

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0465694	(X3) Date Survey Completed 10/05/2018
Name of Provider or Supplier Little River Memorial Hospital	Street Address, City, State 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. 1. Through a review of the first, second and third Proficiency testing events of 2018 and 2017, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to maintain copies of Proficiency test records for at least two years. As evidenced by: A. During a review of three of three Chemistry Proficiency testing events of 2018, it was determined the laboratory failed to maintain the attestation forms for the second Chemistry event of 2018 (1 of 3 events). B. During a review of two of two Hematology Proficiency testing events of 2018, it was determined the laboratory failed to maintain the attestation forms for the first Hematology event of 2018 (1 of 2 events). C. In an interview at 13:00 on 10/3/2018, technical consultant (as listed on the form CMS-209) confirmed the laboratory failed to retain copies of the attestation forms for at least two years (2 of 3 events). 2. Through a review of the first, second and third Proficiency testing event of 2018 and 2017, it was determined the Respiratory Laboratory failed to maintain copies of Proficiency test records for at least two years. As evidenced by: A. During a review of three of three Proficiency testing events of 2017, it was determined the Respiratory</p>

laboratory failed to maintain the attestations forms for the second and third Proficiency event of 2017. C. In an interview at 13:00 on 10/3/2018, technical consultant (as listed on the form CMS-209) confirmed the Respiratory laboratory failed to retain copies of the attestation forms for at least two years.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

. 1. Through a review of the Laboratory policies and procedures, a review of personnel files for all staff, lack of documentation, and interviews with staff, it was determined the laboratory failed to follow written procedures for competency assessment. As evidenced by: A. A review of the Laboratory Policy and Procedure Manual revealed the Competency Assessment Policy which states: "Evaluating and documenting competency of personnel responsible for testing is performed at least semiannually during the first year the individual test patients. Thereafter competency assessments are performed at least annually." B. Through a review of the personnel files for employees #3, #6, and #7 (as listed on form CMS 209), it was determined that there was no documentation of competency assessment in 2017 for three of six laboratory employees. C. In an interview on 10/3/2018 at 1315, the technical consultant (as listed on form CMS-209) stated that the 2017 competency assessments were not available. 2. Through a review of the Respiratory Laboratory policies and procedures, a review of personnel files for all staff, lack of documentation, and interviews with staff, it was determined the Respiratory Laboratory failed to follow written procedures for competency assessment. As evidenced by: A. A review of the Respiratory Policy and Procedure Manual revealed the Competency Assessment Policy which states: "Evaluating and documenting the performance of individuals responsible for testing Human specimens is done semiannually during the first year of employment and annually thereafter." B. Through a review of personnel files for employees #1, #2, #3, #4, #5 and #6 (as listed on form CMS 209), it was determined that there was no documentation of competency assessment in 2017 for six of six Respiratory personnel. C. In an interview on 10/3/2018 at 1400, the technical consultant (as listed on form CMS-209) stated that the 2017 competency assessments were not available.

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, it was determined the laboratory had Becton-Dickinson (BD) Vacutainer collection tubes available for use when they had exceeded their expiration date. As evidenced by: A. During a tour of the laboratory on 10/05/2018 at 10:30, the Surveyor observed 22 of 22 BD Dark Blue

top (used for Heavy Metals) (lot # 7256520 expiration date 9/30/2018); 16 of 16 BD red top tubes (lot # 7157861 expiration date 06/30/2018) and 2 of 2 BD gray top collection tubes (lot # 7100990 expiration date 08/03/2018) located in the laboratory available for use when they had exceeded their expiration date. B. On 10/05/2018, at 1030, the technical consultant (as listed on CMS-209) confirmed the vacutainer tubes were available for use after they had exceeded their expiration date.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Through a review of Streck Erythrocyte Sedimentation Rate (ESR) Chex package inserts, ESR quality control, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to establish the criteria for acceptability of ESR control. As evidenced by: A. Streck Auto Plus analyzer is utilized by the laboratory to perform ESR assay. A review of package insert for ESR-CHEX for automated Sedimentation Rate states: "The assay values are derived from replicate analysis on both automated and manual methods. Upon receipt of a new control lot, it is recommended that an individual laboratory establish its own mean and limits. However, the control means established by the laboratory should fall within the Expected range specified for the control." B. In a review of ESR quality control data, it was determined the mean and acceptable range in three of three months (April, July and September 2018) reviewed matched the expected range as listed on the ESR-Chex package insert. Level I control range (1-17) and Level II control range (64-110). C. The surveyor requested documentation of established ranges for ESR quality controls. None was provided. D. In an interview on 10/4/2018 at 10:00, technical consultant (as listed on CMS-209) confirmed that the laboratory has not established their own mean and range for ESR quality controls. The laboratory uses the manufactures ranges for the ESR control.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
 . Through observations made during a tour of the laboratory, lack of documentation, and interviews with staff, it was determined the laboratory failed to document semi-annual test comparison for testing performed on the Beckman Coulter AU680 Chemistry Analyzer and the Alere Triage Analyzer. As evidenced by: A. During an initial tour of the laboratory at 1130 on 10/3/2018, the surveyor observed Beckman Coulter AU680 Chemistry analyzer and the Alere Triage Analyzer in the Chemistry section of the laboratory. B. At the time of the tour (10/3/2018 at 1130), the technical consultant (as listed form CMS-209) stated that the Alere Triage serves as a secondary analyzer for the analytes Troponin (TNI) and Creatine Kinase Muscle/Brain (CK: MB). C. The surveyor requested documentation of semi-annual comparison of TNI and CKMB tests performed on both the Beckman Coulter Au680 and the Alere Triage. None was provided. D. In an interview at 11:40 on 10/3/2018 the Technical Consultant (as listed form CMS-209) stated the semi-annual comparisons were not performed by the Laboratory.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
 . Through a review of the new instrument validation documentation for the Sysmex XN-450 Hematology Analyzer, lack of documentation, as well as interviews with staff, it was determined the Laboratory failed to have the director approve verification procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics as evidenced by: A. A review of the verification documentation for the Sysmex Hematology Analyzer which was performed on 7/31 /2018 revealed the verification procedures were not approved and signed by the Laboratory Director. B. In an interview on 10/4/2018 at 1330, technical consultant (as listed on CMS form 209) confirm the verification procedure for the Hematology Analyzer were not approved or signed by the Laboratory Director.

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 Laboratory personnel files, lack of documentation, and interviews with staff, it was determined the Laboratory Director failed to specify, in writing, which examinations and procedures each individual is authorized to perform and whether supervision is required. As evidence by: A. A review of personnel records for six of six testing personnel revealed laboratory testing personnel #4, and #5 (as listed on the form CMS-209) failed to include the Laboratory Director's written authorization to perform moderate complexity testing. B. In an interview at 14:00, on 10/3/2018, technical consultant (as listed on the form CMS-209) confirmed there were no written authorizations from the Laboratory Director stating the tests that each individual is authorized to perform.