

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0465694	<b>(X3) Date Survey Completed</b> 01/31/2025
<b>Name of Provider or Supplier</b> Little River Memorial Hospital	<b>Street Address, City, State</b> 451 West Locke Street, Ashdown, 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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Bases on through review of Laboratory policy and procedure manual, lack of documentation and interview with staff, it was determined the laboratory failed to have a written procedure for Blood Bank. Survey findings follow: A) Upon request, the laboratory was unable to provide policy and procedure for blood banking. The only policy provided was for Emergency Release. No policy was provided for how, what, when, and who is responsible for maintaining the blood banking refrigerator. B) In an interview on 01/31/2025 at 09:20 am, Testing Personnel (TP-1 on form CMS 209), confirmed there was no written procedure for blood banking.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with laboratory staff determined that the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 1/31/2025 at 11:58 am, one of two phlebotomy</p>

trays containing 4 Sodium Citrate (Blue Top) blood collection tubes lot 4045036, expiration date 11/30/2024 was observed in the phlebotomy area, available for use beyond the expiration date. B) In an interview on 1/31/2025 at 12:18 pm the testing personnel (TP - 1 on form CMS 209), confirmed that the items, identified above, had exceeded the expiration date and were available for use.

**D5555**

**IMMUNOHEMATOLOGY**  
CFR(s): 493.1271(c)(f)

(c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policy and procedure for Blood Bank showed only one procedure titled, "Emergency Release". No procedures were provided for the continuous monitoring systems currently used for the blood bank refrigerator. No procedure were provided for the blood bank refrigerator storage alarm checks, lack of documentation function checks, and interview demonstrated that the laboratory failed to perform periodic alarm checks for the blood bank blood storage refrigerator for the calendar year 2023 through 2025. Findings follow: A) Review of the laboratory's policy and procedure for Blood Bank revealed no procedures on how the laboratory is conducting daily monitoring, temperature verification of the temperature alarms, notification of system checks, and the results recorded on the appropriate log. B) Review of the laboratory documentation for blood bank refrigerator alarm check revealed that no alarm check was documented in 2023 through 2025 for the Blood Bank refrigerator. C) Upon request, the laboratory was unable to provide documentation of blood bank refrigerator alarm checks performed for 2023 through 2025. D) In an interview on January 31, 2025, at 12:10 pm, the testing personnel (TP- 1 on form CMS 209), stated that the laboratory had not performed alarm checks on the blood storage refrigerator.

**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 on review of personnel files for fourteen testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, determined the laboratory director failed to authorize one of fourteen testing personnel to perform testing without direct supervision. Survey findings include: A) During a review of personnel files for fourteen testing personnel (TP), TP- 10 (as listed on the form CMS-209) failed to have written authorization from the laboratory director, to perform

moderate complexity testing without direct supervision. B) In an interview on 1/31 /2025 at 12:01 pm, the testing personnel (TP-1 on form CMS 209) confirmed the lack of written authorization to TP-10 on form CMS 209.

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(14)

(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:

Based on lack of laboratory policies and procedures and interviews it was determined that the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Cross refers to D5401