Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2032976	04/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Sedona Medical Center Laboratory	3700 West State Route 89a, Sedona, 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
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 test procedure for Troponin I testing performed on the Pathfast analyzer, review of patient test results and interview with the technical consultant (TC-2), the Pathfast Troponin I test procedure failed to include the laboratory's system for entering results in the patient record and reporting test results with a calculated unit of measure conversion. Findings include: 1. The laboratory performs Troponin I testing on the Pathfast analyzer with a reported annual test volume of 1,650. It is the practice of the laboratory to enter the test results into the

	Laboratory Information System (LIS), Cerner. 2. The test procedure, "Pathfast Troponin I" reviewed during the survey failed to include the laboratory's system for entering and reporting test results in the LIS (Cerner). 3. Test results reviewed for patient# 00-022-12-33 from 2/12/25 revealed the Pathfast instrument printout result for Troponin I as 0.062 ng/mL. The final result maintained in the LIS indicated a test result of 62.00 ng/L. 4. The test procedure referenced above failed to include information on converting the Troponin I test result from ng/mL to ng/L prior to reporting patient test results. 5. The GS-1 interviewed on 4/04/25 at 2:45 PM confirmed the Pathfast Troponin I test procedure lacked information regarding the laboratory's system for entering and reporting Troponin test results in Cerner and failed to include information on converting the units of measure to ng/L prior to reporting patient test results.
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 review of the established humidity criteria defined by the laboratory, review of the manufacturer's environmental specifications for the Pathfast chemistry analyzer and the ACL Elite coagulation analyzer and interview with the Technical Consultant (TC-1), the laboratory failed to establish an ambient humidity range consistent with the manufacturer's required humidity range for operation of the analyzers. Findings include: 1. The laboratory reports an annual test volume of 137,506 in the specialties of Chemistry and Hematology. 2. The manufacturer's environmental specifications reviewed during the survey for the Pathfast chemistry analyzer listed the operating relative humidity range as 20-80%. 3. The manufacturer's environmental specifications reviewed during the survey for the ACL Elite coagulation analyzer listed the operating relative humidity range as 15-85%. 4. Review of laboratory humidity records from September 2023 through April 4, 2025 indicated the laboratory's established humidity range as 0-85%. 5. The TC-1 interviewed on 4/04/25 at 1:40 PM confirmed that the laboratory's established humidity range was not consistent with the manufacturer's operating humidity ranges for the Pathfast analyzer and ACL Elite analyzer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At

	least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration verification documentation for the Siemens Dimension EXL chemistry analyzer and the DXH Hematology analyzers and interview with the Technical Consultant (TC-1), the laboratory failed to perform and document calibration verification procedures at least once every 6 months during 2024. Findings include: 1. The laboratory utilizes the Siemens Dimension EXL chemistry analyzer to conduct patient testing in the specialty of Chemistry with a reported annual test volume of 96,262. 2. No documentation was presented for review to indicate the laboratory performed calibration verification procedures on the Dimension EXL analyzer at least once every six months during 2024 for the analytes Sodium (Na), Potassium (K) and Chloride (Cl), including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results. 3. The laboratory utilizes the Beckman Coulter DXH520 and DXH600 hematology analyzers to conduct patient testing in the specialty of Hematology with a reported annual test volume of 39,707. 4. No documentation was presented for review to indicate the laboratory performed calibration verification procedures on the DXH520 and DXH600 analyzers at least once every six months during 2024, including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results. 5. The TC-1 interviewed on 4/04/25 at 2: 00 PM confirmed the laboratory failed to perform calibration verification procedures at least once every 6 months during 2024 on the analyzers indicated above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (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. This STANDARD is not met as evidenced by: Review of 2024 instrument comparisons for chemistry and hematology testing and interview with the technical consultant (TC-1), the laboratory failed to perform comparisons for two chemistry analyzers and two hematology analyzers. Findings include: 1. Review of 2024 instrument comparison records revealed the laboratory failed to perform and document instrument comparisons twice a year between the Dimension EXL and Chemstat chemistry analyzers in 2024. 2. No instrument comparison records were provided for review from 2024 for the DXH520 and DXH600 hematology analyzers. 3. Interview with the TC-1 on 4/04/25 at 1:50 PM

	confirmed the laboratory failed to provide instrument comparison records from 2024 for the chemistry and hematology analyzers as indicated above. 4. The laboratory reports approximately 137,506 tests annually in the specialties of Chemistry and Hematology.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation and interview with the technical supervisor (TS-1), the technical supervisor failed to evaluate and document the performance of two out of two testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for two out of two testing personnel (TP-4 and TP-5) who began patient testing in 2024. 2. The TS-1 interviewed on 4/04/25 at 11:00 AM confirmed the technical superviosr failed to perform and document a semiannual competency evaluation for the two testing personnel indicated above.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation from 2024 and 2025 and interview with the technical supervisor (TS-1), the technical supervisor (TS) failed to evaluate and document the performance of four out of four individuals responsible for high complexity testing at least annually. Findings include: 1. No documentation of an annual competency evaluation from 2024 was presented for review for three out of three testing personnel (TP-1, TP-2, TP-3). 2. No documentation of an annual competency evaluation from 2025 was presented for review for one out of one testing personnel (TP-5). 3. The TS-1 interviewed on 4/04/25 at 11:15 AM confirmed the TS failed to evaluate and document the performance of the testing personnel indicated above at least annually during 2024 and 2025.