

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D2167355	<b>(X3) Date Survey Completed</b> 01/10/2024
<b>Name of Provider or Supplier</b> Pain Clinic Of Michigan	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor, the laboratory director and testing personnel failed to attest to the integration of proficiency testing samples into the patient workload for 4 (UT-A 2022, UT-B 2022, UT-C 2022, and UT-B 2023) of 5 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathology proficiency testing events revealed a lack of attestation by the laboratory director and the testing personnel for the following urine toxicology proficiency testing events: a. UT-A 2022 b. UT-B 2022 c. UT-C 2022 d. UT-B 2023 2. An interview on 1/10/24 at 11:58 pm with the Technical Supervisor confirmed the laboratory director and testing personnel had not attested to integration of proficiency testing samples into the patient workload.</p>
<b>D3001</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review and interview with the Technical Supervisor, the laboratory failed ensure appropriate ventilation necessary for performing urine toxicology testing reagent preparation for 2 (January 2022 to January 2024) of 2 years</p>

reviewed. Findings include: 1. The surveyor observed a lack of ventilation hood in the laboratory on 1/10/24 at 9:02 am. 2. A review of the laboratory's "Acetonitrile HPLC Grade" Safety Data Sheet (SDS) revealed a section titled "Precautions for safe handling" stating, " Work under hood. Do not inhale substance/mixture. Avoid generation of vapors/aerosols. Observe label precautions." 3. A review of the laboratory's "iso-Propyl Alcohol HPLC Grade" SDS revealed a section titled "Precautions for safe handling" stating, " Work under hood. Do not inhale substance /mixture. Avoid generation of vapors/aerosols. Observe label precautions." 4. An interview on 1/10/24 at 1:07 pm with the Technical Supervisor confirmed the laboratory did not have a hood to ensure ventilation when working with the above reagents.

**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 interview with the Technical Supervisor, the laboratory failed to establish a competency assessment policy to include Clinical Consultant competency for 2 (January 2022 to January 2024) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Personnel Requirements" policy revealed a lack of process for ensuring Clinical Consultant competency. 2. An interview on 1/10/24 at 10:07 am with the Technical Supervisor confirmed the laboratory had not established a competency assessment policy to include Clinical Consultant competency.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the Technical Supervisor, the laboratory failed to verify the accuracy of analytes not graded by the proficiency testing program for 2 (UT-B 2022 and UT-B 2023) of 5 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists' proficiency testing records revealed the laboratory had not reported its results to the proficiency testing program before the deadline for testing events UT-B 2022 and UT-B 2023. 2. The surveyor requested the laboratory's documentation of the verification of accuracy of the UT-B 2022 and UT-B 2023 testing events on 1/10/24 at 11:53 am and it was not made available. 3. An interview on 1/10/24 at 12:27 pm with the Technical Supervisor revealed the laboratory had not documented its verification of accuracy of the UT-B 2022 and UT-B 2023 testing events.

<p><b>D5311</b></p>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to establish a written policy for conditions of specimen transportation for 2 (January 2022 to January 2024) of 2 years. Findings include: 1. An interview on 1/10/24 at 9:54 am with the Testing Personnel revealed the specimens received by the laboratory from outside clinics are received by local drop-off. 2. A review of the laboratory's "Specimen Handling and Requisition Procedure" revealed a lack of conditions of specimen transportation via local drop-off. 3. An interview on 1/10/24 at 11:14 am with the Technical Supervisor confirmed the laboratory had not established a policy to include the conditions for specimen transportation via local specimen drop-off.</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the laboratory failed to monitor and document the urine specimen freezer temperatures for 2 (January 2022 to January 2024) of 2 years reviewed. Findings include: 1. A review of the laboratory's temperature monitoring logs revealed a lack of monitoring the freezer holding urine specimens. 2. The surveyor requested the specimen freezer temperature logs on 1/10/24 at 11:28 am and they were not made available. 3. An interview on 1/10/24 at 11:35 am with the Testing Personnel confirmed the laboratory did not have the urine specimen freezer temperature monitoring documentation available.</p>
<p><b>D6079</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities</p>

to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure the laboratory notified the State Agency when a change in laboratory director was made in accordance with 493.51 for 14 (November 2022 to January 2024) of 14 months. Findings include: 1. An interview on 1/10/23 at 9:12 am with the Technical Supervisor revealed the laboratory had changed their laboratory director in November 2022. 2. A review of the laboratory's records and the CMS database revealed the laboratory failed notify the State Agency when the laboratory changed its laboratory director in compliance with 493.51, which states: "Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory ' s certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance."

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Supervisor, the Laboratory Director failed to ensure the quality assessment program was maintained for 2 (January 2022 to January 2024) of 2 years. Findings include: 1. A review of the laboratory's "Quality Assessment Plan" revealed a section stating, "Reviews will be conducted quarterly by the supervisor" and "The file containing completed quality assurance reports will be reviewed at least 2 times a year to verify that reviews are performed as scheduled and there are not recurrent problems requiring attention." 2. A review of the laboratory's quality assessment documentation revealed a lack of quality assessments performed quarterly between January 2022 and January 2024. 3. The surveyor requested documentation of the quarterly quality assessment reviews on 10: 53 am and they were not made available. 4. An interview on 1/10/24 at 11:46 am with the Technical Supervisor confirmed the laboratory had not performed quality assessments at least quarterly according to their quality assessment program.