Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0382761	10/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Guthrie County Hospital	710 North 12th Street, Guthrie Center, IA	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of D-dimer calibration records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 10:26 am on 09/27/2023, the laboratory failed to retain the Sysmex CA-600 Innovance D-dimer calibration records for at least two years from 11/10/2021- 09/27/2023. At the time of the survey, the laboratory could not locate Sysmex CA-600 Innovance D-dimer calibration records for the time period of 11/10/2021- 09/27/2023.
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 hematology and chemistry quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 10:17 am and 12:58 pm on 09/27/2023, the laboratory failed to perform two levels of QC each day of patient testing for three out of 30 days of patient testing

	reviewed from April 2023. The findings include: 1. Review of Sysmex XN-550 hematology QC records at 10:17 am revealed that the laboratory did not perform any levels of QC and reported complete blood count and automated differential patient test results on the following dates: *04/12/2023- 19 patients reported *04/20/2023- 17 patients reported 2. Review of Siemens Dimension EXL chemistry QC records at 12: 58 pm revealed that the laboratory only performed level three QC on 04/05/2023 and reported patient test results for the following analytes: *sodium- 14 patients reported *potassium- 14 patients reported *chloride- 14 patients reported *carbon dioxide- 14 patients reported *urea nitrogen- 14 patients reported *calcium- 14 patients reported *creatinine- 14 patients reported *glucose- 14 patients reported *albumin- 8 patients reported *alkaline phosphatase- 8 patients reported *total bilirubin- 8 patients reported *alanine transaminase- 9 patients reported *aspartate aminotransferase- 8 patients reported *amylase- 1 patient reported *total cholesterol- 4 patients reported *high-density lipoprotein cholesterol- 4 patients reported *triglycerides- 4 patients reported *thyroid stimulating hormone- 2 patients reported *magnesium- 1 patient reported *ethanol- 1 patient reported 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have additional QC records for the dates and analytes listed above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, the laboratory's quality control policy, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 12:58 pm on 09/27/2023, the laboratory failed to take and document corrective action when Dimension EXL QC fell outside the laboratory's established criteria for acceptability for 17 out of 30 days of patient testing reviewed from April 2023. The findings include: 1. The laboratory performs chemistry testing on the Siemens Dimension EXL instrument. 2. For the Siemens Dimension EXL, the laboratory's quality control policy stated, "Two levels of quality control material are to be run each day of use. Westgard rules as defined below will be used to determine acceptability." It also stated, "The following outlines Westgard's rules. Reject run if any of the following criteria are met: One control exceeds control limits set at +/- (plus or minus) 3 SD (standard deviation) from the mean; or Two controls exceed control limits set at +/- (plus or minus) 2 SD two times in a row." 3. Review of Dimension EXL QC records revealed that the laboratory had unacceptable QC results for the following dates and analytes: *04/03/23:alanine transaminase (ALT)- level 3 *04/08/23: free thyroxine (FT4)- level 3 *04/09/23: ALT- level 1; FT4- level 3 *04/10 /23: FT4- level 3; prostate specific antigen (PSA)- level 1 *04/11/23: FT4- level 3 *04 /12/23: ALT- level 1; alkaline phosphatase (ALP)- level 3 *04/13/23: ALT- level 1; ALP- level 3 *04/14/23: ALT- level 1; PSA- level 1; ALP- level 3 *04/15/23: ALP- level 3 *04/18/23: FT4- level 3 *04/20/23: PSA- level 1 *04/21/23: FT4- level 1; human chorionic gonadotropin (HCG)- level 3 *04/24/23: ALT- level 3; FT4- level 1;

	ALP- level 3; magnesium- level 1; creatine kinase MB (CK-MB)- level 3 *04/25/23: FT4- level 1; ALP- level 3 *04/26/23: FT4- level 1; magnesium- level 1 *04/27/23: ALT- level 1; ALP- level 3 *04/28/23: ALP- level 3; CK-MB- level 3; thyroid stimulating hormone (TSH)- level 3 4. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have documented corrective action for the unacceptable QC listed above.