

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2328136	(X3) Date Survey Completed 06/24/2026
Name of Provider or Supplier Sonoran Vein And Endovascular	Street Address, City, State 3411 N 5th Ave, Phoenix, 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
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on review of test verification documentation for the Chem8+ and Protime (PT) test cartridges performed on the i-Stat analyzer, and interview with the testing personnel (TP-1), the technical consultant failed to ensure the verification of performance specification documentation was signed and approved by a qualified laboratory director or qualified technical consultant prior to the start of patient testing. 1. The laboratory began using the Chem8+ and PT test cartridges on the i-Stat analyzer for patient testing on in August 2025. 2. The Chem8+ and PT test cartridge verification documentation reviewed during the survey on 6/24/26 lacked the signature and approval of the laboratory director or technical consultant. 3. The TP-1 interviewed on 6/24/26 at 8:45 AM confirmed the Chem8+ and PT test cartridge performance specification documentation failed to include the approval and signature of the laboratory director or technical consultant prior to the start of patient testing 4. The laboratory's annual test volume under the specialties of Chemistry and Hematology is 1,220.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on a record review of competency assessments from 2026, and interview with the testing personnel (TP-1), the technical consultant failed to evaluate the competency of one of two testing personnel. Findings include: 1. A review of competency records indicated a qualified technical consultant failed to perform and evaluate the 2026 semi-annual competencies for one of two testing personnel. 2. The TP-1 interviewed on 6/24/26 at 8:30 AM confirmed the technical consultant failed to evaluate the semi-annual competency for one of two testing personnel in 2026.