Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465694	04/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Little River Memorial Hospital	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Through a review of the form CMS-209 and blood gas proficiency test records, lack of documentation, and interviews with staff, it was determined the blood gas samples were not tested by all of the personnel who routinely perform patient testing. Survey findings include: A. Five testing personnel (laboratory employees #7, #8, #9, #10, and #11) who perform blood gas testing were listed on the form CMS-209. B. A review of blood gas proficiency test records for three events in 2020 and one event in 2021 revealed that laboratory employee #7 (as listed on the form CMS-209) had signed the attestation stating she had performed testing on three of four events (First and Second Chemistry Core Events in 2020 and the First Chemistry Core Event in 2021) and laboratory employee #8 had signed the attestation for the Third Chemistry Core Event of 2020. There was no documentation that laboratory employees #9, #10, or #11 (three of five) had performed blood gas proficiency testing in 2020 or 2021. C. In an interview, at 10:23 a.m. on 4/14/2021, the technical consultant (as listed on the form CMS-209) confirmed that three of five personnel who routinely run patient blood gas tests have not performed proficiency testing in 2020 or 2021.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a

	proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Through a review of proficiency test documentation for the Third Hematology Event 2019 through the First Hematology Event 2021 (five events), a review of corrective actions for proficiency faiures, and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions and failed to correct problems to prevent recurrent proficiency test failures for Automated WBC Differential. Survey findings include: A. Through a review of proficiency test results for the Third Hematology Event of 2019, First Hematology Event of 2020, Second Hematology Event of 2020, and Third Hematology Event of 2020, it was determined the laboratory failed the automated differential in three of four events reviewed. In the Third Hematology Event of 2019, the laboratory scored 0% for Basophils, Eosinophils, IG (immature granulocytes) absolute, IG percent, and Neutrophils. In the First Hematology Event of 2020, the laboratory scored 40% for Basophils, Eosinophils, IG (immature granulocytes) absolute, IG percent, and Neutrophils. In the Third Hematology Event of 2020, the laboratory scored 60% for Basophils, Eosinophils, IG (immature granulocytes) absolute, IG percent, and Neutrophils. B. Corrective actions taken for the Third Hematology Event of 2019, and First Event of 2020 failed to prevent the failure again on the Third Event 2020. No corrective actions for the WBC Differential failures were documented for the Third Event 2020. C. In an interview, at 2:43 p.m. on 4/15/2021, the technical consultant confirmed the recurrence of WBC Differential failures and the lack of corrective action documentation for the failed third event.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Through a review of quality control records for July and November of 2020 and March 2021, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to retain Dimension EXL 200 quality control Levy Jennings graphs and documentation of calculation of quality control acceptable ranges for at least two years. Survey findings include: A. The surveyor requested quality control documentation for July and November 2020 and March 2021. The laboratory provided Levy-Jennings graphs for evaluating quality control over time for shifts and trends. The graphs were available for November 2020 and March 2021 but no graph was provided for July 2020. B. In an interview, at 10:30 4/15/2021, the technical consultant (as listed on the form CMS-209) stated that the Levy Jennings graphs for July 2020 were deleted without printing them. C. The surveyor requested documentation of data used to calculate the 2 standard deviation (SD) acceptable quality control ranges of Multiqual quality control used for chemistry tests on the

	Dimension EXL 200. At 1:02 on 4/15/2021 the technical consultant stated that the SD calculations were not available and that the laboratory was unable to print data from the instrument because previous lots had been deleted.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Through a review of the laboratory policy and procedure manual, lack of documentation, and interviews with laboratory personnel, it was determined the laboratory had a written policy to order and perform "Chest Pain and Stroke Protocol" tests without physician orders for the tests. Survey findings include: A. The laboratory policy titled, "Chest Pain and Stroke Protocol" includes the following written instructions: "If doctor has not ordered labs then tech will order test and result out as they normally would." The tests listed in the protocol are CMP, CBC, Cardiac Enzymes, UA, and BNP for Chest Pain and CMP, CBC, Lipid Profile, UA, D-dimer, Cardiac Enzymes, PT/PTT Profile, Drug Screen, and Pregnancy Test (if within child bearing age) for Stroke. B. The surveyor requested documentation of standing orders or medical staff approval of the "Chest Pain and Stroke Protocol" but none was provided. C. During an interview, at 9:00 a.m. on 4/15/2021, the technical consultant (as listed on the form CMS-209) confirmed that laboratory personnel have not been approved by medical staff to order tests without the physicians orders and confirmed there are no standing orders by any medical staff for the tests listed in the "Chest Pain and Stroke Protocol".
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through observations made during a tour, a review of quality control package inserts, a review of blood gas quality control and patient results, a review of the corrective action log and AD-Hoc reports of patient testing, lack of documentation, and interviews with staff, it was determined the laboratory failed to meet the applicable analytic systems requirements as evidenced by: D5415 - the laboratory failed to document the date opened and the expiration date of three of three vials of XN Check Hematology controls D5417 - the laboratory had TBI/DBI Calibrators and TP/Alb Calibrators available for use when they had exceeded their expiration dates. D5537 - the laboratory failed to perform blood gas quality control each 8 hours of testing D5783 - the laboratory failed to document corrective actions when Cholesterol and Total Protein quality control results were outside of acceptable range

