

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2296020	(X3) Date Survey Completed 09/24/2025
Name of Provider or Supplier Apex Heart And Vascular Center	Street Address, City, State 21360 N 75th Avenue, Glendale, 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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.</p> <p>This STANDARD is not met as evidenced by: Based on lack of instrument comparison results from April 2024 through September 2025 and interview with the testing personnel (TP-1), the laboratory failed to perform instrument comparisons on three separate i-Stat instruments. Findings include: 1. The laboratory began patient testing on April 20, 2024 in the specialties of Chemistry and Hematology, with an annual test volume of 10,620. 2. The laboratory utilizes 3 separate i-Stat instruments to perform Chem8+, Protime (PT/INR), and Activated Clotting Time (ACT) testing. I-Stat serial numbers include 440365, 440368 and 440382. 3. The laboratory failed to provide evidence of instrument comparison activities for each i-Stat analyzer from 4/20/24 through the date of the survey, 9/24/25. 4. TP-1 interviewed on 9/24/25 at 3:00 PM confirmed the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results generated from each i-Stat analyzer.</p>