Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0968924	10/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Consultants Laboratory Of Wi, Llc	145 N Main St, Fond Du Lac, 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 procedures, calibration records and interview with the technical consultant, the laboratory did not calibrate the Cell Dyn Ruby hematology analyzer at least every six months as required. The laboratory did not complete two of the four six-month calibrations required between September 2021 and September 2023. Findings include: 1. The laboratory's Cell Dyn Ruby Calibration procedure (SAT0020) defined the minimum frequency of calibration as, "at least every six months". 2. Review of laboratory records showed the laboratory calibrated the analyzer on September 16, 2021, November 30, 2022, and July 19 and 27, 2023. No additional records of calibration were available. 3. Interview with the technical consultant (staff B) on October 19, 2023, at 2:30 PM confirmed the records showed the laboratory had not calibrated the Cell Dyn Ruby analyzer every six months as required in their procedures. This is a repeat deficiency previously cited on November 18, 2019.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of competence evaluation records and interview with the previous technical consultant, the technical consultant did not evaluate the competence of six of six testing personnel for each non-waived test performed in the laboratory on a semi-annual basis for new employees or annually for testing personnel employed for more than one year at this laboratory. Findings include: 1. Review of competence evaluations for testing personnel revealed: Staff C: Started at this location in January 2023, records showed no site-specific competence evaluation documentation for this location and no semi-annual competence documentation. Staff D: The records showed no competence evaluations from 2022 or 2023. Staff E: The records showed training in March 2022 but no other competence evaluation records and no semi-annual competence evaluation documentation. Staff F: The records showed annual competence evaluations in January 2022 and August 2023 for urine microscopic exams, mononucleosis testing, and testing on the Cell Dyn Ruby analyzer. The records included no annual wet prep or manual differential competence evaluation documentation in 2022 or to date in 2023. Staff G: The records showed annual competence evaluation in January 2022 for urine microscopic exams, mononucleosis testing, and testing on the Cell Dyn Ruby analyzer. The records included no annual wet prep or manual differential competence evaluation documentation in 2022 or to date in 2023. Staff H: The records showed annual competence evaluation in January 2022 for urine microscopic exams, mononucleosis testing, and testing on the Cell Dyn Ruby analyzer. The records included no annual wet prep or manual differential competence evaluation documentation in 2022 or to date in 2023. 2. Interview with the previous technical consultant (staff A) on October 19, 2023, at 10:45 AM confirmed the laboratory procedures require semi-annual competence evaluations the first year and annual evaluations after the first year. Further interview confirmed the technical consultant did not complete the evaluations as required. This is a repeat deficiency previously cited on December 14, 2021, and November 18, 2019.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the previous technical consultant, the laboratory director did not ensure six of six testing personnel had demonstrated the ability to identify abnormal cells and morphology identified during performance of a hematology differential when the laboratory added abnormal differentials to their test menu in December 2022. Findings include: 1. Review of

	laboratory records including training and competence evaluations showed no evidence the laboratory evaluated the ability of the six testing personnel to accurately identify abnormal findings when performing hematology differentials. 2. Interview with the previous technical consultant (staff A) on October 19, 2023, at 12:45 PM revealed the laboratory started reporting abnormal cells and morphology on differentials in December 2022 and confirmed the technical consultant had not evaluated testing personnel to ensure they had demonstrated the ability to accurately identify abnormal cells and morphology prior to testing patient specimens.