

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0465678	<b>(X3) Date Survey Completed</b> 01/22/2026
<b>Name of Provider or Supplier</b> Southwest Arkansas Regional Medical Center	<b>Street Address, City, State</b> 2001 South Main Street, Hope, 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>D5317</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on , review of laboratory policy and procedure, lack of documentation and interview of laboratory staff, the laboratory did not provide clients with written instructions for specimen submission, handling, and referral as specified in CFR 493.1242 paragraphs (a)(1) through (a)(7). A) Review of the laboratory's "Client Information Policy" revealed "clients will also be furnished with specimen collection supply requirements and blood collection instructions". B) In an interview on 1/20/26 at 10:45 a.m., the laboratory staff member (number two on the form CMS 209) said that the laboratory received and tested specimens referred from two nursing homes, as well as home health agencies and hospice agencies. C) Upon request, the laboratory could not provide a copy of a client services manual or evidence of instructions for specimen collection and handling that is provided to clients . D) In an interview on 1 /21/26 at 3:30 p.m., the laboratory staff member (number two on the form CMS 209) confirmed that the laboratory did not provide instruction manuals for specimen submission, handling, and referral to outside clients that referred testing to the laboratory .</p>
<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</p>

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, review of temperature records, lack of documentation and interview the laboratory failed to monitor the temperature on each day of operation in two of five rooms in which supplies with storage temperature requirements were stored. Findings follow: A) During a tour of the laboratory on 1/20/26 at 10:45 a.m. the surveyor observed four rooms (core laboratory, blood bank room, microbiology room, small storage room and phlebotomy room) separated by closable doors containing laboratory items with a temperature storage requirement. B) A review of the laboratory's temperature records revealed that no room temperatures were recorded for the small storage room or the Phlebotomy room for the year 2025. C) During a tour of the laboratory on 1/22/26 at 09:07 a.m. the surveyor observed a box of 50 UTM Kit lot # 41923000 expiration date of 2026-04-01 with a storage temperature requirement of 2 degrees to 25 degrees Centigrade (C) in the small storage room and 4 Vacuette 2ml Na Citrate Blue Top blood collection tubes lot # 454322 expiration date 2026-04-01 with a storage temperature requirement of 4- 25 degrees C and 7 Vacuette 2ml Heparin Green Top blood collection tubes lot # 454497P expiration date 2026-09-30 with a storage temperature requirement of 4 - 25 degrees C in the Phlebotomy room. D) Upon request, the laboratory could not present the temperature records for the Phlebotomy room and the small storage room in which the supplies identified above were stored. E) In an interview on 1/22/26 at 09:30 a.m., the laboratory staff member (# 2 on form CMS 209) confirmed that temperature records for the Phlebotomy room or small storage room were not recorded.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

. Based upon review of personnel files for testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, the laboratory director failed to authorize eighteen of eighteen testing personnel reviewed to perform testing without direct supervision. Survey findings include: A) Review of personnel files for eighteen testing personnel listed on form CMS-209 (Personnel #'s 2 through 5 and, 8 through 21) revealed written authorization from the laboratory director to perform moderately complex testing without direct supervision was not present. B) In an interview, at 12:50 p.m. on 1/20/26 laboratory staff representative #4 (as listed on the Entrance Conference Attendance Record) confirmed the lack of written authorizations to perform tests for employees identified above.