Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0444828	04/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Community Hospital Association Inc	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
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 the Individualized Quality Control Plan (IQCP), quality control (QC) records, and interview with the technical supervisor (TS) #2, the laboratory failed to follow the established IQCP for d-dimer for one of five months in 2021. Findings: 1. Review of the IQCP for Triage d-dimer states that "D-Dimer level 1 and level 2 quality controls are performed every month and on each new kit lot or shipment." 2. Review of d-dimer QC records showed no documentation of d-dimer QC in February 2021. 3. Interview with TS #2 on April 27, 2021 at 10:15 AM confirmed the laboratory failed to follow the established IQCP for d-dimer.
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 Quidel Triage procedure manual, patient report and interview with Technical Supervisor #2, the laboratory failed to ensure the D-Dimer procedure manual reference ranges matched the references ranges on the patient report. Findings: 1. Review of the Quidel Triage D-Dimer test procedure manual showed the reference range as: 100-400 ng/mL. 2. Review of the patient report showed the D-Dimer reference range as: 100-600 ng/mL. 3. Interview with Technical Supervisor #2 on April 27, 2021 at 10:30 AM confirmed that the D-Dimer procedure reference ranges did not match the D-Dimer patient report reference range.