Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2186867	01/13/2025
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to retain analytical system records for at least 2 years in the subspecialty of toxicology. Findings Include: 1. Based on record review on 01/13/2025 of the laboratory's analytical system electronic records revealed lack of retention of the following documentation for 2023 and 2024: a. Daily, weekly and monthly function checks for the Agilent Ultivo Liquid Chromatography Tandem Mass Spectrometer. b. Room temperature readings. c. Refrigerator temperature readings. d. Freezer temperature readings. e. Humidity readings. f. Quality control data. g. Calibration verification data. 2. Staff interview on 01/13/2025 at 11:45 AM with the technical supervisor (TS) confirmed the above findings. The TS further commented that he/she had lost all the electronic data after a system wide update that corrupted the above records 3. The laboratory performs 259,597 tests annually in the subspecialty of toxicology.
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) and the general supervisor (GS) in the subspecialty of toxicology. Findings include: 1. Record review on 01/13/2025 of the staff training and competency files revealed lack of competency assessment documentation for the regulatory positions of TS and GS for the year 2024. 2. Staff interview on 01/13/2025 at 10:30 AM with the TS confirmed the above findings. 3. This is a repeat deficiency. 4. The laboratory performs 259,597 tests annually in the subspecialty of toxicology.
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 liquid chromatography tandem mass spectroscopy test system for all reportable analytes twice annually in the subspecialty of toxicology. Findings Include: 1. Record review on 01/13/2025 of the laboratory's proficiency testing binder for 2023 and 2024 revealed lack of documentation of biannual accuracy assessment for the following analytes: a. Flunitrazepam b. Triazolam c. Aripiprazole d. Bupropion e. Citalopram f. Duloxetine g. Fluoxetine h. Paroxetine i. Venlafaxine 2. Staff interview on 01/15/2024 at 1:29 PM with the technical supervisor confirmed the above finding. 3. This is a repeat deficiency. 3. The laboratory performs 37,683 tests annually for the analytes listed in 1 above in the subspecialty of toxicology.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) 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. (b)(1)(ii) 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 and staff interview, the laboratory failed to Establish a 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 01/13/2025 at 9:30 AM of the toxicology laboratory area revealed the following ancillary equipment lacking calibration for the year 2024: a. Eppendorf Research Plus 1 Channel (100-1000 ?L), serial number: I49461K, expiration date: 05 /31/2024. b. Eppendorf Research Plus 1 Channel (10-100 ?L), serial number: K47206K, expiration date: 05/31/2024. c. Eppendorf Research Plus 1 Channel (20-200 ?L), serial number: H53618K, expiration date: 05/31/2024. d. Multi-Channel Pipette (1-10 ?L), serial number: B53810143, expiration date: 05/31/2024. e. Multi-Channel Pipette (20-200?L), serial number: B5380303, expiration date: 05/31/2024. f. VWR excursion-trac thermometer, serial number: 911833, expiration date of 11/28 /2024. 2. Staff interview on 01/13/2025 at 9:45 AM with the technical supervisor (TS)

	confirmed the above findings. The TS further commented that he/she was planning on sending them out to be calibrated but they are the only set available to utilize. 3. This is a repeat deficiency. 4. The laboratory performs 259,597 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)(1) 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. 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 01/13/2025 of the laboratory's liquid chromatography tandem mass spectrometry 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 01/13/2025 at 12:10 PM with the technical supervisor (TS) confirmed the above findings. 3. This is a repeat deficiency. 4. The laboratory performs 259,597 tests annually in the subspecialty of toxicology.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to document corrective action when equipment performance was outside the manufacturer's performance specification in the subspecialty of toxicology. Findings Include: 1. Record review on 01/13/2025 of the laboratory's 'Agilent Ultivo LC/TQ and Infinity Lab LC/MSD iQ Preventative Maintenance (PM) Checklist' completed on 07/09/2024 revealed the following test results: a. 'Checktune - Pre PM: Fail' b. 'Autotune - Pre PM: Fail' c. 'Autotune - Post PM: Fail' 2. Record review on 01/13/2025 of the laboratory's 'MS Autotune Report - Ultivo' completed on 09/30/2024 revealed an 'Overall Result: Out of Tolerance'. 3. Record review on 01/13/2025 of the laboratory's quality assessment 'Monthly Review Summary Form' for July and September 2024 revealed the following: a. 'Confirmation instrument troubleshooting log - any ongoing

	issues? No, are there any pending resolutions? No.' b. Lack of documentation of a corrective action for the failed post autotune PM listed in 1(c) above and the failed autotune listed in 2 above. 4. Staff interview on 01/13/2025 at 11:45 AM with the technical supervisor (TS) confirmed the above findings. 5. The laboratory performs 259,597 tests annually in the subspecialty of toxicology.