Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2328832	07/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
New Mexico Vascular Consulting Dba Sonoran Vein	520 Nm 564, Gallup, NM	

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
D0000	An onsite initial survey conducted on July 1, 2026, at New Mexico Vascular Consulting DBA Sonoran Vein and Endovascular found the laboratory to be not in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions for the Chem8+ and PT Plus cartridges, i-STAT operator's manual, the laboratory's temperature log, and interview with Testing Personnel 1, the laboratory failed to ensure daily temperature monitoring was being documented for the reagent refrigerator for six of six months reviewed in 2026 and failed to monitor temperature and humidity in the testing room since beginning testing in October 2025. Findings included: 1. During a tour on 07/01/2026 at 9:42 am, one box of i-STAT Chem8+ cartridges and one box of i-STAT PT Plus cartridges were observed being stored in the reagent refrigerator. One i-STAT analyzer was observed in use in the testing room. 2. Review of the manufacturer's instructions on the boxes of the Chem8+ and PT Plus cartridges revealed required storage temperature of 2-8C (Celsius). 3. Review of the operator's manual for the i-STAT analyzer revealed the required operating temperature 16-30C

	and humidity 90% (maximum). 4. Review of the laboratory's Daily Temperature Log revealed the temperature for the reagent refrigerator was only documented on the following days in 2026: - 5 days in January (8th,9th, 21st, 22nd, and 23rd) - 6 days in February (4th,5th,6th,18th,19th, and 20th) - 6 days in March (4th,5th,6th,19th, 20th, and 21st) - 5 days in April (2nd, 3rd, 16th, 17th, and 30th) - 5 days in May (1st, 14th, 15th, 28th, and 29th) - 3 days in June (24th, 25th, and 26th) 5. Review of the laboratory's Daily Temperature Log also revealed temperature and humidity were not being monitored for the testing room where the i-STAT analyzer was being used since beginning testing in October of 2025. 6. An interview on 07/01/2026 at 9:55am with Testing Personnel 1 confirmed the above findings. 7. The laboratory reported performing 74 Chem8+ annually and 0 PT/INR tests since beginning testing in October of 2025.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, the laboratory's Test Method Verification and Validation policy, the laboratory's Validation Report, lack of documentation, and interview with Testing Personnel 1, the laboratory failed to follow their policy for verifying precision on their i-STAT using chem8+ cartridges and failed to perform a performance verification for the i-STAT using PT/INR cartridges. Findings included: 1. Review of the laboratory's test menu revealed the laboratory performed i-STAT testing using the Chem8+ and PT/INR testing cartridges. 2. Review of the laboratory's Test Method Verification and Validation policy listed the following instructions for verifying instrument precision, "Run at least two levels of controls (low and high) twice daily for 5 consecutive days. Calculate: Mean, Standard Deviation (SD), and Coefficient of Variation (CV)" 3. Review of the laboratory's Validation Report for the i-STAT Chem8+ cartridges revealed the following description under precision, "The Abbott Tricontrol Verification Set Levels 1 through 5 were tested using the i-STAT Chem8+ cartridge during a one-day validation study". Data from the validation report confirmed the laboratory did not run their testing twice daily for 5 consecutive days. The Validation Report also revealed the laboratory did not calculate the mean, standard deviation, and coefficient of variation. 4. Review of the laboratory's Validation Report revealed the facility failed to perform performance verification on the i-STAT for the PT/INR cartridges. The laboratory was asked to provide documentation of performance verification for the PT/INR cartridges. The laboratory was unable to provide documentation. 5. An interview on 07/01/2026 at 10:45 am with Testing Personnel 1 confirmed the above findings. 6. The laboratory reported performing 74 Chem8+ annually and 0 PT/INR tests since beginning testing in October of 2025
D5805	TEST REPORT CFR(s): 493.1291(c)

	(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with testing personnel 1, the laboratory failed to ensure patient test reports included the facility's address and specimen source for one of one patient report reviewed. Findings included. 1. Review of the laboratory's patient test reports revealed the reports do not list the facility's address or include the specimen source. 2. During an interview on 07/01/2026 at 11: 08 am, Testing Personnel 1 verified the same format of patient test reports is provided to all patients, confirming the above findings. 3. The laboratory reported performing 74 Chem8+ annually and 0 PT/INR tests since beginning testing in October of 2025.