

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2049626	(X3) Date Survey Completed 06/18/2025
Name of Provider or Supplier Sonoran Vein And Endovascular	Street Address, City, State 9192 W Union Hills Dr, Peoria, 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	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of established policies, review of patient test records for specimens tested on the i-Stat analyzer and interview with the technical consultant (TC-1), (A) the laboratory failed to establish written policies and procedures to 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; and (B) the laboratory failed to positively identify one out of four patient specimens tested by the laboratory. Findings include: 1. The laboratory began patient testing in August 2023 on the i-Stat analyzer and reports 105 tests annually in the specialties of Chemistry and Hematology. A2. The laboratory failed to provide evidence of an established written policy and procedure to 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 for Chem8+ and PT/INR testing. A3. The TC-1 interviewed on 6/18/25 at 12:07 PM confirmed the laboratory failed to provide evidence of written policies and procedures to ensure positive identification and optimum integrity of a patient's specimen throughout the entire testing process, for testing performed on the i-Stat analyzer. B1. The TC-1 interviewed on 6/18/25 at 11:50 AM stated that the testing personnel manually enter the patient's birth date into the i-Stat analyzer as the unique patient identifier prior to testing the sample. The patient identifier is included on the i-Stat instrument printout. B2. One out of four patient test records reviewed during the survey failed to include a unique specimen identification number. Review of the</p>

instrument printout for Chem8+ test results from 8/26/24 indicated the testing personnel manually entered the patient ID into the analyzer as '333'. B3. The TC-1 interviewed on 6/18/15 at 11:50 AM confirmed the laboratory failed to positively identify the specimen throughout the entire test process for the patient indicated above.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of established Quality Assessment (QA) policies, review of Proficiency Testing (PT) records from 2023, 2024 and 2025 and interview with the Technical Consultant (TC-1) on June 18, 2025, the laboratory failed to establish policies and procedures for the enrollment and performance of PT samples. Findings include: 1. The laboratory began patient testing in August 2023 in the subspecialties of Routine Chemistry and Hematology with a reported annual test volume of 105. 2. No evidence was provided for review to indicate the laboratory established policies and procedures specific to the enrollment and performance of proficiency testing, including but not limited to, enrollment, testing of the PT samples, PT referral, review of graded PT results and corrective action to take for any unsatisfactory PT results. 3. The TC-1 interviewed on 6/18/25 at 9:56 AM confirmed the laboratory failed to establish policies and procedures specific to PT.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual on 6/18/25 for Chem8+ testing performed on the i-Stat analyzer and interview with the technical consultant (TC-1), the Chem8+ test procedure failed to include imminently life-threatening test results, or panic or alert values. Findings include: 1. The laboratory began patient testing in the specialty of Chemistry in August 2023 with a reported annual test volume of 100. 2. The laboratory's test procedure failed to include imminently life-threatening test results, or panic or alert values for the parameters of the Chem8+ test, including the procedure(s) to follow in order to document notification of these critical results to the ordering provider. 3. The TC-1 interviewed on 6/18/25 at 11:22 AM confirmed the laboratory failed to provide evidence of panic or alert values for Chem8+ testing performed on the i-Stat analyzer.

D5425

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(3)

