Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0449946	01/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Community Memorial Healthcare	708 N 18th Street, Marysville, KS	

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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and staff interview reveals that the laboratory failed to evaluate its proficiency testing results that were not scored by the PT program. Findings: 1. 2019 1st event Chemistry-Miscelleneous PT performance evaluation included 1 ungraded response a. ungraded:MA-02 Microalbumin, semi-qual 2019 2nd event Hematology/Coagulation PT performance evaluation included 5 educational responses a. Educational samples included: Ungraded samples included:ECI 06-10 Blood cell ID 2019 3rd event Microbiology. PT performance included 8 ungraded educational responses a. Educational samples included:Culture ID ES-03 and ES 03- MIC Azithromycin, Cefotaxime, Cetriaxone, Cefuroxime, Clindamycin ,Levofloxacin,vancomycin 2. No evidence of lab investigation and evaluation was available for all three PT testing results at the time of survey. 3. Interview with Technical Supervisor #3 at 1120 am on 01/09/2020 confirmed ungraded/educational results for all three PT surveys were not evaluated or investigated.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of instrument type and test settings, reagent package insert, and interview, the laboratory failed to follow manufacturer's instruction for the ISI setting in prothrombin time testing. Findings include: 1. Prothrombin time testing is performed on the ACL Elite using RecombiPlasTin reagent. 2. ACL instrument setting for prothombin time testing showed lot #N0929757, ISI set to 1.020 and patient normal pool of 11.35 sec 3. Lot to lot change study indicated for lot #N0929757, ISI set to 1.020 and geometric mean of patient normal pool of 11.58 sec 4. Interview with GS #1 01/09/2020 @1120AM confirmed the laboratory failed to follow manufacturer's instructions for the resetting of patient normal pool using geometic mean setting in prothrombin time testing for the new lot #N0929757.