Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2204989	07/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Wisconsin Spine And Pain, Sc	2124 Kohler Memorial Drive, Suite 100, Sheboygan, 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: Item 1 Based on surveyor review of personnel records and procedures and interview with a testing personnel (Staff A), the laboratory did not establish and follow written procedures to assess employee competency for two of two personnel performing technical consultant responsibilities. Findings include: 1. Review of laboratory records showed two individuals (Staff B and Staff C) perfromed technical consultant responsibilities. Further review showed no evidence that the laboratory director evaluated the competency of the individuals performing technical consultant responsibilities. 2. Review of the laboratory's policy, 'Laboratory Competency Policy,' revealed no evidence of a procedure that defined the process for competency evaluation of the technical consultants. 3. Interview with Staff A on July 9, 2026, at 11:45 AM confirmed the laboratory did not have a written procedure for competency evaluation of personnel performing technical consultant responsibilities. Item 2 Based on surveyor review of the laboratory's competency assessment procedures and records, and interview with a testing personnel (Staff A), the laboratory did not follow its written policies and procedures to assess employee competency for one of one testing personnel. Findings include: 1. Review of 'Laboratory Competency Policy,' showed the policy stated, "A Six Month and Annual Laboratory Competency Assessment will be conducted on each employee performing patient testing. The six month competency evaluation should take place approximately six months after the employee has been trained to perform the testing. The annual competency evaluation should be as close to the one year mark from initial training as possible. The annual

	competency evaluation must not exceed the one year mark." 2. Review of training and competency assessment records for Staff A showed: -'Viva-ProE TRAINING CHECKLIST', completed on November 3, 2023 -'POL and Clinic Laboratory Competency Assessment' form marked "six month assessment", completed April 23, 2024 -'POL and Clinic Laboratory Competency Assessment' form marked "annual", completed October 30, 2025. There was no evidence Staff A had an annual competency assessment within one year of the date on the initial training checklist, November 3, 2023. 3. Interview with Staff A on July 9, 2026, at 11:50 AM confirmed Staff A did not have an annual competency evaluation within one year of their initial training, confirming the laboratory did not follow its written procedures to assess employee testing personnel competency for one of one testing personnel.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of the laboratory procedures and interview with a testing personnel (Staff A), the one of one procedure manual failed to include information to describe the laboratory's system for entering results in the patient record and reporting patient results. Findings include: 1. Review of the laboratory's approved procedure manual revealed no evidence the laboratory had a procedure to describe the laboratory's system for entering results in the patient record and reporting patient results. 2. During an interview with Staff A on July 9, 2026, at 12:00 PM, Staff A described that testing personnel scan the instrument printout into the Toxicology tab in the patient's electronic medical record and confirmed the laboratory did not have an approved procedure that described the laboratory's system for entering results in the patient record and reporting patient results. Item 2: Based on surveyor review of the laboratory's records and procedure manual, and interview with a testing personnel (Staff A), the laboratory's one of one quality control procedure failed to include control procedures specific for the laboratory's testing. Findings include: 1. Review of quality control records revealed the laboratory used two controls, "OXY NEG" and "OXY POS" for the oxycodone test, and two controls, "Level 0" and "Level 5", for the opiate, methadone, benzodiazepine, barbiturate, and amphetamines tests. 2.

	Review of the laboratory's 'Quality Control Policy' stated, "Both Positive and Negative controls must be run each day of testing for each analyte assayed." The policy in section C. 'Quality Control Policy Addendum' stated, "Level 0, Level 5 and all other qualitative controls should perform within manufacturer's stated limits." Further review of the policy showed no evidence of information for the separate oxycodone controls (type of control and identity) and did not include information about the specific type of controls (e.g. manufacturer) in use in the laboratory. 3. Interview with Staff A on July 9, 2026, at 12:25 PM confirmed the procedure did not include the type of control in use for the six drug monitoring assays and did not include identity of the controls used for the oxycodone assay.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of problem log and quality control (QC) records and interview with a testing personnel (Staff A), the laboratory did not evaluate all patient test results for amphetamine (Amph) obtained since the last acceptable test run to determine if patient test results were adversely affected for one of one day in January 2026 when QC was not acceptable and testing personnel made changes to the test system to obtain acceptable QC results. Findings include: 1. Review of the problem log dated January 15, 2026 stated, "Level 5 QC for Amph too high & exceeded cut off limit. x2 Ref. #3630906. Reran QC for Amph w/fresh reagent & fresh QC - same issue. Called Siemens - PM yearly maint. done yesterday by Siemens tech. Ran calibrations & QC for Amph. OK." The laboratory indicated no patient results were affected. There was no evidence of records showing how the laboratory made the determination that no patient results were affected. 2. Review of the QC History - Level 5 report for Amphetamines showed two QC results from January 15, 2026, that did not meet the expected separation of 0.021 and the Calibration Report for Amphetamines on January 15, 2026, confirming the statement on the problem log. Further review showed the laboratory obtained acceptable QC results after performing calibration. 3. Interview with Staff A on July 9, 2026, at 12:55 PM confirmed the laboratory did not review amphetamine patient test results obtained since the last acceptable QC run when the laboratory made changes to the test system that could have affected patient test results.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel

	meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) 'Laboratory Personnel Report (CLIA)' form (Form CMS-209), laboratory records, and interview with a testing personnel (Staff A), the director failed to delegate in writing technical consultant duties to two of two individuals performing the duties, and did not document evaluation of competency for the individuals performing the delegated duties. Findings include: 1. Review of the Form CMS-209 showed the director named Staff B as a technical consultant but did not identify Staff C as a technical consultant. 2. Review of competency evaluation records showed Staff C performed the technical consultant responsibility of evaluating competency of testing personnel when Staff C performed Staff A's annual competency evaluation in 2025. 3. Review of laboratory records revealed no evidence the laboratory director delegated technical consultant responsibilities to Staff B and Staff C. Further review showed no documented competency evaluations of Staff B and Staff C in performing technical consultant responsibilities. 4. Interview with Staff A on July 9, 2026, at 11:45 AM confirmed the laboratory director had not delegated technical consultant responsibilities to Staff B and Staff C in writing and confirmed the laboratory had no record of evaluation of the individuals' competency in performing technical consultant responsibilities.