Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2264258	04/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Insight Surgical Hospital - Dearborn	5111 Auto Club Drive Suite 101, Dearborn, MI	

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
D0000	A validation survey was performed on April 13, 2026 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) with standard-level deficiencies.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on observation and interviews, the laboratory failed to ensure positive identification of patient urine specimens after aliquoting specimens into sample cups to be used on the Siemens Viva-Pro E urine toxicology instrument for one urine specimens observed. Findings include: 1. The surveyor observed one urine specimen tube in a specimen rack to the right of the Siemens Viva-Pro E urine toxicology instrument labeled "PA" on 4/13/26 at 9:27 am. 2. An interview with testing personnel #1 on 4/13/26 at 9:28 am included a verbal walkthrough of the specimen collection, handling, aliquoting, and loading onto the instrument. Patients collect their specimens in a urine cup, put the cup in the specimen door and it is labeled with a pre-written label with first and last name and date of birth. The laboratory aliquots urine into a tube, labels with patient initials, and it is used for testing in the laboratory. 3. An interview on 4/13/26 at 9:36 am with the laboratory director confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	(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. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with testing personnel #1, the laboratory failed to ensure its Syva EMIT II Plus Specialty Drug Level 2 Calibrator /Control had not been used beyond its stability for one of 15 bottles observed. Findings include: 1. The surveyor observed the laboratory's controls and calibrators in the laboratory on 4/13/26 at 9:14 am. One bottle for the Syva EMIT II Plus Specialty Drug Level 2 Calibrator/Control, used to calibrate the laboratory's buprenorphine test, included an open date of 12/26/25. 2. A review of the laboratory's "Siemens Syva EMIT Calibrators/Controls" manufacturer instructions revealed a section titled "Stability" stating, "Once opened, the Emit Calibrators/Controls are stable for 5 weeks when recapped and stored at 2-8 degrees Celsius when not in use." The expiration of the vial with an open date of 12/26/25 would have been 1/30/26. 3. An interview on 4 /13/26 at 11:38 am with testing personnel #1 revealed they had not been aware of the stability of the controls and calibrators and confirmed the vial opened on 12/26/25 had exceeded its stability.