Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2104448	02/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Omni Spine Pain Management, Pllc	8380 Warren Pkwy Suite 100, Frisco, TX	

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
D0000	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation, and confirmed in interview, the laboratory failed to ensure storage temperatures were within manufacturer's specifications for one of one reagent in February 2026. Findings included: 1. During a tour of the facility on 02/18 /2026 at 09:35 AM, the surveyor observed one flammable cabinet in the laboratory storage area. Upon further inspection, the flammable cabinet contained the following two bottles: XZ Formic Acid Lot Number: 252749 Manufacturer temperature requirements: 15-25 C The laboratory was asked to provide room temperature documentation of the laboratory storage area. No documentation was provided. 2. In an interview on 02/18/2026 at 09:37 AM in the laboratory storage area, the general supervisor (GS-1) confirmed the laboratory failed to ensure storage temperatures were within manufacturer's specifications for one of one reagent in February 2026. Word Key C-Celsius
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

	CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, Liquid Chromatography Mass Spectrometry (LCMS) establishment study performed in 2025, and confirmed in interview, the laboratory failed to document all performance characteristics for test performance of a laboratory developed test (LDT), to include column specifications for one of one FDA-modified test system performed in March 2025. Findings included: 1. During a tour of the facility on 02/18/2026 at 09:35 AM, the surveyor observed one LCMS analyzer available for patient testing (Serial Number: B121621304). 2. Review of laboratory policy, "Method Development Standard Operating Procedure" (Approved by the Laboratory Director on 03/25/2025) revealed the following: "Summary Standardizing LCMS/MS method validation is critical for ensuring the accuracy, reliability, and reproducibility of analytical results, particularly in clinical and diagnostic laboratories. ...5. Equipment and Materials ...5.3 LCMS/MS Materials ...LCMS Column and Guard Column" 3. Review of laboratory LCMS toxicology establishment summary, "Pain Panel LCMS/MS Validation Study" (Approved by the Laboratory Director on 03/25/2025) revealed the laboratory failed to document LCMS column performance characteristics in the establishment study. 4. Review of LCMS column manufacturer's instructions revealed the laboratory performed toxicology patient testing with the Restek LC Column (Serial Number: 919035396). The laboratory was asked to provide documentation of the established Restek LCMS Column performance characteristics, and none were provided. 5. In an interview on 02/18/2026 at 10:48 AM, the general supervisor (GS-1) confirmed the laboratory failed to document all performance characteristics for test performance of a laboratory developed test (LDT), to include column specifications for one of one FDA-modified test system performed in March 2025. Word Key FDA- Food and Drug Administration
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of laboratory policy, environmental records, patient reports, and confirmed in interview, the laboratory failed to document corrective actions when temperatures fell outside acceptable range, for 36 of 50 randomly reviewed days in 2025. Findings included: 1. Review of laboratory policy, "Specimen Management

