Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0965138	(X3) Date Survey Completed 05/27/2025
Name of Provider or Supplier Pediatric Associates Of West Memphis-Marion	**Street Address, City, State** 200 Pine Street, Marion, 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
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 temperature and humidity records, lack of documentation and interview; the laboratory failed to document corrective action when the humidity was outside ranges on each day of operation in which supplies and instruments with storage temperature and humidity requirements were located. Findings follow: A) The Daily Temperature / Humidity Log for 2024 has five days of operation for the month of January that the Humidity was below the 20-85% range and two days the Humidity was not recorded for the room. B) A review of the laboratory's policy titled, "Daily Temperature Checks", states, "The temperature of the laboratory must be monitored and kept between the posted ranges to ensure the proper storage and/or testing environments for all reagents used". This policy does not include any Humidity requirements for testing equipment, and/or reagents. C) In an interview on 5/27/25 at 12:46 pm, the laboratory technical consultant confirmed that humidity records for the above dates were not recorded, and there was no quality assurance remediation on dates humidity was out of range.