Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2011968	02/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Savida Health Pc	12 Dallaire Ave, Chicopee, MA	

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 record review and staff interview with the Laboratory Director (LD) the laboratory failed to verify at least twice annually the accuracy of Xylazine in the subspecialty of Toxicology. Findings include: 1. Record review on 2/10/2025 of the laboratory's CMS form 116 and test list revealed the laboratory is now performing Xylazine testing. 2. Record review on 2/10/2025 of the laboratory's validation records for Xylazine revealed: a. The Xylazine testing procedure was signed by the LD on 7/3/2023 and the laboratory began Xylazine testing on 7/3/2023. b. The accuracy of the Xylazine test was performed once in 2023 as part of the validation. 3. Record review on 2/10/2025 of the laboratory's 2023, 2024 and 2025 to date Toxicology College of American Pathologists (CAP) proficiency testing (PT) records revealed the laboratory was not enrolled in PT for Xylazine testing because CAP does not offer PT testing for Xylazine. 4. Staff interview with the LD on 2/10/2025 at 11:00 AM confirmed the above findings. The LD stated, "There isn't any PT for Xylazine and we did not check the accuracy twice annually by any other method after the validation in 2023." 5. The laboratory performs 1, 980,000 Toxicology tests annually.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section.

	Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and staff interview with the Laboratory Director (LD), the laboratory did not define a function check protocol for all equipment to ensure test system performance that is necessary for accurate and reliable test results in the subspecialty of Toxicology. Findings include: 1. Record review on 2/10/2025 of the laboratory's maintenance and function check records revealed, the laboratory did not have documented function checks for laboratory pipettes. 2. Record review on 2/10 /2025 of the laboratory's procedure manual revealed the laboratory did not have a procedure for the calibration of laboratory pipettes. 3. Staff interview with the LD on 2 /10/2025 at 12:00 PM, the LD stated, "Laboratory pipettes are purchased every year. We purchased new 8 channel pipettes, consisting of (1) 100 to 300 uL and (1) 50-1250 uL in March of 2022 and single channel pipettes, consisting of (1) 20-200 uL and (1) 100-1000 uL in October of 2022. The laboratory did not calibrate or check the function of the pipettes in 2023 or 2024. We do not have a procedure in place to calibrate the pipettes. I am not sure what the manufacturer's requirements are for calibrating the pipettes." 4. The laboratory performs 1,980,000 Toxicology tests annually.