Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385677	07/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Manning Regional Healthcare Center	1550 6th Street, Manning, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the Laboratory Test List & Annual Volume form, the BioFire Film Array Torch - Procedure, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 7/15/2021, the laboratory failed to report negative SARS-CoV-2 test results to the Iowa Department of Public Health (IDPH) for 13 out of 14 days of patient testing from 3/1 /2021 - 3/31/2021. The findings include: 1. The Laboratory Test List & Annual Volume form stated the laboratory performed SARS-CoV-2 testing using the BioFire Film Array Torch and the Abbott ID Now test systems. 2. The BioFire Film Array Torch - Procedure stated, "If a sample is positive for severe acute respiratory syndrome coronavirus (SARS-CoV-2) it needs to be emailed to IDPH as soon as possible." 3. The laboratory received negative SAR-CoV-2 results using the BioFire Film Array Torch on the following dates: *3/1/21 - 1 patient *3/4/21 - 2 patients *3/11 /21 - 1 patient *3/13/21 - 1 patient *3/15/21 - 1 patient *3/17/21 - 2 patients *3/19/21 - 1 patient *3/23/21 - 3 patients *3/24/21 - 1 patient *3/25/21 - 4 patients *3/27/21 - 1 patient *3/29/21 - 4 patients *3/30/21 - 4 patients 4. At the time of the survey, the laboratory did not have documentation of sending the negative SARS-CoV-2 results

	using the BioFire Film Array Torch test system to IDPH. 5. At the time of the survey, the laboratory provided documentation of sending positive SARS-CoV-2 results using Biofire Film Array Torch and positive and negative SARS-CoV-2 results using the Abbott ID Now test systems to IDPH.
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 proficiency testing (PT) records, the Laboratory Test List and Annual Volume report, and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 10:45 am on 07/15/2021, the laboratory failed to evaluate the accuracy for manual white blood differential testing twice annually for three out of three semiannual time periods (1/1/2020 - 7/15/2021). The findings include: 1. The Laboratory Test List and Annual Volume report stated the laboratory performed both manual and automated white blood cell differentials. 2. Review of PT records indicated the laboratory performed PT testing for automated white blood cell differentials, but not manual white blood cell differentials. 3. At the time of the survey, the laboratory did not verify the accuracy of manual white blood cell differentials twice annually.