Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2167355	03/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pain Clinic Of Michigan	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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to have a electronic test request for patient testing for 9 (patients #1-#9) of 9 patient results reviewed. Findings include: 1. Record review of patient test requests revealed patients #1-#9 did not have orders indicated on the electronic test request for the following tests that were performed and resulted: Zolpidem and Ethyl Sulfate (ETS). 2. During the interview on 3/16/2020 at approximately 2:20 pm, the TS confirmed the laboratory did not have an electronic test request for all the tests reported out on the final test reports.
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) and Testing Personnel (TP) #1, the laboratory failed to label the toxicology reagents located in the refrigerator and on the toxicology analyzer for 9 (July 2019 to

	March 2020) of 9 months of operation with the open date and content with the concentration of the reagent. Findings include: 1. During a tour of the laboratory on 3 /16/2020 at 9:10 am, the surveyor observed reagents in use in the refrigerator and located on the AB Sciex Triple Quad 4500 toxicology analyzer that did not have documentation of the open date and content with the concentration of the reagent as follows: a. refrigerator - no open dates 1. Internal Standard 2. IMCSzyne >50 ku/ml 3. IMCS Rapid Hydrolysis Buffer b. AB Sciex Triple Quad 4500 analyzer - no content with the concentration of reagent 1. Phase A 2. Phase B 3. Needle Wash 2. Review of the laboratory's established procedure manual revealed a procedure "Quality Assurance Plan" that stated in Section III "Laboratory Reagents and Glassware" the following that was not followed: "A. Reagents 3. 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. f. All reagents will be labeled to indicate content and if appropriate, concentration or titer. g. Reagents shelf life will be observed and will not be used after their expiration date, have deteriorated or are of substandard quality." 3. During the interview on 3/16/2020 at 9:10 am, TS and TP1 confirmed the policy was not followed and the reagents listed above were not labeled properly.