

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2167355	(X3) Date Survey Completed 01/18/2022
Name of Provider or Supplier Pain Clinic Of Michigan	Street Address, City, State 2820 Crooks Road, Rochester Hills, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to verify the accuracy of its quantitative toxicology testing at least twice annually for 2 (January 2020 to January 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's verification of accuracy data revealed it tests the following toxicology analytes: a. 6-Monoacetylmorphine b. 7-Aminoclonazepam c. alpha-hydroxyalprazolam d. alprazolam e. amphetamine f. benzoylecgonine g. buprenorphine h. bupropion i. butalbital j. carisoprodol k. clonazepam l. codeine m. cyclobenzaprine n. desipramine o. diazepam p. doxepin q. duloxetine r. EDDP s. ETS t. fentanyl u. fluoxetine v. gabapentin w. hydrocodone x. hydromorphone y. imipramine z. ketamine aa. lorazepam bb. MDMA cc. meperidine dd. meprobamate ee. methadone ff. methamphetamine gg. midazolam hh. mitragynine ii. morphine jj. naloxone kk. naltrexone ll. N-desmethyl-Tapentadol mm. norbuprenorphine nn. norcodeine oo. nordiazepam pp. norfentanyl qq. norhydrocodone rr. normeperidine ss. noroxycodone tt. nortriptyline uu. O-Desmethyltramadol vv. oxazepam ww. oxycodone xx. oxymorphone yy. PCP zz. phenobarbital aaa. pregabalin bbb. ritalinic acid ccc. secobarbital ddd. sertraline eee. tapentadol fff. temazepam ggg. thc-cooh hhh. tramadol iii. venlafaxine jjj. zolpidem 2. A review of the laboratory's verification of accuracy records revealed the laboratory performed testing once in March 2021 and once in March 2020. 3. The surveyor requested the second verification of accuracy testing events for 2020 and 2021 on 1/18/22 at 10:52 am and they were not made available. 4. An interview on 1/18/22 at 10:52 am with the TS confirmed the laboratory did not perform verification of accuracy testing for the analytes listed above at least twice annually in 2020 and 2021.</p>

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, record review and interview with the Technical Supervisor (TS), the laboratory failed to label reagents with the concentration and expiration date for 4 of 5 solutions observed. Findings include: 1. The surveyor observed the following reagents during a tour of the laboratory on 1/18/22 at 8:59 am: a. One bottle with "Water" and "12/2/21" and no expiration date listed. b. One bottle with "MeOH" and "1/12/22" and no expiration date listed. c. One bottle with "MPA" and "Prep: 1/3/22" and no concentration or expiration date listed. d. One bottle with "B" and "Prep: 1/13/22" and no concentration or expiration date listed. 2. A review of the laboratory's policy revealed a section titled "Laboratory Reagents and Glassware" stating, "Reagents shall adhere to the following standards: a. All reagents prepared by the laboratory will be marked with initials of preparer, preparation and expiration date. b. All reagents purchased from a commercial vendor will be marked with date of receipt and initials of receiver. c. All reagents will be marked with date opened. d. All reagents will be marked with expiration date. e. All reagents will be stored in accordance with manufacturer's specifications." 3. An interview on 1/18/22 at 9:10 am with the TS confirmed the reagent bottles listed above were not labeled with concentration and expiration dates. ***This is a repeated deficiency from the 3/16/20 initial certification survey***

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 observation, record review, and interview with the Technical Supervisor (TS), the laboratory failed to ensure centrifuge and fume hood function checks were performed for 2 (January 2020 to January 2022) of 2 years reviewed. Findings include: 1. The surveyor observed a VWR centrifuge and a fume hood in the laboratory during a tour on 1/18/22 at 8:59 am. 2. A review of the laboratory's "PERFORMANCE CHECK POLICY FOR INSTRUMENTS OF MEASURE" revealed a section titled "Centrifuges, Pippettes, Balances, Hoods" stating, "All centrifuges, Pippettes, Balances and hoods are to be assessed for performance on a yearly basis. This laboratory issues Vitec Calibration as its performance check vendor." 3. The surveyor requested documentation of the performance assessed annually for the fume

hood and the centrifuge on 1/18/22 at 10:57 am and it was not made available. 4. An interview on 1/18/22 at 10:57 am with the TS confirmed the laboratory did not perform function checks for the centrifuge and fume hood.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

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

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure the laboratory's corrective action plan was followed when results from the laboratory's verification of accuracy testing were unacceptable for 8 (Alprazolam, Buprenorphine, Bupropion, Meprobamate, Midazolam, Norbuprenorphine, Normeperidine, and THC-COOH) analytes failing laboratory criteria during the March 2021 testing event. Findings include: 1. A review of the laboratory's verification of accuracy records revealed the following analytes fell outside of the laboratory's specified range during the March 2021 testing event: a. Alprazolam b. Buprenorphine c. Bupropion d. Meprobamate e. Midazolam f. Norbuprenorphine g. Normeperidine h. THC-COOH 2. The surveyor requested the corrective action performed because the accuracy testing for the above analytes failed on 1/18/22 at 10:44 am and it was not made available. 3. An interview on 1/18/22 at 10:44 am with the TS confirmed the laboratory did not perform corrective action for analytes failing verification of accuracy testing.