Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384982	08/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Chi Health Mercy Corning	603 Rosary Drive, Corning, 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
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 the Prothrombin Time (PT) on Sysmex CA-600 Series Instruments procedure, PT quality control (QC) results and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9: 48 am on 8/29/2024, the laboratory failed to take and document correct action when PT QC failed to meet the laboratory's established criteria for one out of 31 days from 5 /1/2024 - 5/31/2024. The findings include: 1. The Prothrombin Time (PT) on Sysmex CA-600 Series Instruments procedure stated, 'The instrument gives an audible warning when QC fails to meet expected limits. The error message will read "QC exceeds FLAG limit," if a QC value is outside of 2 SD. If either or both levels of control fail defined tolerance limits, patient test results will be held until they are retested once troubleshooting of the testing system has occurred.' 2. On 5/18/2024 at 21:08 the laboratory received a PT QC level 1 result of 11.6 (2.2 SD). 3. On 5/18 /2024 at 21:23 the laboratory received PT QC level 1 result of 11.7 (2.5 SD). 4. On 5 /18/2024 at 21:13 the laboratory reported out one patient PT result. 4. At the time of the survey, the laboratory did not document corrective action for the above out of range QC results. This is a repeat deficiency.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 8:21 am on 8/29/2024, the laboratory director failed to ensure the laboratory documented corrective action for unacceptable PT results received on three out of seven PT events from 10/1/2022 - 8/29/2024. The findings include: 1. For 2022 testing event 3, the laboratory received an unacceptable PT score of 80% for the analyte, white blood cell identification. 2. For 2023 testing event 1, the laboratory received an unacceptable PT scores of 80% for the analytes: prothrombin time, activated partial thromboplastin time and international normalized ratio. 3. For 2023 testing event 3, the laboratory received an unacceptable PT score of 80% for the analyte, vancomycin. 4. At the time of the survey, the laboratory did not have corrective action documented for the above unacceptable PT analytes.