Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2316316	09/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
University Of Arkansas For Medical Sciences	4301 W Markham, Little Rock, AR	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual, lack of documentation, and interviews with laboratory staff, the laboratory director failed to approve, sign, and date all the laboratory procedures. Survey findings include: A. During a review of the laboratory procedures, it was determined the laboratory director failed to sign the procedure manual and individual policies. B. In an interview at 09:54 9/12/2025, employee #1 (as listed on the entrance/exit interview form) confirmed the laboratory director's written approval of the laboratory procedures was not available.
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 a review of 2025 temperature and humidity records, laboratory

	instrumentation manuals, and interview with laboratory staff, the laboratory failed to document daily humidity of the main laboratory. Survey findings include: A. A review of laboratory instrumentation manuals revealed performance specifications of a maximum of 60% relative humidity for the Avantik QS12 Cryostat (QS12 Cryostat Instruction Manual, 388159, English). B. Through a review of temperature records for 2025 it was revealed the laboratory failed to document humidity on 6 of 6 months for 2025 C. Upon request, humidity recordings were not available for 2025. D. In an interview, at 09:18 on 9/12/2025, employee #1 (as listed on entrance/exit interview form) confirmed the laboratory humidities were not documented on days the laboratory was in operation.