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Through observation, review of package insert, and interview it was determined that the laboratory failed to document the date opened and the expiration date of three of three vials of XN Check Hematology controls in current use. A) The package insert of the XN Check Hematology controls states that the product expiration date changes to seven days after the vial is opened and the product is placed into use. B) During a tour of the laboratory on 4/14/2021 9:20 a.m. three vials of XN Check Hematology controls (lot 10161401, 10161402, and 10161403) were observed in the laboratory refrigerator without labels of the date opened or the amended expiration date. C) In an interview on 4/14/2021 at 9:20 a.m. the technical consultant, identified as number two on the CMS 209 form, verified that the vials of controls were not labeled with the date opened and/or the amended expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: Through observations made during a tour of the laboratory as well as interviews with laboratory staff, it was determined the laboratory had TBI/DBI Calibrators and TP /Alb Calibrators available for use when they had exceeded their expiration dates. Survey findings include: A. During a tour of the laboratory, conducted on 4/14/2021 at 9:20 a.m., the surveyor observed 1 box of TBI/DBI Calibrators (lot #DFD088) and 1 box of TP/Alb Calibrators (lot # ODD036), both which expired on 4/1/2021. B. During an interview at the time of the tour, Employee # (from the CMS-209 form) confirmed the calibrators were available for use when they had exceeded their expiration.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through a review of blood gas quality control and patient results for July and

	November 2020 and March of 2021, as well as interviews with laboratory staff, it was determined the laboratory failed to perform blood gas quality control each 8 hours of testing. Survey findings include: A. On one of thirty days in November 2020 a patient blood gas was documented after 8 hours had elapsed from the previous blood gas quality control. Blood gas quality control was tested on 11/3/2020 at 16:57 (4:57 p. m.). Patient #1176447 had blood gas results reported at 08:01 (8:01 a.m.) on 11/8 /2021. The patient was tested 111 hours and 4 minutes since the last quality control was documented. The next quality control was documented at 15:30 (3:30 p.m.) on 11 /8/2020. B. On two of thirty-one days in March 2021 patient blood gas results were documented after 8 hours had elapsed since last quality control. Blood gas quality control was tested at 06:48 (6:48 a.m.) on 3/17/2021. The eight hour limit elapsed at 14:48 (2:48 p.m.). Patient #1168331 had blood gas results reported at 16:00 (4:00 p. m.) on 3/17. The pateint was tested nine hours and twelve minutes after the last quality control was documented. On 3/18/2021 blood gas quality control was documented at 09:43 (9:43 a.m.). The next quality control documented was on 3/28 /2021 at 17:51. Patient #1151403 had blood gas results reported at 17:42. The patient blood gas results were reported 247 hours and 59 minutes after the last acceptable quality control and 9 minutes before the next quality control was tested. C. In an interview at 2:41 p.m. on 4/15/2021 the technical consultant confirmed patients were tested when the eight hour limit had elapsed since last quality control.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through a review of quality control documentation for November 2020 and March 2021, a review of the corrective action log and AD-Hoc reports of patient testing, lack of documentation, and an interview with laboratory staff, it was determined the laboratory failed to document corrective actions when Cholesterol and Total Protein quality control results were outside of acceptable range. Survey findings include: A. A review of the daily quality control results for November 2020 revealed that on one of thirty days the Multiqual Level 3 control was flagged as unacceptable (11/17/2020 at 11:06) for Cholesterol. Level 3 control was tested again at 12:11 and 12:48 with both results being flagged as unacceptable. There were no acceptable Cholesterol results documented for Multiqual Level 3 on 11/17/2020. B. The AD-Hoc report for patient Cholesterol results on 11/17/2020 shows that six patients had Cholesterol results reported on 11/17/2020, when quality control results were unacceptable. C. A review of the daily quality control results for March 2021 revealed that on one of thirty-one days the Multiqual Level 3 control was flagged as unacceptable (3/10/2021) for Total Protein. Level 3 control was tested three additional times with results in the acceptable range. The only corrective action documented is, "rerun in". Rerunning the control multiple times does not insure the failure is corrected. D. The AD-Hoc report for patient Total Protein results on 3/10/2021 includes twenty-two patients who had Total Protein results reported on 3/10/2021, when quality control was unacceptable on three

