Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2150353	07/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Smart Physician Systems Pc	10176 W 400 N, Suite A, Michigan City, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observation, policy/procedure review, medical record review and interview, the laboratory failed to perform twice annual verification in 2025 for 4 of 4 unregulated analytes (naltrexone, ketamine, amitriptyline and nortriptyline) tested in the subspecialty toxicology for 2 of 9 patients reviewed. Findings include: 1. During the laboratory tour on 7/27/2026 at 9:45 am, analyzers LC/MS Agilent Triple Quad 6460 (SG14537302) and LC/MS Agilent Triple Quad 6460 (SG15267305) were in use for patient testing including analytes naltrexone, ketamine, amitriptyline and nortriptyline. 2. Review of document titled, "Split Sample Comparison PT 2024-B" showed the verification for the analyte's amitriptyline, nortriptyline, ketamine and naltrexone was performed on 10/24/2024. 3. Review of document titled, "Alternative Proficiency Testing" indicated the next verification for analytes naltrexone, ketamine, amitriptyline, and nortriptyline was performed on 7/15/2026. 4. Review of policy titled, "Proficiency Testing (E07)" approved by the Laboratory Director (LD) on 9/15 /2025, states, "For any analytes not tested by an approved PT (Proficiency Testing) program, the laboratory will establish the accuracy and reliability of the testing procedure twice per year. This can be accomplished through split samples analyzed in conjunction with another laboratory ..." 5. The following patients reviewed were tested for the unregulated analyte's amitriptyline, nortriptyline, ketamine and naltrexone without acceptable split sample comparisons in 2025: Patient Collection Test (Pt) Date Results Pt#5 5/08/2025 Negative Pt#6 12/09/2025 Negative 6. In an interview on 7/27/2026 at 10:35 am, SP-01 (Technical Supervisor) confirmed twice annual verification was not performed in 2025 for unregulated analyte's (amitriptyline, nortriptyline, ketamine and naltrexone). 7. In an interview on 7/27/2026 at 1:40 p.m.,

	SP 01 confirmed that the laboratory verified these analytes on 10/24/2024 and did not verify them again until 7/15/2026.