Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1038350	09/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Arkansas Surgical Hospital Llc	5201 North Shore Drive, North 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
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 upon observation, manufacturer's temperature requirements for Biorad IH Card AHG, Biorad IH Card ABO, and Vacuette blood collection tubes, the manufacturer's operating humidity requirement for Vitek 2 Compact microbiology analyzer, lack of documentation and interview with laboratory staff, the laboratory failed to monitor the room temperature in two of four rooms in which items with a storage temperature requirement were stored and room humidity in one of two rooms in which instruments with a required operatng humidity level were operated. Findings follow: 1. The laboratory failed to monitor humidity in one of two rooms in which instruments with an operating humidity level were used. A) During a tour of the laboratory on 9/23/25 at 09:00 a.m., a Vitek 2 Compact microbiology analyzer was observed in a room separated from the main laboratory area by a closed door. B) Review of the user's manual for the Vitek 2 Compact microbiology analyzer revealed a operating requirement of a non-condensing humidity level of 20 to 80 percent. C) Review of the laboratory records for environmental monitoring revealed that no humidity levels were presented for the room in which the Vitek 2 Compact microbiology analyzer was operated. D) In an interview on 9/24/25 at 10:40 a.m., the laboratory staff members (numbers 2 and 3 on the form CMS 209) confirmed that humidity was not recorded in

	the room in which the Vitek 2 Compact analyzer was used in microbiological analysis. 2. The laboratory failed to monitor the room temperature in two of four rooms in which supplies with a storage temperature requirement were stored. A) During a tour of the laboratory on 9/23/25 at 09:00 a.m., four separate rooms (main laboratory, blood bank, phlebotomy room, and microbiology laboratory) were observed containing items with a temperature storage requirement. B) During a tour of the laboratory on 9/24/25 at 10:00 a.m. 450 Biorad IH Card AHG cassettes lot # 9506010 expiration date 2026-06-03 temperature storage requirement 18 degrees Centigrade (C) to 25 degrees (C)., and 642 Biorad IH Card ABO cassettes lot # 9079020 expiration date 2026-09-07 temperature storage requirement 18 degrees (C) to 25 degrees (C) were observed in the blood bank room. C) During a tour of the laboratory on 9/24/25 at 10:00 a.m. 500 Vacutette 3 ml Na Citrate Blue Top blood collection tubes lot # B250133u expiration date 2026-01-01 with a storage temperature requirement of 4 degrees (C) to 25 degrees (C), and 700 Vacutette 3 ml Na Citrate Blue Top blood collection tubes lot # B250233g expiration date 2026-02-14 and a storage temperature requirement of 4 degress (C) to 25 degrees C were observed in the phlebotomy room. D) Review of the laboratory records for environmental monitoring revealed that no temperatures were presented for the blood bank and phlebotomy rooms. E) In an interview on 9/24/25 at 10:40 a.m., the laboratory staff members (numbers 2 and 3 on the form CMS 209) confirmed that room temperature was not recorded in the blood bank or phlebotomy rooms.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based upon review of laboratory policies and procedures, review of quality control (QC) results for Prothrombin Time (PT) for November 2025, review of corrective action reports, and interviews with laboratory staff, the laboratory failed to follow written policies and procedures for corrective actions when quality control results failed to meet acceptable criteria. Survey findings follow: A) A review of the laboratory general policies and procedures for "Quality Control Plan" revealed that " all unacceptable QC and troubleshooting issues must be documented as corrective action". B) Review of the laboraotry general policies and procedures for "Quality Control Plan" revealed under the heading "Coagulation" "hold patient results and reject the run if either level is outside 2SD. The following steps will be taken: a. rerun old control, b. reconstitute fresh control and rerun, c. check/replace reagents, d. troubleshoot instrument, e. call service". C) A review of QC results for PT assays performed in November 2024 revealed that on 11/21/24 Dade Citrol level 1 lot # 564897 with an acceptable range of 10 - 11 seconds was recorded as 11.4 with a flag "2SD"at 15:26 hrs, as 11.4 with a flag "2SD" at 15:38 hrs, as 11.3 with a flag "2SD"at 16:00 hrs, as 11.2 with a flag "2SD" at 16:37 hrs, as 11.1 with a flag "2SD"at 17:31 hrs. before being acceptable as 11.0 at 17:42 hrs. D) Review of documentation of corrective action revealed that for all unsucessful QC events identified above the corrective action documented was " QC failed, rerun". E) Upon request, the laboratory was unable to provide the corrective action taken to bring the controls identified above into acceptable range. . F) In an interview at 01:52 on 9/23/25 laboratory staff member (#2 as listed on the form CMS-209) confirmed the lack of written corrective

	action for the quality control failure identified above that the corrective action documented did not follow policy and procedure and did not represent actual corrective action. .