

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2178906	(X3) Date Survey Completed 02/05/2024
Name of Provider or Supplier Integrated Pain Solutions, Inc	Street Address, City, State 1210 Gemini Place, Suite 300, Columbus, OH	
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 record review and an interview with the Technical Supervisor (TS), the laboratory failed to follow and document procedures for performing maintenance on the pipettes and repeating pipettes (repeaters) used, that were peripherally involved in patient testing for the year 2022. All 3,860 patients tested in the subspecialty of Toxicology in 2022 had the potential to be affected. Findings Include: 1. Review of the laboratory's policy and procedure manual found the following: "Laboratory Maintenance...Laboratory instruments and equipment must be well maintained, clean and in good working condition to provide accurate and meaningful results... Pipettes and repeaters 1. Calibration or accuracy assessment of all pipettes and repeaters should be performed at least once per year. 2. Calibration should be documented and kept within the records of equipment maintenance..." 2. The Surveyor requested the laboratory's 2022 and 2023 pipette maintenance documentation from the TS. The TS provided the following maintenance record: [Yearly Pipette Calibration] 02/06/2023 3. The TS confirmed that the laboratory failed to follow the established maintenance policy for pipettes and repeaters, did not document any pipette maintenance in 2022 and was unable to provide the requested documentation. The interview occurred on 02/05/2024 at 1:02 PM.</p>