

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0444828	(X3) Date Survey Completed 06/26/2018
Name of Provider or Supplier Community Hospital Association Inc	Street Address, City, State 26136 Us Hwy 59, Fairfax, MO	
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
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) for pCO₂, pH and pO₂ and interview with the technical supervisor the laboratory failed to self grade the ungraded analytes. Findings: 1. Review of 2nd event 2017 showed pCO₂, pH and pO₂ were not graded by the PT company and the laboratory did not self grade the results. 2. Interview with the technical supervisor on June 26, 2018 at 11:00 AM confirmed the laboratory failed to document and self grade the ungraded analytes for the 2nd PT event 2017.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency procedure and interview with the technical supervisor the laboratory failed to follow policy and assess and evaluate testing personnel #1</p>

	<p>competency for 2017 to date. Findings: 1. Review of competency procedure states testing personnel competency will be evaluated annually. 2. Review of competencies showed no competency for testing personnel #1 for 2017 to date. 3. Interview with the technical supervisor on June 26, 2018 at 11:45 AM confirmed laboratory did not follow competency procedure.</p>
<p>D5403</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the hematology procedure manual and interview with the technical supervisor on June 26, 2018 at 12:30 PM confirmed, the procedure manual failed to include normal values for high complexity manual differentials. Based on review of the urinalysis procedure manual and interview with the technical supervisor on June 26, 2018 at 12:30 PM confirmed, the procedure manual failed to include the centrifuge speed, time and volume of sample required for processing urine for microscopic examination and normal values for urine sediment microscopic examinations.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with the technical supervisor on June 26, 2018 at 12:30 PM confirmed, the current laboratory director failed to approve, sign and date hematology, chemistry, urinalysis and quality assessment procedures.</p>
<p>D5449</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p>

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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) procedures and interview with the technical supervisor on June 26,2018 at 12:15 PM confirmed, the laboratory failed to perform a positive and negative control each day of testing for Alere Clostridium Difficile Quik Chek Complete and AmniSure ROM (rupture of fetal membranes) kit testing.

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:
Based on the lack of instrument comparison activity documentation for troponin testing and interview with the technical supervisor on June 26, 2018 at 12:30 PM confirmed, the laboratory failed to evaluate and define a relationship between troponin testing performed on the Siemens chemistry analyzer (primary method) and I-stat chemistry analyzer (back-up method) twice a year for 2017.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of patient test reports, laboratory procedure manuals and interview with the general supervisor, the laboratory failed to ensure pertinent patient normal were available for interpretation. Findings: 1. The differences between normal values on patient test reports and those included in the procedure manual are as follows:
Normal values included on patient test reports: Sodium (Dimension)136-142 mmol/L Chloride (Dimension) 96-105 mmol/L TSH (adult) 0.34-4.82 uIU/ml Protime 11.0 -13.0 seconds Normal values included in the procedure manuals: Sodium (Dimension) 136-145 mmol/L Chloride (Dimension) 98-107 mmol/L TSH (adult) 0.358-3.74 uIU /ml Protime 11.5-13.5 seconds 2. Interview with the technical supervisor on June 26, 2018 at 12:30 PM confirmed the normal values stated in the laboratory procedure manuals differed from those included on the test reports.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assurance/ assessment (QA) policies and procedures, laboratory procedure manuals, patient normal values, lack of instrument activity documentation and interview with the technical supervisor, the laboratory director failed to ensure QA programs were maintained to identify failures in quality. Findings: 1. QA section V, #9 states, " To verify or establish reference ranges, either of the following approaches may be utilized: a. Extrapolate reference ranges from literature taking into consideration equivalence of the population and comparability of methodology. b. Perform procedure on patient samples (determined to be normal for analyte in question by utilizing appropriated screening criteria or collaborating analytes) to establish reference values (normal values) or verify manufacturer's stated reference values." 2. Review of hematology and urinalysis procedure manuals revealed the manuals did not include normal values for urine sediment microscopic examinations and high complexity hematology manual differentials. 3. QA section V, #10 states, "Procedure(s) must be reviewed and signed by the lab manager and the pathologist (laboratory director) before implementation." 4. Review of procedures revealed the the laboratory director did not approve, sign and date hematology, chemistry, urinalysis and QA policies and procedures. 5. QA section V, (D) states, "Correlation of multiple methodologies for the same analyte shall be performed twice a year. Equivalency of results may be made by comparing patient samples. The evaluation must span clinically appropriated ranges." 6. The laboratory did not have documentation to show it defined and evaluated a relationship twice a year between two instruments (Siemens Dimension and I-stat) performing troponin testing. 7. Interview with the technical supervisor on June 26, 2018 at 12:30 PM confirmed, the laboratory director failed to approve QA policies and procedures and ensure the QA program was maintained to identify failures.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of competencies and interview with the technical supervisor on June 26, 2018 at 12:15 PM confirmed the technical supervisor failed to evaluate the competency for testing personnel #7, #8, #9 and #10 in 2017 and to date for the moderate complex test AmniSure ROM (rupture of fetal membranes) test.