

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384982	(X3) Date Survey Completed 07/30/2026
Name of Provider or Supplier Chi Health Mercy Corning	Street Address, City, State 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)(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 erythrocyte sedimentation rate (ESR) quality control (QC) records and confirmed by interview with General Supervisor #1 (GS #1) at 10:10 am on 07/30 /2026, the laboratory failed to take and document corrective action when ESR QC fell outside the laboratory's established criteria for acceptability for 1 out of 31 days in March 2026. The findings include: 1. The laboratory performs ESR testing on a Diesse Minicube test system. 2. Patient A had ESR testing performed on 03/26/2026. 3. The laboratory had an acceptable range of 37- 89 mm/hr for level 2 ESR QC. 4. On 03/26/2026, the laboratory ran level 2 QC at 5:44 pm, 6:20 pm, and 9:02 pm. All three QC runs had error flags and gave no numerical result. 5. The laboratory reported one patient ESR test on 03/26/2026. 6. At the time of the survey, GS #1 confirmed that the laboratory failed to documented corrective action for level 2 ESR QC on 03/26/2026.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test

performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the Clinical Laboratory Improvement Amendment (CLIA) application (Form CMS-116), patient test reports, and confirmed by interview with General Supervisor #1 (GS #1) at 12:30 pm on 07/30/2026, the laboratory failed to indicate the name and address of the testing facility for one out of seven patient test reports reviewed from March 2026. The findings include: 1. Patient B had arterial blood gas testing performed on 03/31/2026. 2. The CLIA application listed the name and address of the facility as CHI Health Mercy Corning Hospital; 603 Rosary Drive; Corning, IA 50841. 3. The test report for patient B listed the performing laboratory name and address as BMMC Laboratory; 7500 Mercy Road; Omaha, NE 68124-, USA. 4. At the time of the survey, GS #1 confirmed the test report for patient B failed to include the correct name and address of the performing laboratory.