Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0955865	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Awl Rawson Ave	7400 W Rawson Ave Suite G12, Franklin, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing records and interview with the technical consultant, the laboratory director or qualified designee has not signed the attestation statements for all hematology and chemistry events from the third event of 2016 through the second event of 2018. Findings include: 1. Review of proficiency testing records shows no evidence of the laboratory director's signature on the attestation statement for event three in 2016, events one, two, and three in 2017, and event one and two in 2018 for hematology and chemistry. 2. Interview with the technical consultant on July 25, 2018 at 9:00 AM confirmed that the laboratory director or designee has not signed the proficiency testing attestation statement for event three in 2016, events one, two and three in 2017, and events one and two in 2018 for hematology and chemistry.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit

	of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records in hematology and chemistry, and interview with the technical consultant, the laboratory failed to assess the control values to identify problems and did not perform calibration verification when shifts and trends in QC values are present and not corrected. Findings include: 1. Review of QC records for the Beckman DXC analyzer from March 2018 showed shifts below the laboratory's established means for four analytes reviewed: Magnesium; 19 of 21 values for QC level two were below the mean Total Bilirubin; 35 of 38 values for QC level two were below the mean Pediatric Bilirubin; 32 out of 36 values for QC level two were below the mean Albumin; 23 of 25 values for albumin QC level one were below the mean. QC records were stamped with the statement "no significant shifts/trends" and were initialed by the technical consultant with no evidence of additional assessment or corrective actions. 2. Review of QC records for the Coulter LH500 from April 2018 showed a shift below the mean for 25 out of 30 values for white blood cells, and 24 out of 30 values above the mean for hemoglobin for QC level two. QC records were stamped with the statement "no significant shifts/trends" and were initialed by the technical consultant with no evidence of additional assessment or corrective actions. 3. Interview with the technical consultant on July 25, 2018 at 10:00 AM confirmed that no additional review of QC data or calibration verification procedures were performed in response to shifts or trends in QC values.