Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2055145	03/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Optumcare New Mexico Llc Journal Center Urgent	5150 Journal Center Blvd Ne, Albuquerque, NM	

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
D0000	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 of Health and Human Services in such form and manner, and at such timing and frequency, as the Secretary may prescribe. During an initial survey completed on 03/17/2021 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 493.1100 Condition: Reporting of SARS-CoV-2 test results.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, the review of laboratory procedures, manufacturer instructions, and interview with Testing Person #1, the laboratory failed to follow manufacturer's instructions for SARS-CoV-2 (COVID19) testing and provide the Patient Fact Sheets to each patient tested. The laboratory performed 196 patient tests for COVID19 January 8, 2021 through March 17, 2021. A. Review of the Becton Dickinson Veritor SARS-CoV-2 (Rapid Detection of COVID19) instructions for use (IFU) under "Conditions of Authorization for the Laboratory" indicated "Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. B. Review of the Becton Dickinson Veritor SARS-CoV-2 (Rapid Detection of COVID19), procedure dated 11/12/2020 revealed no reference to providing the Patient Fact Sheets to each patient tested for COVID19. C. During interview on 03/17 /2021 at 03:10 pm, Testing Person #1 stated she did not hand out Patient Fact Sheets to patients. D. During observation of laboratory supplies on 03/17/2021 at 03:11 pm,

	the Technical Consultant and the surveyor did not find any Patient Fact Sheets in the test kit/box to give to patients.
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 the review of the BD Veritor Plus SARS-CoV-2 Patient Quality Control logs, the Procedure for the BD Veritor Plus system for the Detection of SARS-CoV-2 Antigens, the memo from the New Mexico Health Alert Network (HAN), and interviews with laboratory staff, the laboratory failed to provide and retain written verification that all the SARS-CoV-2 results were reported to the New Mexico Department of Health (NMDOH) from January 8, 2021 through March 17, 2021. Findings are: A. Review of the SARS-CoV-2 Patient Quality logs from January 8, 2021 through March 17, 2021 the following was revealed: 1. For the month of January a total of 72 tests were performed. a. Of the total 72 tests performed, 8 were positive, 63 were negative, and 1 was invalid. 2. For the month of February a total of 71 tests were performed. a. Of the total 71 tests performed, 3 were positive, 68 were negative. 3. From March 1, 2021 to March 17, 2021, a total of 55 tests were performed. a. Of the total 55 tests performed, 1 was positive, 53 were negative, and 1 was invalid. B. Review of the written procedure for the BD Veritor Plus system for the Detection of SARS-CoV-2 reveals that the procedure dated 11/12/2020, did not include a process for reporting and tracking the reporting of both positive and negative test results to NMDOH. 1. On page 15 of the SARS-CoV-2 procedure, Section labeled "Clinical Significance" the procedure states "Laboratories within the United States and its territories are required to report all positive results to the appropriate health authorities." The written procedure does not mention that negative results should also be reported to the appropriate health authorities. 2. The written COVID-19 procedure does not include a mechanism/process for tracking which tests have been reported and which ones have not been reported. C. Review of the Memo from the New Mexico Health Alert Network (HAN) , released December 3, 2020, and followed by the laboratory, revealed that the memo does not include guidelines regarding the verification/tracking of the transmitted patient test results. 1. The memo states that the New Mexico Department of Health created a specific fax line/number, to be used to report only the new COVID-19 positive test results daily. 2. The memo also instructs the laboratory to batch all negative COVID-19 results and send to NMDOH on a weekly basis via fax to a specific fax number. D. During interview on 03/17/2021 at 2: 45 pm, the clinic Supervisor, stated that they are not tracking/assuring that the patient test results are being transmitted accurately and reliably to the local/State NMDOH. He stated that they are faxing the positive results as soon as they are obtained but they

	are not keeping the fax transmission sheets to prove they were faxed. He stated that they are following the instructions provided in the December 3 memo from the NM health alert network.