

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0395521	(X3) Date Survey Completed 03/06/2024
Name of Provider or Supplier Aspirus Kronenwetter Clinic	Street Address, City, State 1881 Cty Hwy Xx, Mosinee, 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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Individualized Quality Control Plans (IQCP) and interview with the Laboratory Director, three of four current IQCPs did not specify the number and or type of external quality control required. Findings include: 1. Review of four current IQCP procedures showed references to the laboratory's required external quality controls for three IQCP were as follows: KOH (Potassium Hydroxide) IQCP: "The target level for one of the external quality control is near the medical decision cutoff point. (Positive KOH)." "This lab will perform external QC on this assay monthly; with each new lot; for each new shipment; for each newly trained testing staff." Troponin IQCP: "Level 1 control has a defined mean around 0.5 which is near the 0.3 medical decision cutoff level." "We verify the integrity of cartridges included in every shipment, upon receipt, by analyzing two levels of external controls. We also run two levels of external controls monthly." INR (International Normalized Ratio) IQCP: "The target level for one of the external quality control is near the medical decision cutoff point. Level 2 routinely runs at an INR of 2.8 - 3.2 which is the top of the normal therapeutic range." "We will run QC</p>

monthly and with each new lot to ensure accuracy. QC results must be within the Roche established QC range before testing can proceed." The fourth IQCP identified the number and type of controls required. 2. Interview with the laboratory director on March 6, 2024, at 1:00 PM confirmed the KOH, Troponin, and INR IQCP procedures did not specify the number and or type of external controls required.