Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441688	11/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sullivan County Memorial Hospital Laboratory	630 W 3rd St, Milan, 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
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 laboratory procedures, Ortho Diagnostic Vitros 5600 chemistry analyzer quality control (QC) from November 1, 2023 to date November 29, 2023, patient results, and interview with the general supervisor (GS) #1, the laboratory failed to include two acceptable control materials of different concentrations for aspartate transferase (AST) for 1 of 29 patient testing days. Findings: 1. Review of laboratory procedure "Quality Control Protocol", states "Re-assay out-of-range Control, even if no cause has been determined." 2. Review of the Ortho Diagnostic Vitros 5600 chemistry analyzer quality control (QC) from November 1, 2023 to date November 29, 2023 showed two acceptable levels of AST QC was not performed on November 13, 2023. 3. Review of patient results showed the laboratory reported 12 AST patient results while QC was not acceptable. 4. Interview with the GS #1 on November 29, 2023 at 9:00 AM confirmed the laboratory failed to include two control materials each day of patient testing for AST.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When

	control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Vitros 5600 chemistry quality control (QC) records, and interview with the technical supervisor (TS), the laboratory failed to establish criteria for acceptability of control materials providing quantitative results. Findings: 1. Review of the Vitros 5600 chemistry QC records showed the laboratory did not establish, document, and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative chemistry QC. 2. Review of the Vitros 5600 chemistry analyzer showed cholesterol level 1 QC range of 100.84-113.96 mg/dL. The laboratory could not provide documentation for establishment of the QC range. 3. Review of the Vitros 5600 chemistry analyzer showed cholesterol level 2 QC ranges of 255.9-281.3 mg/dL. The laboratory could not provide documentation for establishment of the QC range. 4. Interview of the TS on November 29, 2023 at 10:00 AM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
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 Instrumentation Laboratory ACL Ellite analyzer quality control (QC), patient results, and interview with the technical supervisor (TS), the laboratory failed to include two levels of control material each 8 hours of operation for prothrombin time (PT) and partial thromboplastin time (PTT) for November 1, 2023 to date November 29, 2023. Findings: 1. Review of Instrumentation Laboratory ACL Elite analyzer QC from November 1, 2023 to date November 29, 2023 showed QC was not performed every eight hours for two of twenty-nine testing days. 2. Review of patient results showed three patient PT results and three patient PTT results were released when QC was not performed. 3. Interview with the TS on November 29, 2023 at 10:00 AM confirmed the laboratory failed to perform two levels of PT and PTT QC each 8 hours of operation.