Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0968924	11/18/2019
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of hematology procedures and interview with the technical consultant, the laboratory performed moderate complexity (normal) manual white blood cell (WBC) differentials but the procedures did not include criteria for referral of high complexity (abnormal) manual differentials. Findings include: 1. Review of "WBC, RBC and Platelet Morphology and Estimates in Peripheral Blood Smears Guidelines for Diffs and Morphs: when to add a manual diff and morph. HEM043 /011" and "Path Review Criteria for Abnormal Peripheral Smear" revealed no defined criteria requiring referral of high complexity (abnormal) manual WBC differentials to

	a reference laboratory. 2. Interview with the technical consultant on November 18, 2019 at 2:40 PM confirmed the hematology procedures did not include criteria for referral of an abnormal manual WBC differential to a reference laboratory.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of Cell Dyn Ruby installation records and interview with the technical consultant, the laboratory did not verify the performance specifications for accuracy and reportable range on the Cell Dyn Ruby prior to reporting patient results. Findings include: 1. Review of Cell Dyn Ruby installation records revealed the laboratory had no documentation showing evaluation of accuracy and reportable ranges before using the hematology analyzer for patient testing in December 2018. 2. Interview with the technical consultant on November 18, 2019 at 2:30 PM confirmed the laboratory did not verify performance specifications for accuracy and reportable range on the Cell Dyn Ruby prior to reporting patient results.
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 hematology calibration procedures, calibration records and interview with the technical consultant, the laboratory did not perform calibration at least every six months from January through August 2019. Findings include: 1. Review of "Cell Dyn Ruby Calibration SAT 0020/Ver 001" procedure showed calibration should be performed every six months. 2. Review of calibration records revealed the laboratory did not perform calibrations between January 2019 and August 2019. 3. Interview with the technical consultant on November 18, 2019 at 2:25 PM confirmed the laboratory did not perform a calibration between January and August 2019 on the Cell Dyn Ruby analyzer as required by their procedure.

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control records and interview with the technical consultant, the laboratory did not perform quality control each day of patient testing on the non-waived OSOM (brand) mononucleosis test. Findings include: 1. Review of the quality control records revealed the laboratory did not perform quality control each day of patient testing on the non- waived OSOM (brand) mononucleosis test. 2. Interview with the technical consultant on November 18, 2019 at 3:00 PM confirmed the laboratory performed the OSOM (brand) mononucleosis test as a non-waived test, did not perform quality control each day of patient testing, and did not develop an Individualized Quality Control Plan (IQCP) for the test.
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 testing personnel competency assessments and interview with the technical consultant, the technical consultant did not document competency to include problem-solving skills for four of four testing personnel and did not complete a semi-annual competency evaluation for one of one new testing personnel. Findings include: 1. Review of the competency assessment records revealed no documented evaluation of problem-solving skills. 2. Review of testing personnel competency assessment records revealed competency evaluation for Staff A was not documented twice during the first year. 3. Interview with the technical consultant on November 18, 2019 at 1:14 PM confirmed that there was no documentation of problem-solving skills in the competency assessment. Further interview on November 18, 2019 at 1:25 PM confirmed competency evaluation for Staff A was not documented twice during the first year of testing.