Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1057542	03/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Neuro Pain Consultants	30675 Stephenson Highway Suite L 3, Madison Heights, MI	

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
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 and interview, the laboratory failed to properly ventilate one of three instruments observed. Findings include: 1. During the tour of the laboratory on March 29, 2018 from approximately 10:00 AM to 12:00 PM, the surveyor observed a missing piece of vent hose connecting the 4500 analyzer to the ventilation system. 2. During the tour of the laboratory on March 29, 2018 from approximately 10:00 AM to 12:00 PM, technical supervisor #1 confirmed that the 4500 analyzer was not connected to the ventilation system and was venting directly into the room.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to meet the requirements for the specialty in Toxicology as specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to order tests correctly. Refer to D5309. 2. The laboratory failed to monitor and document the room temperature and humidity readings. Refer to D5413. 3. The laboratory failed to label

	the toxicology reagents with the preparation and/or expiration date. Refer to D5415. 4. The laboratory failed to document the corrective action taken for the out of range temperatures. Refer to D5785.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to order tests correctly for one of five patients (#1) reviewed. Findings include: 1. Review of the test requisition for patient #1 revealed the Patient Panel 3 (Low Risk) was ordered on 03/12/2018. The test requisition stated "Patient Panel 3 (Low Risk): Benzodiazepines, Methadone, Fentanyl, Opiates (Codeine, Morphine, Hydrocodone, Hydromorphone, Buprenorphine, Norbuprenophine) Opioid and opiate analogues (Fentanyl, Norfentanyl oxaite, Sufentanil, Meperidine, Normeperidine), Oxycodone, Tapentadol, Tramadol, Alcohol, THC. 2. Review of the test report for patient #1 revealed the following: a. No results for Meperidine or Normeperidine. b. Results for Benzoyleggonine Cocaine Metabolite and EDDP. 3. During interview on March 29, 2018 at approximately 2:45 PM, testing personnel #2 acknowledged there were discrepancies between the test requisition and test report.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 observation, record review, and interview, the laboratory failed to monitor and document the room temperature and humidity for 1) nine (March 19-23 and 26-28) of 28 days for the Sciex Qtrap 4500 analyzer room and 2) for two (February and March) of two months for the Sciex Qtrap 3200 and 5500 analyzer room in 2018 to ensure reliable toxicology instrument operation. Findings include: 1. During a tour of the laboratory on March 29, 2018 from approximately 10:00 AM to 12:00 PM, the surveyor observed the "Daily Temperature and Humidity Log" in use. 2. Record review of the "Daily Temperature and Humidity Logs" revealed the laboratory did not monitor and document the daily room temperature and humidity readings as follows: a. Sciex Qtrap 4500 analyzer room - no documentation of the daily room temperature and humidity for March 19-23 and 26-28, 2018 b. Sciex Qtrap 3200 and 5500 analyzer room - no documentation of the daily room temperature and humidity for February and March 2018 3. During the tour on March 29, 2018 from approximately 10:00 AM to 12:00 PM when queried, testing personnel #2 as listed on the CMS-209