	Procedure" (Approved by the Laboratory Director on 03/25/2025) revealed the following: "1. Purpose To ensure proper collection, labeling, acceptance, storage, transport, retention, and disposal of all patient specimens to maintain specimen integrity, accuracy of test results, and compliance with CLIA/COLA requirements. 2. Scope Applies to all laboratory personnel handling specimens for testing in processing and storage. ...4. Specimen Storage 1. Store specimens according to test-specific requirements: ...Refrigerated: 2-8 C ... ...2. Protect specimens from light, contamination, and temperature fluctuations." 2. Random review of laboratory environmental records in 2025, revealed the following days temperatures fell outside the acceptable range: a. Date: 06/18/2025; Temperature Recorded: 1.6 C b. Date: 06 /19/2025; Temperature Recorded: 1.3 C c. Date: 06/20/2025; Temperature Recorded: 1.2 C d. Date: 06/24/2025; Temperature Recorded: 1.5 C e. Date: 07/01/2025; Temperature Recorded: 1.2 C f. Date: 07/03/2025; Temperature Recorded: 1.3 C g. Date: 07/08/2025; Temperature Recorded: 1.2 C h. Date: 07/14/2025; Temperature Recorded: 1.2 C i. Date: 07/15/2025; Temperature Recorded: 1.3 C j. Date: 07/17 /2025; Temperature Recorded: 1.3 C k. Date: 07/18/2025; Temperature Recorded: 1.7 C l. Date: 07/25/2025; Temperature Recorded: 1.3 C m. Date: 07/29/2025; Temperature Recorded: 1.2 C n. Date: 08/01/2025; Temperature Recorded: 1.2 C o. Date: 08/04/2025; Temperature Recorded: 1.3 C p. Date: 08/05/2025; Temperature Recorded: 1.5 C q. Date: 08/11/2025; Temperature Recorded: 1.3 C r. Date: 08/14 /2025; Temperature Recorded: 1.3 C s. Date: 08/18/2025; Temperature Recorded: 1.3 C t. Date: 08/20/2025; Temperature Recorded: 1.3 C u. Date: 08/27/2025; Temperature Recorded: 1.3 C v. Date: 08/30/2025; Temperature Recorded: 1.3 C w. Date: 09/02/2025; Temperature Recorded: 1.3 C x. Date: 09/04/2025; Temperature Recorded: 1.3 C y. Date: 09/08/2025; Temperature Recorded: 1.2 C z. Date: 09/15 /2025; Temperature Recorded: 1.2 C aa. Date: 09/17/2025; Temperature Recorded: 1.2 C ab. Date: 09/22/2025; Temperature Recorded: 1.3 C ac. Date: 09/24/2025; Temperature Recorded: 1.3 C ad. Date: 09/25/2025; Temperature Recorded: 1.3 C ae. Date: 10/05/2025; Temperature Recorded: 1.6 C af. Date: 10/06/2025; Temperature Recorded: 1.6 C ag. Date: 10/10/2025; Temperature Recorded: 1.6 C ah. Date: 10/13 /2025; Temperature Recorded: 1.7 C ai. Date: 10/17/2025; Temperature Recorded: 1.6 C aj. Date: 10/20/2025; Temperature Recorded: 1.7 C The laboratory was asked to provide documentation of corrective actions for the above days temperatures were not within acceptable range in 2025, and no documentation was provided. 3. Review of patient test volumes in 2025 revealed the laboratory processed 3,091 patient specimens from June-October 2025 while the above out of range temperatures were recorded. 4. In an interview on 02/18/2026 at 11:12 AM, in the laboratory office, the laboratory general supervisor (GS-1), confirmed the laboratory failed to document corrective actions when temperatures fell outside acceptable range, for 36 of 50 randomly reviewed days in 2025. Word Key C- Celsius CLIA- Clinical Laboratory Improvement Amendments COLA- Commission on Office Laboratory Accreditation
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) 116 Form, proficiency testing (PT) records, laboratory policy, and confirmed in interview, the laboratory director failed to ensure all regulated analytes were enrolled in proficiency

	testing for one of one regulated analyte in 2025. Findings included: 1. Review of CMS-116 form submitted at time of survey (02/18/2026), revealed the laboratory began toxicology patient testing in March 2025. The toxicology analytes performed included one regulated analyte, Phenobarbital. 2. Review of laboratory PT documentation in 2025, revealed the laboratory failed to enroll in an approved PT program until 2026 for toxicology testing. Resulting in two missed events for the regulated analyte, Phenobarbital. The laboratory was asked to provide PT enrollment for Phenobarbital in 2025, and no documentation was provided. 3. Review of laboratory policy, "Proficiency Testing Procedure" (Approved by the Laboratory Director on 03/25/2025) revealed the following: "1. Purpose To ensure accurate, reliable testing and regulatory compliance through structured participation in proficiency testing (PT) programs and external verification for applicable analytes. ... 3. Policy Requirements (High-level) The laboratory shall maintain annual enrollment in approved PT programs for all regulated and applicable non-waived analytes." 4. In an interview on 02/18/2026 at 10:15 AM in the laboratory office, the general supervisor (GS-1) confirmed the laboratory director failed to ensure all regulated analytes were enrolled in proficiency testing for one of one regulated analyte in 2025.