

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0652158	(X3) Date Survey Completed 03/20/2025
Name of Provider or Supplier Ste Genevieve County Memorial Hospital	Street Address, City, State 800 Ste Genevieve Drive, Sainte Genevieve, 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) 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 the "Rapidec Carba NP" procedure, review of microbiology quality control logs and interview with the technical supervisor (TS) #2, the laboratory failed to follow the Rapidec Carba NP procedure. Findings: 1. Review of the "Rapidec Carba NP" procedure states "After incubating for a maximum of 2 hours, reading is performed visually by comparing the color of a control well without imipenem to a reactions well containing imipenem." 2. Review of the Rapidec Carba NP quality control revealed no documentation to show imipenem reactions from January 2024 to date March 12, 2025. 3. Interview with the TS #2 on March 12, 2025 at 11:00 AM confirmed the laboratory failed to follow the Rapidec Carba NP procedure.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:
Based on observation of the bacteriology refrigerator, review of "QC Cumulative Report", and interview with testing personnel (TP) #4 and the technical supervisor (TS) #2 the laboratory failed to ensure Vitek 2 gram negative (GN) card box sticker that states "ready for use" had the correct date quality control was performed.
Findings: 1. Observation of bacteriology refrigerator showed a box of Vitek 2 GN card lot number 2412765403 with sticker that stated "this lot is ready for use 9/7/24". 2. Review of "QC Cumulative Report" states Vitek 2 GN lot number 2412765403 with date quality control performed on October 5, 2025. 3. Interview with TP #4 stated the sticker with the wrong date was inadvertently put on box. 4. Interview with the TS #2 on March 12, 2025 at 10:00 AM confirmed the laboratory failed to ensure the Vitek 2 GN card box sticker was labeled with correct date quality control was performed.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

(d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:
Based on review of the laboratory's individualized quality control plan (IQCP) for the BioFire blood culture identification panel, BioFire quality control (QC) records, and interview with the technical supervisor (TS) #2, the laboratory failed to ensure that the IQCP for the BioFire blood culture identification panel was followed for 2 of 5 months. Findings: 1. Review of the BioFire blood culture identification panel IQCP states "Each new lot/shipment will have both positive and negative QC performed. In addition, every 30 days positive and negative QC will be performed." 2. Review of the BioFire quality control (QC) records from October 2024 to February 2025 showed QC was not performed in November and December 2024. 3. Interview with the TS #2 on March 12, 2025, at 2:15 PM confirmed the laboratory failed to ensure the BioFire blood culture identification panel IQCP was followed.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:
Based on review of the Biomerieux mini Vidas chemistry analyzer quality control (QC) from November 14, 2024, to date March 12, 2025, patient results, and interview with the technical supervisor (TS) #2, the laboratory failed to include two acceptable control materials of different concentrations for procalcitonin for 5 of 118 patient

testing days. Findings: 1. Review of the Biomerieux mini Vidas chemistry analyzer quality control (QC) from November 14, 2024, to date March 12, 2025 showed two acceptable levels of procalcitonin QC was not performed on January 1, 2025, January 7, 2025, January 17, 2025, February 8, 2025 and February 10, 2025. 2. Review of patient results showed the laboratory reported six procalcitonin patient result while QC was not acceptable. 3. Interview with the TS #2 on March 12, 2025, at 2:15 PM confirmed the laboratory failed to include two control materials each day of patient testing for procalcitonin.

D5507

BACTERIOLOGY
CFR(s): 493.1261(b)(c)

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) 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 October 2024 to January 2025 antimicrobial susceptibility testing (AST) records for the Vitek 2 compact analyzer, patient results and interview with the testing personnel (TP) #4 and technical supervisor (TS) #2, the laboratory failed to follow their procedure and use control organisms to check the procedure each week of patient testing for 2 of 16 weeks. Findings: 1. Review of the AST records for the Vitek 2 compact analyzer which performs bacteria identification and susceptibility revealed the laboratory failed to use the appropriate control organism *Streptococcus pneumoniae* for the week of December 2, 2024 for antimicrobial susceptibility on the Vitek 2. 2. Review of the AST records for Vitek 2 compact analyzer which performs bacteria identification and susceptibility revealed the laboratory failed to use the appropriate control organism *Enterococcus faecali* for the week of December 16, 2024 for antimicrobial susceptibility on the Vitek 2. 3. Interview with the TS #2 on March 12, 2025 at 10:00 AM confirmed the laboratory failed to use control organisms for AST weekly.