

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2190912	(X3) Date Survey Completed 06/29/2026
Name of Provider or Supplier Spine And Wellnes Centers Of America	Street Address, City, State 405 S 21st Ave, Hollywood, FL	
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	An announced CLIA recertification survey was conducted at SPINE AND WELLNESS CENTERS OF AMERICA on June 29, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency cited as follows:
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory failed to have a mechanism to monitor that samples were within the acceptable temperature range during transportation from collection sites to Laboratory from February 2025 to present. Findings included: 1-Review of CMS-116 CLINICAL LABORATORY IMPROVEMENT AMENDEMENTS (CLIA) APPLICATION FOR CERTIFICATION, signed by the Laboratory Director (LD) on 06/02/2026 revealed that the laboratory performed the following tests in urine using Liquid Chromatography Tandem Mass Spectrometry (LC/MS): Screening of the following drugs: Amphetamines, Benzoyllecgonine, Buprenorphine, 3,4-Methylenedioxymethamphetamine (MDMA), Methadone, Morphine, Oxazepam, Oxycodone, Phencyclidine and Secobarbital. Confirmation of the following drugs: 6-MAM (6-Monoacetylmorphine), 7-Aminoclonazepam, Alpha-Hydroxyalprazolam, Amitriptyline, Amphetamine, Benzoyllecgonine, Buprenorphine, Bupropion, Butalbital, Carisoprodol (SOMA), Clonazepam, Codeine, Cyclobenzaprine,

Desipramine, Diazepam, Doxepin, Duloxetine, EDDP (Methadone metabolite), ETS, Fentanyl, Fluoxetine, Gabapentin, Hydrocodone, Hydromorphone, Imipramine, Ketamine, Levorphanol, Lorazepam, MDMA, Meperidine, Meprobamate, Methadone, Methamphetamine, Midazolam, Mitragynine, Morphine, Naloxone, Naltrexone, N-desmethyl-Tapentadol, Norbuprenorphine, Norcodeine, Nordiazepam, Norfentanyl, Norhydrocodone, Normeperidine, Noroxycodone, Nortriptyline, O-Desmethyltramadol, Oxazepam, Oxycodone, Oxymorphone, Phenobarbital, Phencyclidine, Pregabalin, Ritalinic Acid, Secobarbital, Sertraline, Tapentadol, Temazepam, Venlafaxine, Zolpidem. The laboratory had an annual volume of 360,000 tests. 2-Review of procedure signed by LD on 10/23/2025 revealed that the policy "SPE 100.1 Laboratory Sample Collection" -Section "Retrieval of specimens from facilities and transport of specimens to laboratory" stated: -Specimens are picked up by Fedex courier hired by the practice. -Specimens are transported within a climate-controlled environment. -The samples can be stored post collection at room temperature, 20-25 C for up to 24 hours. -Specimens can be sent at ambient temperature." -Section "Specimen Stability" stated "Specimen's stability for the conditions below has been established by the laboratory. 1- Room Temperature: 4-5 days 2-Refrigerated: 14 days" -The policy failed to describe how to monitor sample temperature during the transportation (acceptable range of 20-25 C) and failed to provide instructions to ensure the "climate-controlled environment" to the courier. 3-Review of CHAIN OF CUSTODY FORM from the collection sites for the following months: February 2025, July 2025, April 2026 and May 2026, revealed the laboratory received the following sample quantities: February 2025: The laboratory received 276 samples. July 2025: The laboratory received 298 samples. April 2026: the laboratory received 318 samples. May 2026: The laboratory received 285 samples. 4-Review of the laboratory CHAIN CUSTODY FORM of the laboratory for the following months: February 2025, July 2025, April 2026 and May 2026, revealed that the laboratory failed to monitor the transit time and sample temperature during the transit time based on the acceptable range of 20-25 C. 5-During an interview on 06/29/2026 at 02:30 PM, the Technical Supervisor confirmed that the laboratory was not monitoring the temperatures of the samples during transportation and could not provide documentation that the samples were in a climate-control environment (of 20-25 C) as per their policy.