

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0444828	(X3) Date Survey Completed 09/24/2024
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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: Based on review of laboratory procedures and interview with the general supervisor (GS) #2, the laboratory failed to ensure a written procedure is available for hematology differential slide staining. Findings: 1. Review of laboratory procedures showed no procedure for hematology differential slide staining. 2. Interview with the GS #2 on September 24, 2024 at 11:00 AM confirmed the laboratory failed to ensure a written procedure for hematology differential slide staining is available.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the</p>

range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of 2024 calibration records for the Siemens Dimension EXL 200 chemistry analyzer and interview with the general supervisor (GS) #2, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range in 2024. Findings: 1. Review of the Siemens Dimension EXL 200 chemistry analyzer calibration records for 2024 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: sodium, potassium, and chloride. 2. Interview with the GS #2 on September 24, 2024, at 11:00 AM confirmed the laboratory failed to perform calibration verification procedures at least once every six months for sodium, potassium, and chloride.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of individualized quality control plan (IQCP) for the iStat analyzer, 2023 to date September 24, 2024 CG8+ cartridge, chem 8 cartridge and troponin cartridge quality control (QC), and interview with the general supervisor (GS) #2, the laboratory failed to ensure that the IQCP for the iStat analyzer was followed for 86 of 86 weeks. Findings: 1. Review of the iStat analyzer IQCP for CG8+ cartridge, chem 8 cartridge and troponin cartridge stated "External quality control is performed with each shipment, each new lot, and to verify cartridge performance. Liquid quality controls are also tested every two weeks on each cartridge type". 2. Review of iStat analyzer QC for CG8+ cartridge, chem 8 cartridge and troponin cartridge showed QC was not performed every two weeks since January 2023. 3. Interview with the GS #2 on September 24, 2024 at 11:00 AM confirmed the laboratory failed to ensure iStat IQCP was followed.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the Siemens Dimension EXL 200 chemistry analyzer quality control (QC) from September 1, 2024, to date September 24, 2024, patient results, and interview with the general supervisor (GS) #2, the laboratory failed to include two acceptable control materials of different concentrations for lipase for one of twenty-four patient testing days. Findings: 1. Review of the Siemens Dimension EXL 200 chemistry analyzer quality control (QC) from September 1, 2024, to date September 24, 2024 showed two acceptable levels of lipase QC was not performed on September 4, 2024. 2. Review of patient results showed the laboratory reported one lipase patient result while QC was not acceptable. 3. Interview with the GS #2 on September 24, 2023, at 11:00 AM confirmed the laboratory failed to include two control materials each day of patient testing for lipase.

D5545

HEMATOLOGY

CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of ACL Elite coagulation analyzer quality control (QC), July 1, 2024 to date September 24, 2024 patient results and interview with the general supervisor (GS) #2, the laboratory failed to include two levels of control material each 8 hours of operation for prothrombin time. Findings: 1. Review of the ACL Elite coagulation analyzer QC showed QC was performed on August 5, 2024 at 15:28 PM and a patient was performed at 15:06 PM before QC was performed. 2. Review of the ACL Elite coagulation analyzer QC showed QC was performed on July 5, 2024 at 18:42 PM and a patient was performed at 17:09 PM before QC was performed. 3. Interview with the GS #2 on September 24, 2024 at 10:30 AM confirmed the laboratory failed to perform two levels of prothrombin time QC each 8 hours of operation.

D5555

IMMUNOHEMATOLOGY

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

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (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. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of blood bank procedures, blood bank alarm check log, and interview with the general supervisor (GS) #2, the laboratory failed to perform blood bank refrigerator alarm inspections quarterly from April 2023 to date September 24, 2024. Findings: 1. Review of blood bank procedure "Temperature Recording of Refrigerator and Freezer" states, "Blood Bank alarm checks are performed quarterly to verify proper function of the alarm and the alarm notification system." 2. Review of the laboratory's blood bank alarm check log showed no blood bank refrigerator alarm inspections were completed from April 2023 to date September 24, 2024. 3. Interview with the GS #2 on September 24, 2023, at 11:00 AM confirmed, the laboratory failed to perform blood bank refrigerator alarm inspections quarterly in 2023 and to date September 24, 2024.

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 review of observation of laboratory analyzers, lack of instrument comparisons, and interview with the general supervisor (GS) #2, the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments in 2023. Findings: 1. Observation of the laboratory analyzers showed an iStat analyzer and Dimension EXL chemistry analyzer, both analyzers perform calcium, chloride, creatinine, glucose, potassium, sodium, carbon dioxide (CO₂), and blood urea nitrogen (BUN) testing. 2. Observation of the laboratory analyzers showed an iStat analyzer and Sysmex 550XN analyzer, both analyzers perform hemoglobin and hematocrit testing. 3. Lack of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the iStat analyzer and Dimension EXL chemistry analyzer, the iStat analyzer and Sysmex 550XN analyzer twice a year in 2023. 4. Interview with the GS #2 on September 24, 2024 at 10:00 AM, confirmed the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on lack of testing personnel (TP) training documents and interview with the general supervisor (GS) #2, the laboratory director (LD) failed to ensure one of one

TP received the appropriate training before performing patient testing in 2024. Findings: 1. Lack of TP training documents showed TP #8 had no documented training before performing patient testing in June 2024. 2. Interview with the general supervisor (GS) #2 on September 24, 2024 at 11:00 AM confirmed the LD failed to ensure TP #8 received the appropriate training before performing patient testing.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with the general supervisor (GS) #2, the technical supervisor (TS) failed to evaluate and document competency /performance for six of six testing personnel (TP) at least annually during 2023. Findings: 1. Review of personnel records showed the TS did not evaluate competency /performance for TP #1, TP #2, TP #3, TP #4, TP #5 and TP #6 performing patient testing during 2023. 2. Interview with GS #2 on September 24, 2024, at 11:00 AM, confirmed competency/performance evaluations were not conducted at least annually in 2023.