Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2126022	06/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pima Heart Asc, Llc	1238 W Orange Grove Rd, Ste 101, Tucson, AZ	

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
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 review of i-Stat instrument printouts, i-Stat test procedures and interview with the technical consultant (TC-1), the laboratory failed to follow established policies and procedures to ensure positive identification of the patient's specimen from the time of collection through completion of testing and reporting of results. Findings include: 1. The laboratory utilizes the i-Stat analyzer to perform patient testing under the specialty of Hematology and the subspecialty of Routine Chemistry with an annual reported test volume of 1,972. The laboratory performs Activated Clotting Time (ACT) testing using the ACT cartridge and basic chemistry testing using Chem8+ test cartridge. 2. The laboratory's established test procedure for testing performed on the i-Stat analyzer states, "Follow handheld prompts. Enter Operator ID number as assigned to each user. Enter Patient ID number...Attach printout to Lab Report Form, verifying that patient ID numbers match." 3. Instrument printouts reviewed and printed from the i-Stat analyzer during the survey for one out of four patients, Patient# 436822429101815 from 2/14/25 revealed this patient's ACT was measured. 4. The patient ID number entered into the i-Stat as indicated above (# 436822429101815) was not a valid patient ID number or the patient ID was incorrect, as this patient ID number could not be traced back to a specific patient during the survey. 5. The laboratory failed to follow established policies and procedures to maintain positive patient identification on patient specimens throughout the entire testing process on the i-Stat analyzer. 6. The TC-1 interviewed on 6/24/25 at 1:30 PM confirmed that the laboratory failed to follow established policies and procedures

	related to the i-Stat analyzer to ensure positive patient identification throughout the entire testing process.