Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384982	09/30/2022
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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory's immunohematology policies, lack of Ortho MTS dispenser volume checks, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:15 pm on 09/30/2022, the laboratory failed to define, perform, and document a function check protocol for the Ortho MTS dispenser, including the frequency for performing volume checks. The laboratory failed to perform a volume check on the dispenser from 11/11/2020- 09/30 /2022.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when

	they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plans (IQCP) and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:55 am on 09/30/2022, the laboratory failed to include a quality control plan, quality assessment plan, historical/supporting data for the risk assessment, and laboratory director approval and signature as part of the IQCP for the following test systems: Cardinal Health serum human chorionic gonadotropin (HCG), BioRad ToxSee urine drugs of abuse screen, and Cardinal Mono II serum infectious mononucleosis.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must 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 immunohematology policies, blood bank system alarm check records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:15 pm on 09/30/2022, the laboratory failed to inspect and perform quarterly alarm system checks on the blood bank refrigerator for five out of seven time periods from 01/01/2021- 09/30/2022. The findings include: 1. The laboratory's "Refrigerator Alarm Verification" policy stated that the alarms on the blood bank refrigerator would be checked quarterly. 2. The laboratory performed and documented refrigerator alarm checks on 03/08/2021 and 08 /18/2022. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have any additional blood bank refrigerator alarm check records from 01/01/2021- 09/30/2022.
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 chemistry quality control (QC) records, hematology QC records, coagulation QC records, and confirmed by laboratory personnel identifier #1 (refer to

	the Laboratory Personnel Report) at approximately 10:40 am on 09/30/2022, the laboratory failed to take and document corrective action when chemistry, hematology, and coagulation QC fell outside the laboratory's established criteria for acceptability for 14 out of 31 days of patient testing in March 2022. The findings include: 1. The laboratory performs chemistry testing on the Siemens Dimension EXL instrument; hematology testing on the Sysmex XS1000i instrument; and coagulation testing on the Sysmex CA-660 instrument. 2. Review of chemistry, hematology, and coagulation QC records revealed that the laboratory had out of control results without corrective action on the following dates of testing and analytes: *03/01/22- lipase (levels 1 and 2) *03/07/22- amylase (level 2) *03/08/22- amylase (level 2) and thyroid stimulating hormone (TSH) (level 3) *03/09/22- mean corpuscular volume (MCV) (levels 2 and 3) and total iron binding capacity (IBCT) (level 2) *03/14/22- blood urea nitrogen (BUN) (level 2) and TSH (level 3) *03/15/22- TSH (level 3), lipase (levels 1 and 2), and amylase (level 2) *03/16/22- amylase (level 2) *03/20/22- alkaline phosphatase (level 2) *03/21/22- alkaline phosphatase (level 2) and amylase (level 2) *03/22/22- alkaline phosphatase (level 2), amylase (level 2), and MCV (levels 2 and 3) *03/23 /22- partial thromboplastin time (PTT) (level 1) *03/29/22- alkaline phosphatase (level 2) and amylase (level 2) *03/30/22- amylase (level 2) *03/31/22- MCV (levels 2 and 3) 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have documented corrective action for the out of control QC results listed above.