Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2095211	07/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Oakleaf Clinics Menomonie	2919 Stout Road, Menomonie, 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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of calibration records and interview with the technical consultant, the laboratory failed to document the acceptability of four out of four calibration events for the Sysmex XP 300 hematology analyzer. Findings include: 1. Review of calibration records for the Sysmex XP 300 hematology analyzer show the laboratory failed to review and document the acceptability of four out of four calibrations which were performed by Minnesota Medical from September 15, 2017 through March 20, 2019. 2. Interview with the technical consultant on July 31, 2019 at 10:15 AM confirmed that the laboratory failed to review and document the acceptability of all calibration events as required.