

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2236200	(X3) Date Survey Completed 02/11/2025
Name of Provider or Supplier Pohlman Pain Associates Llc	Street Address, City, State 2710 W Atlantic Ave, 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	A complaint survey was conducted at Pohlman Pain Associates LLC on February 11, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2000 - Enrollment and Testing of Samples 493.801 D6076 - Laboratory Director 493.1441
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on interview, review of the procedure manual, test menu, and proficiency testing (PT) documents, the Laboratory (Lab A) shared five College of American Pathologists (CAP) Urine Toxicology (UT) samples (UT-A #1 - #5) from one of one PT event with another Laboratory (Lab B) (that has its own Clinical Laboratory Improvement Amendments Certificate of Compliance) before the PT testing results due date of 03/28/2024. Refer to D2013.</p>
D2013	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4)</p> <p>(b)(5) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is</p>

certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on interview, review of the procedure manual, test menu, and proficiency testing (PT) documents, the Laboratory (Lab A) shared five College of American Pathologists (CAP) Urine Toxicology (UT) samples (UT-A #1 - #5) from one of one PT event with another Laboratory (Lab B) (that has its own Clinical Laboratory Improvement Amendments Certificate of Compliance) before the PT testing results due date of 03/28/2024. Findings: 1. Review of the procedure manual titled "Proficiency Testing" revealed, "PT samples or portions of samples must not be referred to other laboratories for analysis. A laboratory cannot refer PT samples to another laboratory for confirmatory testing. 1. Note: The laboratory may internally cross check PT samples by running them on multiple instruments / methods or use the PT samples as Quality Assurance by having multiple technicians perform testing on PT samples. 2. This may only be done after submission of PT results to the provider." 2. Review of the CAP's Urine Toxicology Survey Results Form for Lab A showed the "Results are due no later than midnight, Central Time: March 28, 2024." Review of the CAP website showed Lab A submitted their proficiency testing results on 03/07/24. 3. Review of the CAP PT documentation showed the Urine Toxicology 2024 1st event contained 5 samples. 4. Review of the laboratory's test menu showed the following analytes were included in Lab A's screening panel: Alprazolam, Amphetamine, Benzoyllecgonine, Buprenorphine, Butalbital, MDMA (3,4-Methylenedioxymethamphetamine), Methadone, Morphine, Norhydrocodone, Nortriptyline, Oxazepam, Oxycodone, and Phencyclidine. 5. Review of the laboratory's test menu showed the following analytes were included in Lab A's confirmation panel: 6-Monoacetylmorphine, 7-Aminoclonazepam, Alpha-Hydroxyalprazolam, Alprazolam, Amitriptyline, Amphetamine, Benzoyllecgonine, Buprenorphine, Bupropion, Butalbital, Carboxyzolpidem, Carisoprodol, Clonazepam, Codeine, Cyclobenzaprine, Desipramine, Diazepam, Doxepin, Duloxetine, EDDP (2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine), ETS (Ethyl sulfate), Fentanyl, Fluoxetine, Gabapentin, Hydrocodone, Hydromorphone, Imipramine, Ketamine, Lorazepam, MDMA, Meperidine, Meprobamate, Methadone, Methamphetamine, Midazolam, Mitragynine, Morphine, Naloxone, Naltrexone, N-desmethyl-Tapentadol, Norbuprenorphine, Norcodeine, Nordiazepam, Norfentanyl, Norhydrocodone, Normeperidine, Noroxycodone, Nortriptyline, O-Desmethyltramadol, Oxazepam, Oxycodone, Oxymorphone, Phencyclidine, Phenobarbital, Pregabalin, Ritalinic Acid, Secobarbital, Sertraline, Tapentadol, Temazepam, Tramadol, THC-COOH, Venlafaxine, and Zolpidem. 6. During an interview on 02/11/2025 at 4:28 AM, the Technical Supervisor stated the PT samples were tested on 03/04/2024, and the results were submitted to CAP on 03/07/2024. 7. During an interview on 02/11/2025 at 4:29

