Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0968924	01/15/2026
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory policies and interview with a Technical Consultant/Technical Supervisor (TC/TS), Staff A, the laboratory did not establish a process for evaluating the competency of personnel performing delegated responsibilities in three of three Clinical Laboratory Improvement Amendment (CLIA) regulations named positions: TC, TS, and General Supervisor (GS). Findings include: 1. Review of the laboratory's procedure manual revealed no evidence of a written policy to assess employee competency for personnel performing delegated responsibilities in the TC, TS, and GS positions. 2. Interview with Staff A on January 15, 2026, at 9:30 AM confirmed the laboratory did not establish and follow written policies to assess employee competency for the personnel performing delegated responsibilities in the TC, TS, and GS positions.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, and interview with a Technical Consultant/Technical Supervisor (Staff A), the current laboratory director did not

	approve three out of the five procedures reviewed from the laboratory's procedure manual. Findings include: 1. Review of the laboratory's procedure manual revealed no evidence the current laboratory director had approved the test procedures for performing urine microscopic testing, vaginal wet mount testing, and infectious mononucleosis testing using the Sekisui Diagnostics OSOM Mono Test Kit. 2. Interview with Staff A on January 15, 2026, at 1:10 PM confirmed the current laboratory director did not approve all of the procedures in use in the laboratory.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 laboratory records and interview with a Technical Consultant/Technical Supervisor (TC/TS), Staff A, the laboratory could not show they evaluated performance characteristics for one of one new analyzers after moving the Sysmex XN-450 hematology analyzer into the clinic and before patient testing was performed starting on April 22, 2025. Findings include: 1. Review of laboratory records showed no evidence the laboratory demonstrated it could obtain performance specifications comparable to those established by the manufacturer for the Sysmex XN-450 analyzer. 2. In an interview on January 15, 2026, at 1:45 PM, Staff A stated the laboratory started patient testing with the Sysmex XN-450 on April 22, 2025, after verifying performance specifications at this location with the analyzer. Further interview confirmed records for the verification were not available. 52883
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with a Technical Consultant/Technical Supervisor (Staff A), the laboratory director did not meet the requirement of conducting and documenting an onsite visit at least once every six months, with at least four months between onsite visits, for two of two required visits in 2025. Findings include: 1. Review of laboratory records revealed no evidence the laboratory director conducted any onsite visits in 2025. 2. Interview with Staff A on January 15, 2026, at 9:40 AM confirmed the laboratory director had not conducted the two required onsite visits in 2025.

D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on surveyor observation in the laboratory, review of manufacturer specifications and environmental records, and interview with a Technical Consultant /Technical Supervisor (Staff A), the laboratory director did not ensure that the environmental conditions of the laboratory were appropriate for use of the Sysmex XN-450 hematology analyzer, one of one hematology analyzer in use in the laboratory. Findings include: 1. Observation on January 15, 2026, at 2:00 PM revealed a Sysmex XN-450 hematology instrument operating in the laboratory. 2. Review of manufacturer's performance specifications/characteristics for the Sysmex XN-450 showed the ambient temperature range for operating the instrument was 15 to 25 degrees Celsius and the relative humidity range was 20 to 85%. 3. Review of environmental records in the laboratory showed no evidence the laboratory monitored the ambient room temperature and relative humidity of the laboratory when the laboratory was operating and personnel were using the Sysmex XN-450. 4. Interview with Staff A on January 15, 2026, at 1:32 PM confirmed personnel did not monitor the ambient room temperature and relative humidity of the laboratory, and that the director had not ensured the laboratory could maintain temperature and humidity levels appropriate for the testing performed in the laboratory.