Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2167355	09/09/2025
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
D0000	A recertification survey was performed on September 9, 2025 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition-level deficiencies: 493.1213 Condition: Toxicology. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . A. Based on observation and interview with testing personnel #1, the laboratory failed to have an eye wash bottle that had not exceeded its expiration date since 2/26 /22. Findings include: 1. The surveyor observed the laboratory's eye wash bottle on 9/9 /25 at 9:11 am and it expired on 2/26/22. 2. An interview on 9/9/25 at 9:11 am with testing personnel #1 confirmed the eye wash bottle was expired. B. Based on record review, observation, and interview with testing personnel #1, the laboratory failed to follow it's safety procedures to ensure adequate spill kit components were present in the laboratory for three (sorbent powder, a poly apron, and a whisk-on-pan dustpan) of 14 spill kit components. Findings include: 1. A review of the laboratory's "Spill Response Policy" revealed a section titled "Spills and Leaks Procedure" stating, "Spill kits: All laboratories should obtain or create a spill kit, which should contain the following: 5- Universal Pillows 6-Lab Pillows 2- Disposable Bags with Twist Ties 1-Pair of Chemical-Resistant Gloves 1- Whisk-on-Pan Dust Pan 1-Poly Apron 1-Pair of Splash Goggles 1-Carton of Sorbent Powder." 2. The surveyor observed the laboratory's spill kit contents on 9/9/25 at 9:43 am and noted the kit was missing

	sorbent powder, a poly apron, and a whisk-on-pan dustpan. 3. An interview on 9/9/25 at 9:43 am with testing personnel #1 confirmed the spill kit was missing sorbent powder, a poly apron, and a whisk-on-pan dustpan.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observation, record review, and interviews, the laboratory failed to establish policies to ensure positive identification of patient urine specimens from preanalytical aliquoting to specimen storage (refer to D5203) and failed to perform corrective action for patients with test results reported on testing runs with failed calibrations (refer to D5783).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with testing personnel #1, the laboratory failed to establish policies to ensure positive identification of patient urine specimens from preanalytical aliquoting to specimen storage for two (September 2023 to September 2025) of two years reviewed. Findings include: 1. The surveyor observed the laboratory's refrigerator on 9/9/25 at 9:05 am revealed a test tube rack with 95 total tubes with liquid inside numbered on the tube caps from one to 95. The freezer included bags with numbers written on the bag of similarly labeled tubes without unique patient identifiers. 2. An interview on 9/9/25 at 9:05 am with testing personnel #1 revealed the tubes were patient specimen aliquots. Specimen aliquots are kept in the refrigerator in this manner for about one week. These are stored refrigerated until enough specimens are received to create a batch in the laboratory system and stickers can be added to the individual tubes. Stickers were taken off the specimens after testing because the tubes stick together once they are in the storage bags. Specimens are retained in the freezer in the event they need to be retested. 3. A review of the laboratory's "Specimen Handling and Requisitions Procedure" revealed a lack of process for ensuring positive identification once the specimens are aliquoted.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must

	take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1, the laboratory failed to perform corrective action for patients with test results reported on testing runs with failed calibrations for three (06/29/2024, 09/18/2024, and 11/19/2024) of 10 patient testing dates reviewed. Findings include: 1. A review of the laboratory's "Pain Clinic of Michigan Standard Operating Procedure: Quantitative Determination of Drugs and Metabolites in Urine via LCMS/MS" test procedure revealed a section stating, "For positive identification and accurate quantitation, the following criteria must be met: Calibration: Four of six calibrators must be within 20% of target concentration and r^2 >0.980." 2. A review of the laboratory's calibration data for 10 patient testing dates revealed the following calibrations that did not meet the laboratory's criteria: a. 06/29/2024, only three calibrators were within 20% of the target concentration for ketamine. A total of 98 patients had ketamine results reported in this run. b. 09/18 /2024, only three calibrators were within 20% of the target concentration for norbuprenorphine. A total of 73 patients had norbuprenorphine results reported in this run. c. 11/19/2024, only three calibrators were within 20% of the target concentration for tapentadol and norcodeine. A total of 83 patients had tapentadol and norcodeine results reported in this run. 3. The surveyor requested corrective action performed for the patients reported for the runs listed above on 9/9/25 at 11:13 am and it was not received. 4. An interview on 9/9/25 at 9:43 am with testing personnel #1 confirmed corrective action had not been performed for the 254 patients with reported results from runs with failed calibrations.
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 observation, record review, and interviews, the laboratory director failed to be onsite at least once every six months (refer to D6080), failed to establish policies to ensure positive identification of patient urine specimens from preanalytical aliquoting to specimen storage (refer to D6082), and failed to ensure corrective action was performed for patients with test results reported on testing runs with failed calibrations (refer to D6096).
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

	This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1, the laboratory director failed to be onsite at least once every six months for 9 (January 2025 to September 2025) of 9 months reviewed. Findings include: 1. A review of the laboratory's quality assessment records revealed a lack of documentation of laboratory director visits. 2. An interview on 9/9/25 at 9:28 am with testing personnel #1 confirmed the laboratory director had not visited the laboratory.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with testing personnel #1, the laboratory director failed to establish policies to ensure positive identification of patient urine specimens from preanalytical aliquoting to specimen storage. Refer to D5203.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1, the laboratory director failed to ensure corrective action was performed for patients with test results reported on testing runs with failed calibrations. Refer to D5783.