PM, the Technical Supervisor stated she drove the samples to Lab B and returned the samples to Lab A after Lab B was done with them.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on interview, review of the procedure manual, test menu, and proficiency testing (PT) documents the Laboratory Director failed to ensure PT samples were tested as required by Subpart H. The Laboratory (Lab A) shared five College of American Pathologists (CAP) PT Urine Toxicology (UT) samples (UT-A #1 - #5) from one of one PT event with another Laboratory (Lab B) (that has its own Clinical Laboratory Improvement Amendments Certificate of Compliance) before the CAP PT results due date of 03/28/2024. (See D6089)

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

This STANDARD is not met as evidenced by:

Based on interview, review of the procedure manual, test menu, and proficiency testing (PT) documents, the Laboratory Director failed to ensure PT samples were tested as required by Subpart H. The Laboratory (Lab A) shared five College of American Pathologists (CAP) PT Urine Toxicology (UT) samples (UT-A #1 - #5) from one of one PT event with another Laboratory (Lab B) (that has its own Clinical Laboratory Improvement Amendments Certificate of Compliance) before the CAP PT results due date of 03/28/2024. Findings: 1. Review of the procedure manual titled "Proficiency Testing" revealed, "PT samples or portions of samples must not be referred to other laboratories for analysis. A laboratory cannot refer PT samples to another laboratory for confirmatory testing. 1. Note: The laboratory may internally cross check PT samples by running them on multiple instruments / methods or use the PT samples as Quality Assurance by having multiple technicians perform testing on PT samples. 2. This may only be done after submission of PT results to the provider." 2. Review of the CAP's Urine Toxicology Survey Results Form for Lab A showed the "Results are due no later than midnight, Central Time: March 28, 2024." 3. Review of the CAP PT documentation showed the Urine Toxicology 2024 1st event contained 5 samples. 4. Review of the CAP website showed Lab A submitted their proficiency testing results on 03/07/24. 5. Review of the laboratory's test menu showed the following analytes were included in Lab A's screening panel: Alprazolam, Amphetamine, Benzoylcegonine, Buprenorphine, Butalbital, MDMA (3,4-Methylenedioxymethamphetamine), Methadone, Morphine, Norhydrocodone, Nortriptyline, Oxazepam, Oxycodone, and Phencyclidine. 6. Review of the laboratory's test menu showed the following analytes were included in Lab A's confirmation panel: 6-Monoacetylmorphine, 7-Aminoclonazepam, Alpha-Hydroxyalprazolam, Alprazolam, Amitriptyline, Amphetamine, Benzoylcegonine,

Buprenorphine, Bupropion, Butalbital, Carboxyzolpidem, Carisoprodol, Clonazepam, Codeine, Cyclobenzaprine, Desipramine, Diazepam, Doxepin, Duloxetine, EDDP (2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine), ETS (Ethyl sulfate), Fentanyl, Fluoxetine, Gabapentin, Hydrocodone, Hydromorphone, Imipramine, Ketamine, Lorazepam, MDMA, Meperidine, Meprobamate, Methadone, Methamphetamine, Midazolam, Mitragynine, Morphine, Naloxone, Naltrexone, N-desmethyl-Tapentadol, Norbuprenorphine, Norcodeine, Nordiazepam, Norfentanyl, Norhydrocodone, Normeperidine, Noroxycodone, Nortriptyline, O-Desmethyltramadol, Oxazepam, Oxycodone, Oxymorphone, Phencyclidine, Phenobarbital, Pregabalin, Ritalinic Acid, Secobarbital, Sertraline, Tapentadol, Temazepam, Tramadol, THC-COOH, Venlafaxine, and Zolpidem. 7. During an interview on 02/11/2025 at 4:28 AM, the Technical Supervisor stated the PT samples were tested on 03/04/2024, and the results were submitted to CAP on 03/07/2024. 8. During an interview on 02/11/2025 at 4:29 PM, the Technical Supervisor stated she drove the samples to Lab B and returned the samples to Lab A after Lab B was done with them.