

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2149889	(X3) Date Survey Completed 02/04/2025
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation, record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure that reagents on the Indiko Plus Chemistry Analyzer were properly stored for six of six reagent containers. Findings include 1. On 02/04/2025 at 10:00 am, the surveyor observed six reagent containers (Benzo R1, Benzo R2, Cocaine R1, Cocaine R2, Opiate R1, Opiate R2, Oxy R1, and Oxy R2) loaded on the Indiko Plus analyzer without caps while it was not in operation. 2. A review of the laboratory policy titled " Storage Requirement" for each Assay (DRI Benzodiazepine, DRI Cocaine, DRI Opiate, DRI Oxycodone) revealed, "Store the reagents...with screw caps tightly when not in use." 3. An interview with TP1 on 02/04/2025 at 10:02 am confirmed that the reagents stored on the Indiko Plus Chemistry Analyzer did not have screw caps on containers when not in use.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1)</p>

Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

. A. Based on observation, record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure reagents on the Indiko Plus Chemistry Analyzer were labeled with expiration dates for 6 of 6 reagent containers. Findings include: 1. On 02/04/2025 at 10:00 AM, the surveyor observed six reagent containers (Benzo R1, Benzo R2, Cocaine R1, Cocaine R2, Opiate R1, Opiate R2, Oxy R1, and Oxy R2) loaded on the Indiko Plus analyzer without labels indicating the expiration dates. 2. A review of the laboratory policy under the section titled "Reagent Handling" for each analyte states the following: a. DRI Benzodiazepine Assay: Page 4 of 9 states: "... Transfer Reagents A and E into separate and clean reagent containers." "Label the containers with appropriate reagent name, expiration date, lot number..." b. DRI Cocaine Assay: Page 3 of 9 states: "...Reagents A and E come in barcoded containers with lot numbers, expiration date...can be placed directly on the analyzer..." c. DRI Opiate Assay: Page 4 of 11 states: "...Reagents A and E come in barcoded containers with lot numbers, expiration date...can be placed directly on the analyzer..." d. DRI Oxycodone Assay: Page 3 of 9 states: "...Reagents A and E come in barcoded containers with lot numbers, expiration date...can be placed directly on the analyzer..." 3. An interview conducted with TP1 on 02/04/2025 at 10:02 am confirmed that the reagent containers were not labeled with expiration dates. B. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure reagents on the Indiko Plus Chemistry Analyzer were correctly documented in the laboratory's "Reagent Lot Log" for 1 of 4 reagents. Findings include: 1. On 02/04/2025 at 11:45 am, a request was made to TP1 to print the reagent lot number documentation from Indiko Plus Chemistry Analyzer for 4 reagents currently in use (DRI Benzodiazepine Assay, DRI Cocaine Assay, DRI Opiate Assay, DRI Oxycodone Assay). 2. A record review of laboratory's reagent lot log revealed that the lot number documented for Oxycodone (#75155774) did not match the lot number documented in the instrument (#74580047). 3. An interview conducted with TP1 on 02/04/2025 at 11:50 am confirmed that the reagent lot numbers were not documented correctly.