Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2186867	04/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pain Management Partners Llc	1320 West Main St, Bldg-2, Waterbury, CT	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish competency assessment policy and procedures to assess competency for the regulatory requirements for the technical supervisor (TS), the general supervisor (GS) and the clinical consultant (CC) in the subspecialty of toxicology. Findings include: 1. Record review on 04/25/2023 of the staff training and competency files revealed lack of competency assessment documentation for the regulatory positions of TS, GS, and CC for the years of 2021 and 2022. 2. Staff interview on 04/25/2023 at 9:30 AM with the TS confirmed the above findings. The TS further commented that he/she was unaware that a competency assessment is a regulatory requirement for TS, GS, and CC.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the accuracy of the LC/MS/MS test system for all reportable analytes twice annually in the subspecialty of toxicology. Findings Include: 1. Record review on 04/25/2023 of the 2022 proficiency testing binder revealed the following: a. Enrollment in College

	of American Pathologists (CAP) drug monitoring for pain management. b. The above survey results versus the laboratory test menu revealed lack of documentation for the following analytes: amitriptyline, aripiprazole, bupropion, carisoprodol, citalopram, dextromethorphan, diazepam, dihydrocodeine, duloxetine, EDDP, flunitrazepam, fluoxetine, ketamine, MDPV, methylphenidate, mitragynine, N,N-dimethyltryptamine, naloxone, normeperidine, nortriptyline, paroxetine, PCP, phentermine, tapentadol, temazepam, triazolam, venlafaxine, and zolpidem. c. Lack of documentation of biannual accuracy assessment for the analytes in 1B above. 2. Staff interview on 04/25/2023 at 12:45 PM with the technical supervisor (TS) confirmed the above findings. 3. The laboratory performs 22,452 tests annually for the analytes listed in 1B above in the subspecialty of toxicology.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to establish policy and procedures for proper function of ancillary equipment for accurate and reliable test results in the subspecialty of toxicology. Findings include: 1. Surveyor observation on 04/25/2023 at 11:30 AM of the toxicology laboratory area revealed a centrifuge and multiple pipettes, both lacking calibration dates for 2022. 2. Record review on 04/25/2023 of the pipette calibration revealed last calibration was performed in 2021 for the following pipettes: a. Eppendorf Research Plus 1 Channel (100-1000 L), serial number: I49461K b. Eppendorf Research Plus 1 Channel (10-100 L), serial number: K47206K c. Eppendorf Research Plus 1 Channel (20-200 L), serial number: H53618K d. Multi-Channel Pipette (1-10 L), serial number: B53810143 e. Multi-Channel Pipette (1-10 L), serial number: B5380303 3. Record review on 04/25/2023 of the MPC-P25 mini-plate centrifuge performance test statement revealed last calibration was performed on 08/17/2020. 4. Staff interview on 04/25/2023 at 11:46 AM with the technical supervisor (TS) confirmed the above findings. The TS further commented that he/she began the process of sending the pipettes out for calibration. 5. The laboratory performs 139,638 tests annually in the subspecialty of toxicology.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the performance of each lot number and shipment of calibrators, controls, and internal standards prior to patient testing in the subspecialty of toxicology. Findings include: 1. Record review on 04/25/2023 of the LC/MS/MS multi-analyte confirmatory panel laboratory binders revealed lack of documentation of lot-to-lot verification for calibrators, controls, and internal standards. 2. Staff interview on 04/25/2023 at 12:20 PM with the technical supervisor (TS) confirmed the above findings. The TS further commented that he/she was unaware of this requirement. 3. The laboratory performs 139,638 tests annually in the subspecialty of toxicology.