Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0449989	10/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sabetha Community Hospital	603 South 14th Street, Sabetha, 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
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 quality control (QC) documentation and lack of QC data for an unsubstantiated Individualized Quality Control Plans (IQCP)s for Quidel Triage D-Dimer testing, and interview, the laboratory failed to have acceptable QC data for IQCP documentation to allow QC to be performed at the manufacturer's number and frequency and failed to perform a negative and positive control on each day of patient testing from 4/18/2022 to time of survey. Findings: 1. Review of the facility's IQCP documents of the Quidel Triage D-Dimer testing revealed the laboratory only performed QC new lot, new shipment or every thrity (30) days. No substantiated QC data of new lot, new shipment or every thirty (30) could be presented per the IQCP. Two (2) levels of QC were not performed every day of patient testing. 5. Interview with general supervisor #2 (GS#2) on 10/22/2024 at 10:50 a.m. confirmed the laboratory failed to have acceptable IQCP documentation to allow QC to be performed at the manufacturer's number and frequency from 4/18/2022 to time of survey, therefore requiring performing QC at least once each day of patient testing for quantitative procedures, which includes two control materials.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation and lack of QC data for an unsubstantiated Individualized Quality Control Plans (IQCP)s, the Quidel QuickView One-Step hCG-Combo, Cepheid GeneXpert COV-2/Flu/RSV Plus, Cepheid GeneXpert Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) and Cepheid GeneXpert Express Streptococcus pyrogenes (Strep A), and interview, the laboratory failed to have acceptable substantiated QC data for IQCP documentation to allow QC to be performed at the manufacturer's number and frequency and failed to perform a negative and positive control on each day of patient testing at time of survey. Findings: 1. Review of the facility's IQCP documents of the Quidel QuickView One-Step hCG-Combo (serum only) testing revealed the laboratory performed QC new lot or new shipment. No substantiated QC data of new lot or new shipment was presented per the IQCP. Two levels of QC were not performed every day of patient testing. 2. Review of the facility's IQCP documents of the Cepheid GeneXpert for COV-2/Flu /RSV Plus testing revealed the laboratory performed QC every sixty (60) days, new lot or new shipment. Six (6) days of COV-2/Flu/RSV Plus QC was performed, no other QC data was presented for the IQCP. Sixty (60) days, new lot or new shipment could not be substantiated per the QC data for the IQCP. Two levels of QC were not performed every day of patient testing from 4/18/2022 to time of survey. 3. Review of the facility's IQCP documents of the Cepheid GeneXpert for Cepheid GeneXpert CT /NG testing revealed the laboratory performed QC every sixty (60) days, new lot or new shipment. Twelve (12) days of Cepheid GeneXpert CT/NG QC was performed, no other QC data was presented for the IQCP. Sixty (60) days, new lot or new shipment could not be substantiated per the QC data for the IQCP. Two levels of QC were not performed every day of patient testing from 8/19/2024 to time of survey. 4. Review of the facility's IQCP documents of the Cepheid GeneXpert for Express Streptococcus pyrogenes (Strep A) testing revealed the laboratory performed QC every sixty (60) days, new lot or new shipment. Eleven (11) days of Express Streptococcus pyrogenes (Strep A) QC was performed, no other QC data was presented for the IQCP. Sixty (60) days, new lot or new shipment could not be substantiated per the QC data for the IQCP. Two levels of QC were not performed every day of patient testing from 2/19/2024 to time of survey. 8. Interview with general supervisor # 2 (GS#2) on 10/22/2024 at 10:52 a.m. confirmed the laboratory failed to have acceptable substantiated QC data for IQCP documentation to allow QC to be performed at the manufacturer's number and frequency, therefore failed to perform a negative and positive control on each day of patient testing at time of survey.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's Abbott i-STAT procedure, quality control (QC) requirements, QC records, the facility's unsubstantiated Individual Quality Control Plan (IQCP) and interview with general supervisor #2 (GS#2), the laboratory failed to perform required QC every eight hours using the Abbott CG4+ cartridge for Lactate, pO2, pCO2 and pH testing on the i-STAT system. Findings: 1. Review of the laboratory's i-STAT IQCP states under QC: "A positive and negative external control shall be run by new personnel during training and any time the technologist doubts a test result." 2. Review of the IQCP records for i-STAT CG4+ Lactate, pO2, pCO2 and pH showed no supportive data of QC performed from 12/28/2015 to time of survey. No QC was performed every eight hours prior to or after 12/28/2015. 3. Interview with GS#2 on 10/22/2024 at 10:52 a.m. confirmed the laboratory failed to have acceptable IQCP documentation to allow QC to be performed at the manufacturer's number and frequency from 12/28/2015 to time of survey, therefore requiring performing QC of two control materials performed every eight hours for pO2, pCO2 and pH testing on the i-STAT system.