Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2156030	11/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Care United Medical Center Of Laramie Llc	2201 S Douglas Hwy Suite 100, Gillette, WY	

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 observation, review of the SARS-CoV-2 patient testing log, and staff interview, the laboratory failed to report 194 SARS-CoV-2 negative patient test results from 8/1/22 through 11/30/22. The findings were: 1. Observation of the laboratory showed testing for SARS-CoV-2 was performed using the Roche Cobas Liat and the Abbott ID NOW molecular test systems. 2. Review of the laboratory's patient testing log showed the laboratory performed a total of 263 molecular SARS-CoV-2 patient tests with 194 negative patient results from 8/1/22 through 11/30/22. 3. Interview with the laboratory director on 11/30/22 at 2:49 PM confirmed the laboratory did not report the SARS-CoV-2 negative patient test results to the State Public Health Laboratory.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks

	may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the CMS (Centers for Medicare and Medicaid Services) 116 form, lack of documentation, and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 test results to the appropriate agencies. The findings were: 1. Review of the CMS-116 form showed the laboratory performed SARS-CoV-2 testing using the Abbott ID Now and the Roche Cobas Liat test systems. 2. Review of the laboratory's procedure manuals showed no evidence the laboratory had developed a policy and procedure for reporting SARS-CoV-2 test results to the appropriate agencies. 3. Interview with the laboratory director on 11/30 /22 at 2:49 PM confirmed the laboratory did not have a written procedure for reporting SARS-CoV-2 patient test results.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and staff interview, the laboratory failed to ensure the procedure manual contained all the required elements for 1 of 1 procedure manuals reviewed (Sysmex XP-300). The findings were: 1. Review of the Sysmex XP-300 hematology procedure manual failed to include the laboratory's system for entering results in the patient record and the reference intervals established by the laboratory. 2. Interview with the laboratory director on 11/30/22 at 2:39 PM confirmed the laboratory's procedure manual was incomplete.