value of 9.5 used to calculate patient INRs. 4. During interview at 11:45 a.m. on 04/21/21, the laboratory supervisor (Personnel #1) confirmed the laboratory did not calculate a new mean normal PT using the new lot number of Innovin and confirmed the laboratory should use an ISI value of 0.89 for Innovin lot

number 549730. The laboratory supervisor (#1) stated she did not know the exact date the laboratory started using the new lot number of Innovin, but the old lot number expired on 11/30/20. 5. Reviewed on 04/21/21, the Siemens Dade Innovin package insert, dated 05/2008, stated, ". . . Determination of INR (International Normalized Ratio) . . . 1. . . . the PT results for patients on oral anticoagulants should be recorded as INR values. . . The INR is determined according to the following equation: $INR = R \text{ [powered to the ISI value]}$ where $R = \text{Patient PT [divided by] Mean normal PT}^{**}$ ISI is the International Sensitivity Index of the reagent/instrument combination. . . .^{**} The mean normal PT is defined as the mean value of the normal range. It must be determined specifically for each thromboplastin lot using the method used to analyze the patient samples . . ." 6. Reviewed on 04/21/21, the procedure "Dade - Innovin BFT II Prothrombin Time (PT)," dated 09/2014, failed to include a procedure to use when changing lot numbers of Innovin.