

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0394045	(X3) Date Survey Completed 09/16/2024
Name of Provider or Supplier Consultants Laboratory Of Wi, Llc	Street Address, City, State 130 Corporate Dr, Beaver Dam, 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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the technical consultant, 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 three of three Hematology /Coagulation events in 2023. Findings include: 1. Review of API PT records showed no laboratory director or designee signatures on the attestation forms for all three Hematology/Coagulation events in 2023. 2. Interview with the technical consultant on September 16, 2024, at 10:40 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 in 2023.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the technical consultant, the laboratory did not review and evaluate the results obtained on proficiency testing performed for three of three</p>

	<p>events in 2023. Findings include: 1. Review of API PT records show the no documentation of review and evaluation of PT results for all three Hematology /Coagulation events in 2023. 2. Interview with the technical consultant on September 16, 2024 at 10:40 AM confirmed the laboratory did not review and evaluate PT results in 2023.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of reagents, review of laboratory records and interview with testing personnel, staff A, and the technical consultant, the laboratory used one of one expired reagents to perform potassium hydroxide (KOH) testing for patient testing. Findings include: 1. Observation of KOH reagent on September 16, 2024, at 12:10 PM showed KOH 10%, Lot# 613416, expiration date 07/20/2024, available for patient testing. 2. Interview with staff A on September 16, 2024 at 12:10 PM confirmed KOH was used for vaginal wet prep samples to help define elements during testing. 3. Review of patient testing in the laboratory information system (LIS) showed twenty KOH patient tests had been performed between July 21, 2024, and September 16, 2024. 4. Interview with the technical consultant on September 16, 2024, at 12:10 PM confirmed the laboratory used expired reagents to perform KOH testing.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of testing personnel competency records and interview with the technical consultant, the technical consultant did not perform a semiannual evaluation of testing performance for one of one new testing personnel during the first year the individual performed patient testing. Findings include: 1. Review of testing personnel competency records for staff B showed initial training and competency in August 2023. Further review showed no documentation of a semiannual competency evaluation. 2. Interview with the technical consultant on September 16, 2024, at 10:25 AM confirmed the technical consultant did not perform a semiannual evaluation of testing performance for one of one new testing personnel during the first year the individual performed patient testing.</p>