

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2149889	(X3) Date Survey Completed 01/03/2023
Name of Provider or Supplier Mid Michigan Pain Specialty, Pc	Street Address, City, State 42500 Hayes Rd Suite 800, Clinton Township, 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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to perform and document the traceable thermometer calibration checks as required by the manufacturer before the expiration for 1 (traceable Thomas Scientific) of 1 thermometers in use in the laboratory Frigidaire refrigerator. Findings include: 1. During a tour of the laboratory on 1/03/2023 at 9:11 am, the surveyor observed a traceable thermometer in the Frigidaire refrigerator in use past the expiration date of 4/30/2020. 2. A lack of documentation upon review of the laboratory records revealed the thermometer was not calibrated and /or replaced by the expiration of 4/30/2020. 3. A interview on 1/03/2023 at 9:14 am, the TC confirmed the traceable thermometer was not calibrated and/or replaced.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The</p>

laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform quality control (QC) testing each day of patient testing for 2 (oxycodone and opiates) of 4 drugs for the patient testing dates reviewed. Findings include: 1. A review of patient test records from 7/28/2021 to 12/15/2022 revealed a lack of quality control results for 2 of the 4 drugs tested (51 patients tested) as following: a. 12/02/2021 - no QC for oxycodone b. 12/02/2021 - no QC for opiates 2. An interview on 1/03/2023 at 11:20 am, the TC confirmed the laboratory did not have quality control documentation available for all the drugs reported out on 12/02/2021.