

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0397019	(X3) Date Survey Completed 08/29/2018
Name of Provider or Supplier Burnett Medical Center	Street Address, City, State 257 W St George Ave, Grantsburg, WI	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of manufacturer's instructions and laboratory records, observation of the coagulation analyzer, and interview with the general supervisor, the laboratory did not ensure the correct ISI (International Sensitivity Index) and mean patient value were entered in the analyzer for calculation of the INR (International Normalized Ratio) when the extended channel is used. Findings include: 1. Review of the manufacturer's instructions and laboratory records showed Innovin lot 549704 is in use. The manufacturer's instructions showed the ISI for this lot was 1.03 and laboratory records showed the mean patient value was 9.9 seconds. 2. Observation of the coagulation analyzer on August 29, 2018 at 10:15 AM showed the values entered for the PTX (Prothrombin Time Extended) mode were for lot 539230 with an expiration date of April 18, 2015. The entered ISI was 1.04 and the mean patient value was 9.7 seconds. 3. Interview with the general supervisor on August 29, 2018 at 10:15 AM confirmed the current ISI and mean patient values were not entered into the coagulation analyzer for the PTX mode. Further interview confirmed the PTX mode is used for some patient tests. This is a repeat deficiency cited on June 9, 2010 and July 9, 2008.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken</p>

when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on surveyor review of temperature recording charts and interview with the general supervisor, the laboratory has not documented corrective actions taken when the recorded temperature was outside the acceptable range in the refrigerator where blood units are stored. Findings include: 1. Review of the blood bank refrigerator recording chart from July 16, 2018 through July 23, 2018 showed recorded temperatures below one degree Celsius (C) from midnight Tuesday through Thursday noon and temperatures above six degrees C from Saturday noon through midnight Sunday. No documented explanation or corrective action is evident. 2. Interview with the general supervisor on August 29, 2018 at 9:30 AM confirmed the acceptable temperature range for the blood bank refrigerator is one to six degrees C. Further interview confirmed the recording chart shows temperatures outside the acceptable operating parameters with no explanation or corrective action documented.