	of four times tested without any documented corrective actions. E. In an interview at 11:45 a.m. on 4/5/2021, the technical consultant (as listed on the form CMS-209) confirmed there was no corrective action for the quality control failures and patient test results were reported.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (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: Through a review of the form CMS-209, a review of personnel files and interviews with laboratory staff, it was determined the laboratory director failed to give written authorization for personnel to perform testing without direct supervision for three of nine testing personnel listed on the form CMS-209. Survey findings follow: A. The form CMS-209 signed by the laboratory director on 4/13/2021 included nine testing personnel listed as numbers three through eleven on the form. B. During a review of personnel files for nine testing personnel it was determined personnel #5 from the CMS-209 started working as a testing personnel on 12/1/2020 and completed training on 1/15/2021. Personnel #6 hire date was 7/27/2020 and training was completed on 8 /20/2020. C. The authorization to perform testing for laboratory employee #5 was signed by the laboratory director on 4/13/2021 (the day before the survey) although the employee had been performing patient testing since January 2021. The authorization to perform testing for employee #6 was signed on 4/13/2021 although she had been performing patient testing since August 2020. There was no signed authorization to test for employee #7 (who had been performing patient blood gas testing since December 2019). D. The authorization for employee #5 included a note from the laboratory director that stated, "must be supervised" and the authorization for employee #6 stated, "needs supervision". E. A review of the work schedules of laboratory personnel revealed that both employees #5 and #6 work the 6 p.m. to 6 a. m. shifts. The schedules show that they work alone rotating nights between employees #5 and #6. There is no supervisor in the laboratory when employees #5 and #6 are performing patient testing. E. During an interview at 2:43 p.m. on 4/15/2021, the technical consultant (listed as #2 on the CMS-209) confirmed the employees had been testing without written authorizations from the laboratory director and without supervision.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

	This STANDARD is not met as evidenced by: Through a review of competency evaluations and proficiency test records as well as interviews with laboratory staff, it was determined the technical consultant failed to assess test performance through review of results of proficiency test samples. Survey findings include: A. A review of competency evaluations for nine of nine laboratory testing personnel listed on the form CMS-209 it was determined the technical consultant had not identified any failures of testing personnel to report acceptable proficiency test results in three of three clinical laboratory employees who had competency assessments documented. B. A review of competency assessments for employee #3 (as listed on the form CMS) revealed one assessment dated 1/8/2020 and one dated 7/6/2020. The competency assessment dated 1/8/2020 stated that all proficiency results in all test specialties were "OK" although the first hematology event 2020 included failures of Blood Cell ID (60%), Automated WBC Differential (40%), and Urine Sediment (50%) and the graded final report was dated 4/16/2020 (3 months after the competency evaluation was signed and dated. The competency assessment dated 7/6/2020 stated that all proficiency results in all test specialties were "OK" although no other proficiency test results were available for review since the first hematology event 2020 which included failures of Blood Cell ID (60%), Automated WBC Differential (40%), and Urine Sediment (50%) and 2nd chemistry core event 2020 with failures for Total Bilirubin (0%) and BNP (60%). C. A review of competency assessments for employee #4 (as listed on the form CMS) revealed one assessment dated 7/6/2020 and one dated 1/5/2021. The competency assessment dated 7/6/2020 stated that all proficiency results in all test specialties were "OK" although the last proficiency test event for review at the time of the competency assessment was the first hematology event 2020 which included failures of Blood Cell ID (60%), Automated WBC Differential (40%), and Urine Sediment (50%). The competency assessment dated 1/5/2021 stated that all proficiency results in all test specialties were "OK" although the last proficiency test event for review at the time of the competency assessment was the third hematology event 2020 which included failures of Automated WBC Differential (60%), 2nd chemistry core event 2020 with failures for Total Bilirubin (0%) and BNP (60%), and 3rd chemistry core event with a failure for D-Dimer (60%). D. A review of competency assessments for employee #6 (as listed on the form CMS) revealed one assessment dated 7/6/2020 and one dated 1/5/2021. The competency assessment dated 7/6/2020 (although her hire date is documented as 7 /27/2020) stated that all proficiency results in all test specialties were "OK" although the last proficiency test event for review at the time of the competency assessment was the first hematology event 2020 which included failures of Blood Cell ID (60%), Automated WBC Differential (40%), and Urine Sediment (50%). The competency assessment dated 1/5/2021 stated that all proficiency results in all test specialties were "OK" although the last proficiency test event for review at the time of the competency assessment was the third hematology event 2020 which included failures of Automated WBC Differential (60%), 2nd chemistry core event 2020 with failures for Total Bilirubin (0%) and BNP (60%), and 3rd chemistry core event with a failure for D-Dimer (60%). E. In an interview about the competency assessments, at 2:43 p.m. on 4/15/2021, the technical consultant stated that she should've looked more closely at the proficiency testing results.
D6069	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(a) Each individual performs only those moderate complexity tests that are authorized by

	the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. This STANDARD is not met as evidenced by: Through a review of the form CMS-209, a review of personnel files and interviews with laboratory staff, it was determined three of nine testing personnel failed to perform only those moderate complexity tests that are authorized by the laboratory director. Survey findings include: The laboratory director failed to give written authorization to perform testing without supervision in three of nine testing personnel as cited at D6032.