	was not able to provide the surveyor documentation to show the daily room temperature and humidity readings had been monitored and documented. 4. During the tour on March 29, 2018 from approximately 10:00 AM to 12:00 PM, testing personnel #2 confirmed the daily temperatures and humidity readings were not monitored and documented.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation and interview, the laboratory failed to label the toxicology reagents with the preparation and/or expiration date for the reagents curve A, curve B, curve AB, ETG, ETGB, Meth, and the needle wash on the day of the survey. Findings include: 1. On March 29, 2018 from approximately 10:00 AM to 12:00 PM during a tour of the laboratory, the surveyor observed bottled reagents in use that did not have documentation of a preparation and/or expiration date as follows: a. reagent prep room - 1. curve B (100% MeOH + 0.1% formic acid) no preparation or expiration date 2. curve AB (1900 ml H20 + 100 ml MeOH + 1900 Ammonium formate + 100 ml formic acid) no expiration date b. flammable cabinet - ETG (1 ml Aceto + 1 ml Acetic acid) no expiration date c. Sciex Qtrap 3200 analyzer room 1. Meth - no expiration date 2. ETGB - no preparation or expiration date d. Sciex Qtrap 4500 analyzer room 1. curve A - 2L H20 + 2 ml formic acid no expiration date 2. curve AB -1900 ml H20 + 100 ml MeOH 1900 Ammonium formate + 100 ml formic acid) no expiration date 3. needle wash (IPA and methanol) - no label with preparation or expiration date 2. During the tour on March 29, 2018 from approximately 10:00 AM to 12:00 PM, testing personnel #2 confirmed the reagent bottles are inconsistently labeled with the preparation and/or expiration dates.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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 observation, document review, and interview, the laboratory failed to document the corrective action taken for the out of range temperatures for 1) refrigerator #1, #2, and the freezer for 21 (March 2018) of 29 days and for 2) specimen prep room refrigerator for 20 (March 2018) of 28 days and for 3) specimen prep room humidity for 17 (March 2018) of 28 days, and for 4) Sciex Qtrap 4500 analyzer room for 12 (March 2018) of 28 days of operation to ensure reliable toxicology instrument operation, specimen, standards, and reagent storage. Findings include: 1. During a tour of the laboratory on March 29, 2018 from approximately 10: 00 AM to 12:00 PM, the surveyor observed the "Daily Temperature and Humidity

	Log" in use. 2. Document review of the "Daily Temperature and Humidity Log" revealed there was no documentation to show corrective action was taken for the temperatures and/or humidity readings out of the stated ranges (include memory low and high) on the logsheets as follows: a. refrigerator #1 and #2 (2-8 degree C) - March 1-2, 5-9, 12-16, 19-23, and 26-29 b. freezer (-15 to -25 degree C) - March 1-2, 5-9, 12-16, 19-23, and 26-29 c. specimen prep room (refrigerator 2-8 degree C) - March 1-2, 5-9, 12-16, 19-23, and 26-28 d. specimen prep room humidity (20-70%) - March 2, 5-9, 12-16, 19-23, and 26-28 e. Sciex Qtrap 4500 analyzer room humidity (20-70%) - 1-2, 5-9, and 12-16 3. During the laboratory tour on March 29, 2018 at approximately 10:00 AM to 12:00 PM, testing personnel #2 as listed on the CMS-209 confirmed there was no documentation of corrective action taken for the temperature and humidity readings outside of the stated ranges of operation.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory director failed to provide a safety shower and chemical fume hood for safe handling of chemicals used in one of one testing procedures reviewed. Findings include: 1. During tour of the laboratory on March 29, 2018 from approximately 10:00 AM to 12:00PM, the surveyors observed Methanol, Acetonitrile, Formic acid, and Acetic acid in use. The surveyors did not observe a safety shower or chemical fume hood. 2. Record review of the testing procedure revealed the following chemicals listed under Solvents and Buffers: Water, Methanol, Isopropyl Alcohol, Acetonitrile, Formic Acid, Sodium acetate, Glacical acetic acid, Surine Negative Urine Control, Ammonium Formate, and Beta Glucuronidase powder. 3. Review of the Material Safety Data Sheet (MSDS) provided by the laboratory revealed the following: a. Methanol (Methyl Alcohol) MSDS under section labeled "Section 8 - Exposure Controls, Personal Protection" lists the following under "Engineering Controls", "Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower." and "Use only under a chemical fume hood." b. Isopropyl Alcohol MSDS under section labeled "Section 8 - Exposure Controls, Personal Protection" lists the following under "Engineering Controls", "Ensure that eyewash stations and safety showers are proximal to the work-station location." c. Acetonitrile MSDS under section labeled "Section 8 - Exposure Controls, Personal Protection" lists the following under "Engineering Controls", "Ensure that eyewash stations and safety showers are proximal to the work-station location." d. Formic Acid MSDS under section labeled "Section 8 - Exposure Controls, Personal Protection" lists the following under "Engineering Controls", "Ensure that eyewash stations and safety showers are proximal to the work-station location." e. Acetic acid MSDS under section labeled "Section 8 - Exposure Controls, Personal Protection" lists the following under "Engineering Controls", "Ensure that eyewash stations and safety showers are proximal to the work-station location." 4. During interview on March 29, 2018 at approximately 12:35 PM, technical supervisor #1 acknowleged the laboratory did not currently have a safety shower or chemical fume hood.