

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 35D0408659	<b>(X3) Date Survey Completed</b> 08/22/2018
<b>Name of Provider or Supplier</b> Towner County Medical Center	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5447</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on quality control (QC) record review, staff interview, patient record review, and policy review, the laboratory failed to perform two levels of QC for thirteen chemistry analytes on the Vitros 350 analyzer on 1 of 26 patient testing days (from 11:30 a.m. on 05/17/18 until 1:00 p.m. on 05/18/18) in May 2018. The laboratory tested and reported results for thirteen Vitros 350 analytes for approximately 13 patients during this timeframe. Findings include: 1. Reviewed at approximately 9:30 a.m. on 08/22/18, the May 2018 Vitros 350 chemistry QC records lacked evidence the laboratory performed two levels of QC from 11:30 a.m. on 05/17/18 until 1:00 p.m. on 05/18/18. Upon request, the laboratory failed to provide evidence of QC performance for this timeframe. 2. During interview at approximately 10:45 a.m. on 08/22/18, a technical supervisor (#1) stated the laboratory should perform QC every 24 hours of patient testing on the Vitros 350. A technical supervisor (#1) confirmed the laboratory did not have evidence of QC performance from 11:30 a.m. on 05/17/18 until 1:00 p.m. on 05/18/18 for thirteen analytes on the Vitros 350, and the laboratory reported patient results during this timeframe. 3. Reviewed at 10:50 a.m. on 08/22/18, the patient test records indicated the laboratory reported Vitros 350 chemistry results from 11:30 a.m. on 05/17/18 until 1:00 p.m. on 05/18/18 for the following patient samples: #374251, #374505, #374726, #374829, #376264, #375297, #375411, #375417, #375419, #375489, #376186, #376593, and #376736. 4. Reviewed at 1:40 p.m. on 08/22/18, the policy "General Laboratory Policy &amp; Laboratory Operation," dated 11/2015, stated, ".</p>

. . Quality Control runs and re-runs are as follows: . . . Vitros/Chemistry 2 levels (Level 1 & Level 2). Good for 24 hours. . . "