

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0449946	(X3) Date Survey Completed 12/19/2023
Name of Provider or Supplier Community Memorial Healthcare	Street Address, City, State 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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the bioMerieux Vitek2 and Biofire Filmarray Torch (BCID2, RP 2.1, ME panel) microbiology instrument procedures, lack of comparison records and interview, the laboratory failed to evaluate and define the relationship between microbiology organism identification results using different methodologies and instruments twice annually. Findings include: 1. Review of sixteen microbiology organisms: Enterococcus faecalis, Enterococcus faecium, Listeria monocytogenes, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus lugdunensis, Streptococcus agalactiae (Group B), Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Pseudomonas aeruginosa, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group and Proteus spp. showed they are performed with two methods: bioMerieux Vitek2 and Biofire Filmarray Torch (BCID2, RP 2.1, ME panel) a. No procedure was available on how to evaluate and define the relationship between the microbiology organism identification results twice annually. b. No comparison testing records performed twice annually from April 14, 2022 to December 19, 2023 were made available at the time of survey. 3. Interview with the technical consultant # 5 on December 19, 2023 at 13:20 p.m. confirmed the laboratory failed to evaluate and define the relationship twice annually between the bioMerieux Vitek2 and Biofire Filmarray Torch (BCID2, RP 2.1, ME panel) microbiology identification method procedures.</p>