

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0930919	(X3) Date Survey Completed 11/06/2018
Name of Provider or Supplier Aspirus Rib Lake Clinic	Street Address, City, State 1121 Hwy 102, Rib Lake, 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's quality control (QC) records and the Individualized Quality Control Plan (IQCP) for the Prothrombin Time test and interview with the laboratory director, the laboratory did not perform two levels of external QC as required and did not develop an acceptable IQCP. Findings include: 1. Review of QC records for the i-STAT analyzer showed two levels of external control material were not tested each day patient PT / INR (Prothrombin Time / International Normalized Ratio) testing was performed. 2. Review of the laboratory's i-STAT PT / INR IQCP showed the document specifies the Aspirus Medford Hospital Lab, CLIA number 52D0395481. The plan shows no reference to the Aspirus Rib Lake Clinic laboratory. 3. Interview with the laboratory director on November 6, 2018 at 2:00 PM revealed the laboratory's PT/INR IQCP was developed with data from multiple laboratories and is not specific for this laboratory. Further interview confirms the laboratory is performing quality control procedures based on the Aspirus Medford Hospital Laboratory PT/INR IQCP and is not performing two levels of external controls each day of patient testing as required.</p>
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on surveyor review of personnel records and interview with the laboratory director, annual competency records were not available for 2017 for two of two testing personnel. Findings include: 1. Review of personnel records showed no evidence of competency evaluation in 2017 for two of two testing personnel. 2. Interview with the laboratory director on November 6, 2018 at 1:00 PM confirmed the records of competency evaluation for 2017 could not be found.