Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1097563	(X3) Date Survey Completed 08/20/2024
Name of Provider or Supplier Pain Consultants Of East Tennessee, Pllc	**Street Address, City, State** 1540 Member Lane Suite 100, Knoxville, TN	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the procedure manual, and staff interview, the laboratory failed to follow its policy for labeling secondary reagent containers used for liquid chromatography-mass spectrometry (LCMS) patient testing with contents, preparation and/or expiration dates. The findings include: 1. Observation of the laboratory on 08.13.2024 at 9:00 a.m. revealed a Shimadzu LCMS-8040 (serial number O10575000171) chemistry analyzer used for drugs of abuse confirmatory patient testing. Also observed were the following reagents in secondary containers used on the LCMS test system: -A bottle of Ethanol with no expiration date -A bottle of Mobile Phase A: 15mM (milliMoles) Ammonium Formate in Water, pH 8.0; with no expiration date -A bottle of 100mM Sodium Acetate; with no date of preparation -A bottle with "100 ACN" on the removable cap; with no contents, date of preparation, or expiration date on the bottle -A bottle of Enzyme Hydrolysis Working Internal Standard (EHWIS) containing sodium acetate buffer with enzyme and internal standard; with no date of preparation or expiration date -A bottle of Working Internal Standard (WIS) containing LCMS grade water, 0.2% formic acid, and internal standard; with no date of preparation or expiration date 2. A review of the laboratory's "General Policies and Procedures" procedure revealed the following statement: "Chemicals transferred to other containers including prepared solutions, must be labeled appropriately and must be marked with the contents, date of

	preparation, expiration date, and storage requirements if necessary." 3. An interview with the laboratory director on 08.13.2024 at 9:15 a.m. confirmed the above survey findings.
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 of the laboratory, review of laboratory records, review of the instrument operator manual, and staff interviews, the laboratory failed to monitor temperature and humidity in the area where Liquid Chromatography-Mass Spectrometry (LCMS) patient testing occurred in 2023 and 2024. The findings include: 1. Observation of the laboratory on 08.13.2024 at 9:50 a.m. revealed the Shimadzu LCMS-8040 (serial number O10575000171) chemistry analyzer used for drugs of abuse confirmatory patient testing. 2. A review of the laboratory temperature and humidity records revealed no documentation for temperature or humidity monitoring in the area where the LCMS-8040 analyzer was used for patient testing in 2023 through the survey date 08.13.2024. 3. A review of the operator's manual for the LCMS-8040 revealed the following temperature and humidity requirements: Temperature: 18-28C Humidity: 20 to 70% 4. Interviews with Testing Personnel 2 (TP2) as listed on the Centers for Medicare and Medicare Services Form 209 on 08.13.2024 at 10:00 a.m. and the laboratory director on 08.13.2024 at 10:15 a.m. confirmed the above survey findings. Word Key: C = degrees Celsius % = percent
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test records, and staff interviews, the laboratory failed to ensure that it did not use quality control (QC) for urine creatinine past the expiration date of 08.07.2024, with 106 patients reported. The findings include: 1. Observation of the laboratory on 08.13.2024 at 09:45 a.m. revealed the Synermed IR-500 (serial number 171110) chemistry analyzer used for patient testing. Additionally, observation of urine creatinine QC in use on the survey day (08.13.2024) revealed: -Synermed QC level 50 mg/dL; lot number 0723081; expiration date 08.07.2024 -Synermed QC level 300 mg/dL; lot number 0723082; expiration date 08.07.2024 2. A review of patient records revealed the laboratory performed urine creatinine testing on 106 patients from 08.08.2024 to the survey date (08.13.2024). 3. Interviews with Testing Personnel 3 (TP3) as listed on the Centers for

	Medicare and Medicare Services Form 209 on 08.13.2024 at 09:55 a.m. and the laboratory director on 08.13.2024 at 10:00 a.m. confirmed the above survey findings. Word Key: mg = milligram dL = deciliter