

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2126022	<b>(X3) Date Survey Completed</b>  05/23/2023
<b>Name of Provider or Supplier</b>  Pima Heart Asc, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of Chem8+ test cartridges used for the i-Stat analyzer, review of the manufacturer's storage requirements and interview with the facility personnel, the laboratory used test cartridges that exceeded the expiration date. Findings include: 1. The laboratory began patient testing in the subspecialties of Chemistry and Hematology, with an approximate annual test volume of 5,810. The laboratory performs the Chem8+ test on the i-Stat analyzer. 2. During the survey conducted on 5/23/2023, direct observation of two separate Chem8+ test cartridges stored on a laboratory counter at room temperature and used for patient testing revealed a hand written expiration date of 5/06/23. 3. Review of the manufacturer's storage requirements for i-Stat test cartridges indicated Chem8+ test cartridges may be stored at room temperature for up to 14 days. 4. The two Chem8+ test cartridges referenced above were expired on the date of the survey. The test cartridges expired on 5/20/23. 5. The number of patients tested using expired Chem8+ test cartridges could not be determined at the time of the survey. 6. The facility personnel interviewed on 5/23/2023 at 4:35pm confirmed that the Chem8+ test cartridges indicated above were expired.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on lack of education credentials for review and interview with the technical consultant, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education for the type and complexity of services offered. Findings include: 1. No evidence of education credentials was presented for review for one testing personnel. 2. The technical consultant interviewed on 05/23/2023 at 3:30pm confirmed the laboratory failed to provide a copy of the education credentials for the testing personnel indicated above. 3. The laboratory began patient testing in the specialties of Chemistry and Hematology in October 2021, with an approximate annual test volume of 5,810.