

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2080211	<b>(X3) Date Survey Completed</b>  03/03/2025
<b>Name of Provider or Supplier</b>  Comprehensive Pain Specialists, PLLC	<b>Street Address, City, State</b>  5154 Miller Road, Flint, 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>D5415</b>	<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, interview with the Technical Supervisor (TS) and record review, the laboratory failed to ensure all reagents used for toxicology testing were labeled with the date of expiration. Findings include: 1. During a tour of the laboratory on 03/03/2025 at 9:30 am, the surveyor observed the bottles of reagents, quality controls, and calibration reagents available for patient testing were not labeled with a date of expiration. 2. An interview with the TS on 03/03/2025 at 10:00 am confirmed that all reagents, quality controls and calibration reagents were not labeled with expiration dates. 3. A review of the laboratory's policy titled "QA 100.0 Quality Assurance Plan", revealed on page 3 of 8, section III A, number 3, a. All reagents prepared by the laboratory will be marked with the initials of preparer, preparation and expiration date...d. All reagents will be marked with the expiration date." 4. A review of the laboratory policy titled "QC 104.0 Reagent Check" revealed on page 1 of 3, section "Reagent Labeling" section B, "All laboratory reagents must be labeled to identify the contents:"...number 4. "Expiration date".</p>