Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0038924	08/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Henry County Health Center Inc	407 South White Street, Mount Pleasant, 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
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (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. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:05 am on 08/30/2022, the laboratory failed to perform comparison activities for serum human chorionic gonadotropin (HCG) testing performed by two methods twice annually for four out of four time periods from January 2020- December 2021. The findings include: 1. The Laboratory Test List and Annual Volume form listed serum HCG testing performed by both quantitative and qualitative methods. 2. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not perform comparison activities for serum HCG testing performed by two methods twice annually from January 2020- December 2021.
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 Vitros 7600 chemistry instrument quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:45 pm on 08/30/2022, the laboratory failed to take and document corrective action when total iron-binding capacity (dTIBC) QC fell outside the laboratory's established criteria for acceptability for three out of 31 days of patient testing in March 2022. The findings include: 1. For level 2 dTIBC QC, the laboratory had an acceptable range of 263.4- 307.2 ug/dL. 2. At 8:15 pm on 03/15/2022, the laboratory recorded a result of 310.2 ug/dL for level 2 QC. 3. The laboratory did not record an acceptable dTIBC result for level 2 QC until 5:47 pm on 03/18/2022. 4. The laboratory performed and reported dTIBC testing for three patients between 8:15 pm on 03/15/2022 and 5:47 pm on 03/18/2022: one patient at 7:27 am on 3/16/2022; and two patients at 12:43 pm and 1:37 pm on 03/17/2022. 5. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not perform or document corrective action for the out of range dTIBC QC from 03/15/2022- 03/18/2022.