

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2058128	(X3) Date Survey Completed 02/23/2026
Name of Provider or Supplier Michiana Adult Medical Specialist	Street Address, City, State 212 W Edison Rd, Mishawaka, IN	
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
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) 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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to ensure the open and expiration dates were labeled for 2 of 2 toxicology controls, H-TROL 1 and 2, used for analyte(s) cocaine, benzodiazepine, opiate and oxycodone from 11-1-2025 to the date of the survey, 2-23-2026. Findings include: 1. During a tour of the laboratory on 2-23-2026 at 10:15 am, the following was observed: a) The laboratory refrigerator contained 2 bottles of QC material, H-TROL 1 and 2, with no open or expiration date (s) on the QC materials. 2. In an interview on 2-23-2026 at 1:00 pm, SP-01 confirmed the QC vials were not dated since patient testing started on 11-1-2025. 3. Patients PT#2 through PT #8 were tested without QC vials being labeled. Refer to D5416. 4. Annual testing volume for Toxicology is approximately 7,200. Legend: QC=Quality control, SP= Staff person, SP-01= Technical Consultant</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

This STANDARD is not met as evidenced by:

Based on observation, document review, and interview, the laboratory failed to ensure that 2 of 2 bottles of QC material(s), H-TROL 1 and 2, were not used beyond the expiration date(s) for the analyzer, Diatron P500 SN#902020082 and the following analytes(s), cocaine, benzodiazepine, opiate and oxycodone from 11-26-2025 to surveyed date of 2-23-2026. Findings include: 1. During a laboratory tour on 2-23-2026 at 10:15 am the following was observed: a) A Diatron P500 SN# 902020082 analyzer was in use and running patient test samples. b) The laboratory refrigerator contained 2 bottles labeled H-Trol 1 for Lot# CC02280 and H-Trol-2 for Lot# CC02281 with expiration date 2026-10-31. 2. Review of the package insert titled "H-Cal and H-TROL Custom Liquid Control Package Insert" under Storage & Stability, After Opening states "The controls and calibrators are stable for 31 days or until the expiration date, whichever comes first ..." 3. Document titled "Laboratory Reagent Log: Routine Chemistry" confirmed the H-Trol 1 and 2 quality control material was put in use on 10-14-2025. 4. Policy and procedure titled "General Quality Control Policy signed and dated by the Laboratory Director on 11-05-2025 states on page 3 of 10, "If opening the vial changes the expiration date, write the opened expiration date on the container" 5. In an interview on 2-23-2026 at 1:00 pm, SP-01 confirmed the control materials were not dated at the start of patient testing that begun on 11-1-2025. 6. The following test samples were analyzed without valid quality control: Patient(PT) Test Date Test Result(s) PT#2 11-26-25 Benzo, Coc, Op = Neg, Oxy= Pos. PT#3 12-19-25 Coc, Op, Oxy = Neg, Benzo=Pos. PT#5 01-21-26 Benzo, Coc, Op = Neg, Oxy= Pos. PT#7 02-20-26 Coc, Op = Neg, Oxy, Benzo=Pos. PT#8 02-06-26 Coc, Op = Neg, Oxy, Benzo= Pos 7. Annual testing volume for Toxicology is approximately 7,200. Legend: QC= Quality Control, SP-01= Technical Consultant, PT.= Patient, Benzo= Benzodiazepine, Coc= Cocaine, Op= Opiate, Oxy= Oxycodone. Neg= Negative, Pos= Positive.