(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:
Based on lack of Quality Control (QC) and calibration procedures for review during the survey performed on 6/18/25 and interview with the technical consultant (TC-1), the laboratory failed to determine control and calibration procedures for the i-Stat analyzer for Chem8+ and PT/INR testing. Findings include: 1. The laboratory began Chem8+ and PT/INR testing on the i-Stat analyzer in August 2023 with a reported annual test volume of 105. 2. No written documentation was presented for review to indicate the laboratory determined QC and calibration procedures for testing performed on the i-Stat analyzer, including but not limited to, documentation to show the laboratory defined the frequency for calibration and control performance as well as the type, number, and concentration of calibration and control materials used to monitor, detect errors, and evaluate method performance. 3. The TC-1 interviewed on 6/18/25 at 11:22 AM confirmed the laboratory failed to provide evidence of written QC and calibration procedures for Chem8+ and PT/INR testing performed on the i-Stat analyzer.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) records for Chem8+ testing performed on the i-Stat analyzer and interview with the Technical Consultant (TC-1), the laboratory failed to perform two control materials of different concentrations each day patient testing occurred for 23 out of 23 testing dates between 3/18/24 and 9/23/24. Findings include: 1. The laboratory performs patient testing in the subspecialty of Routine Chemistry with a reported annual test volume of 100. 2. The Chem8+ QC documentation presented for review revealed the laboratory performed only one level of control material (TriControl Level 1) on 23 out of 23 testing dates between 3/18/24 and 9/23/24. 3. The laboratory performed Chem8+ testing on 46 patients during the

time frame indicated above. 4. The TC-1 interviewed on 6/18/25 at 10:40 AM confirmed the laboratory failed to perform 2 levels of quality control material on the testing dates indicated above for Chem8+ testing.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:
Based on review of monthly quality assessment (QA) documentation and interview with the Technical Consultant (TC-1), the laboratory's QA processes failed to monitor, identify and correct errors found in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory began utilizing the i-Stat analyzer for patient testing in August 2023, with a reported annual test volume of 105. The laboratory performs a "Monthly Lab Quality Assessment Audit Form" each month. 2. The laboratory's monthly QA process failed to monitor, identify and correct errors found with the laboratory's quality control process and performance for the i-Stat analyzer. See D5425 and D5447 for finding. 3. The TC-1 interviewed on 6/18/25 at 12:15 PM confirmed the laboratory's QA processes failed to monitor, identify and correct issues found with quality control performance on the i-Stat.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of the approved reference ranges in the laboratory procedure manual and interview with the technical consultant (TC-1), the laboratory failed to ensure the test report included pertinent normal ranges as determined by the laboratory. Three of the eight chemistry parameters listed on the laboratory's test report differed from those in the approved procedure manual. Findings include: 1. Review of patient test reports for Chem8+ testing revealed three of the eight parameters for chemistry testing failed to correctly match those reference ranges in the procedure manual as evidenced below: - Sodium: Test report = 136-144 mmol/L, Reference range in procedure manual = 138-144 mmol/L - BUN: Test report = 6-20 mg/dL, Reference range in procedure manual = 8-26 mg/dL - Creatinine: Test report = 0.8-1.2 mg/dL, Reference range in procedure manual = 0.6-1.3 mg/dL 2. Interview with the TC-1 on 6/18/25 at 11:00 AM confirmed the laboratory failed to ensure correct reference ranges approved in the procedure manual were included on the patients' test report. 3. The laboratory reports approximately 100 Chem8+ panels annually.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established

and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on laboratory personnel interview and i-Stat quality control record review, the laboratory director failed to ensure that a quality control program was established and maintained to assure the quality of laboratory services provided for Chem8+ and PT /INR testing. Findings include: 1. The laboratory failed to establish quality control procedures for the Chem8+ and PT/INR test panels performed on the i-Stat analyzer. Refer to D5425. 2. The laboratory failed to perform two levels of quality control material each day of patient testing for the Chem8+ test on 23 out of 23 testing dates in 2024. Refer to D5447.

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 review of 2024 competency evaluation documentation and interview with the technical consultant (TC-1), the technical consultant failed to perform the annual competency evaluation for TP-1 in 2024. Findings include: 1. Competency documentation reviewed for TP-1 from 2024 revealed the competency evaluation was performed by TP-2 and not the Technical Consultant. TP-2 was not listed as TC on the CMS-209, Laboratory Personnel Form provided during the survey. 2. Interview with TC-1 on 6/18/25 at 10:00 AM confirmed the Technical Consultant, or another testing personnel who meets the qualifications of TC and performance of competency assessment is delegated in writing to the individual, failed to evaluate the competency of TP-1 in 2024.