

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0948582	<b>(X3) Date Survey Completed</b> 09/16/2025
<b>Name of Provider or Supplier</b> Arkansas Heart Hospital Clinic Llc- Little Rock	<b>Street Address, City, State</b> #7 Shackelford West, Little Rock, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>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 instruments with humidity requirements were affected. Findings follow: A) The AHH Clinic Temperature and Humidity Log for 2024 and 2025 has eight (of 23) days of operation for the month of January 2024 that the Humidity was below the 20-80% range. B) A review of the laboratory's policy titled, "Daily Temperature Checks", states, "Temperatures falling outside the acceptable ranges must have corrective action taken." It also states "The acceptable ranges, if applicable are: ...Humidity: 20%-80%" This policy does not include any corrective action directives for humidity requirements C)The "XN-L series XN-550/XN-450/XN-350 General Information Manual" states the operating environment for the XN-550 has a relative humidity requirement of 20 to 85%. D) In an interview on 9/16/25 at 12:19 pm, the laboratory director confirmed that there was no quality assurance remediation on dates humidity was out of range.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and interview with laboratory staff, the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 9/16/25 at 2:53pm, one (of three) container of "Siemens QuikLYTE Integrated Multisensor Na+ / K+ / CL-" (lot 5CD806, REF S600, SMN 10445056, expiration date 9/13/25) was observed in the laboratory, available for use beyond the expiration date. C) In an interview on 9/16/25 at 2:54pm the lab director confirmed that the item, identified above, had exceeded its expiration date and was available for use in the laboratory.