Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0397949	01/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Consultants Laboratory Of Wi, Llc	845 Parkside St, Ripon, 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: Item 1 Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the general supervisor, the laboratory director or designee did not attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods for one of three core chemistry events and two of three microbiology events in 2021 and one of three miscellaneous chemistry events, one of three core chemistry events, and one of three microbiology events in 2022. Findings include: 1. Review of API PT records from 2021 and 2022 showed the laboratory director or designee did not sign the attestation form for core chemistry event 1, microbiology events 1 and 2 in 2021 and miscellaneous chemistry event 2, core chemistry event 3, and microbiology event 3 in 2022. 2. Interview with the general supervisor on January 11, 2023, at 10:35 AM confirmed the laboratory director or designee did not attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods for one of three core chemistry events and two of three microbiology events in 2021 and one of three miscellaneous chemistry events, one of three core chemistry events, and one of three microbiology events in 2022. Item 2 Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the general supervisor, the laboratory director, or a qualified designee, did not attest to the routine integration of the immunohematology PT samples into the patient workload using the laboratory's routine methods for five of six immunohematology events in 2021 and 2022. Findings include: 1. Review of the API immunohematology PT records showed the general supervisor signed the immunohematology attestation

	statements as the designee. Further review showed the laboratory director, who is the immunohematology technical supervisor, did not sign five of six immunohematology attestation statements in 2021 and 2022. 2. Interview with the general supervisor on January 11, 2023, at 10:35 AM confirmed the laboratory director, or a qualified designee, did not attest to the routine integration of the immunohematology PT samples into the patient workload using the laboratory's routine methods for five of six immunohematology events in 2021 and 2022.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the general supervisor, the laboratory did not retain the lot and expiration dates for the hematology differential stains used on the Aerospray hematology slide stainer. Findings include: 1. Review of hematology logs showed no documentation of lot and expiration dates for the stains used on the Aerospray hematology slide stainer. 2. Interview with the general supervisor on January 11, 2023, at 2:18 PM confirmed the laboratory did not retain the lot and expiration dates for the hematology differential stains used on the Aerospray hematology slide stainer.
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: Item 1 Based on surveyor review of calibration verification records and interview with the general supervisor, the laboratory did not perform calibration verification every

	six months on the Beckman Coulter DxH520 hematology analyzer in 2021 and 2022. Finding include: 1. Review of calibration verification records showed calibration verification performed on the Beckman Coulter DxH520 Hematology analyzer on March 11, 2021, October 8, 2021 (due on September 11, 2021), April 13, 2022, and November 29, 2022 (due October 13, 2022). Further review showed no evidence of additional calibration verification performed on the analyzer between the due dates and the performed dates in 2021 and 2022. 2. Interview with the general supervisor on January 22, 2023, at 1:40 PM confirmed the laboratory did not perform calibration verification every six months on the Beckman Coulter DxH520 hematology analyzer in 2021 and 2022. Item 2 Based on surveyor review of calibration verification records and interview with the general supervisor, the laboratory did not perform calibration verification every six months on the Siemens CA-660 coagulation analyzer in 2021 and 2022. Finding include: 1. Review of calibration verification records showed calibration verification performed on the Siemens CA-660 coagulation analyzer on November 30, 2022. Further review showed no evidence of additional calibration verification performed on the analyzer in 2021 and 2022. 2. Interview with the general supervisor on January 11, 2023, at 3:20 PM confirmed the laboratory did not perform calibration verification every six months on the Siemens CA-660 coagulation analyzer in 2021 and 2022. Item 3 Based on surveyor review of calibration verification records and interview with the general supervisor, the laboratory did not perform calibration verification every six months on the Beckman AU700 chemistry analyzer in 2021 and 2022. Finding include: 1. Review of calibration verification records showed calibration verification performed on the Beckman AU700 chemistry analyzer on October 29, 2021, and May 22, 2022 (due April 29, 2022). Further review showed no evidence of additional calibration verification performed on the analyzer between April 29, 2022 and May 22, 2022. 2. Interview with the general supervisor on January 12, 2023, at 9:20 AM confirmed the laboratory did not perform calibration verification every six months on the Beckman AU700 chemistry analyzer in 2021 and 2022.