Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2134978	04/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Certified Spine And Pain Care Llc	160 Congress Park Drive Suit 101, Delray Beach, 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 initial certification survey was conducted in conjunction with an unannounced complaint survey, #2023004759, on 04/10/2023 to 04/12/2023 at Certified Spine and Pain Care LLC clinical laboratory. The facility was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. The following Condition was cited: D3000- Facility Administration 493.1100
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation, review of laboratory records, and interview, the laboratory failed to have separate supplies and records for Toxicology testing since 06/01/2022 (See D3007).
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

	This STANDARD is not met as evidenced by: Based on observation, review of chemical safety data sheets (SDS), and interview, the laboratory failed to have a fume hood since the instrument was installed and in use for toxicology testing on 04/29/2022. Findings Included: During a tour of the laboratory on 04/10/2023 at 11:00 AM the following chemicals for toxicology were observed in use: Acetonitrile Non-UV for Gas Chromatography and Residue Analysis Omnisolv (R), Methanol LC-MS Grade For Liquid Chromatography, and Formic acid 98 - HPLC LiChropur. No fume hood was observed. Review of the SDS for "Acetonitrile Non-UV For Gas Chromatography and Residue Analysis Omnisolv(R)" stated under handling and storage "Work under hood." Review of SDS for "Methanol LC-MS Grade For Liquid Chromatography- Mass Spectrometry OmniSolv" stated under handling and storage "Work under hood." Review of SDS for "Formic acid 98 - HPLC LiChropur" stated under handling and storage "Work under hood." During interview on 04/11/2023 at 2:00 PM, the Technical Supervisor confirmed that the chemicals had been used since the installation of the LCMS Toxicology instrument on 04/29/2022 and that a hood was required per the SDS.
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on observation, review of laboratory records, and interview, the laboratory failed to have separate supplies and records for Toxicology testing since 06/01/2022. Findings Included: Record review of the CLIA 116 Application and observation on April 10, 2023 revealed 2 laboratories located at the same physical address, this laboratory and another Certificate of Registration laboratory (to be referred to as Lab B). During a tour of the laboratory on 04/10/2023 at 11:00 AM it was observed there was a single Sciex Exion LC + Sciex 4500 MD Mass Spectrometer instrument that was located in the laboratory. This Toxicology instrument was being used by this Laboratory and Lab B. There was no hours of operation for when this laboratory and Lab B would be using the instrument. The hours of operation were corrected while on-site during survey. There was no differentiation between this Laboratory and Lab B in the flammable cabinet, refrigerator, or freezer. During an interview on 04/10/2023 at 12:02 PM, the General Supervisor stated that this Laboratory and Lab B Patient samples were ran on the instrument at the same time and were only separated by the account number. Review of the CMS 116 signed by the Laboratory director on 04/10 /2023 revealed that the Laboratory performed Toxicology screens for the following drugs: Amphetamine, MDMA, Barbiturates, Methadone, Benzodiazepines, Opiates, Benzoylecgonine, Oxycodone, Buprenorphine, and PCP and confirmation testing for the following drugs: 6-MAM, Meprobamate, 7-amino-Clonazepam, Methadone, alpha-hydroxy-Alprazolam, Methamphetamine, Alprazolam, Mitragynine, Amitriptyline, Morphine, Amphetamine, Naloxone, Benzoylecgonine, Naltrexone, Buprenorphine, N-desmethyl-Tapentadol, Bupropion, Norbuprenorphine, Butalbital, Norcodeine, Carisoprodol, Nordiazepam, Clonazepam, Norfentanyl, Codeine, Norhydrocodone, Cyclobenzaprine, Normeperidine, Desipramine, Noroxycodone, O-Desmethyl-Tramadol, Nortriptyline, Diazepam, Oxazepam, Doxepin, Oxycodone, Duloxetine, Oxymorphone, EDDP (Methadone primary metabolite), PCP, Ethyl Sulfate,

	Phenobarbital, Fentanyl, Pregabalin, Fluoxetine, Ritalinic Acid, Gabapentin, Secobarbital, Hydrocodone, Sertraline, Hydromorphone, Tapentadol, Imipramine, Temazepam, Ketamine, Tramadol, Lorazepam, Venlafaxine, MDMA, Zolpidem, and Meperidine. The annual testing volume was documented as 645,000. Review of the Laboratory records revealed that since there was one instrument with samples being ran together, this Laboratory and Lab B had the same documents. There was one validation performed in May 2022 being used by this Laboratory and Lab B. All of the maintenance, calibrations, quality control, and preparation logs contained the same data but were each on separate letterhead for this Laboratory and Lab B since the labs were intermingled. On 04/11/2023 at 9:30 AM, the Technical Supervisor confirmed this Laboratory and Lab B had everything combined.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of Patient final reports and interview, the laboratory failed to accurately indicate the address of where the testing was performed for 2 out of 2 Patient final reports reviewed. Findings Included: Review of the final reports for Patient #1 (performed on 04/05/2023) and Patient #2 (performed on 03/28/2023) revealed the testing was performed at the laboratory. During an interview on 04/12 /2023 at 10:00 AM, the Technical Supervisor stated the interpretation of results were occasionally performed remotely and confirmed that the final reports for Patients #1 and #2 did not reflect the interpretation being performed off-site.