Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2170759	01/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Artesia General Hospital	2319 W Pierce St, Carlsbad, 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 in such form and manner, and at such timing and frequency, as the Secretary may prescribe. During an initial survey completed on 01/14/2021 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 493.1100 Condition: Facility administration
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, the review of laboratory reporting policies, faxes to the New Mexico Department of Health including the patient fax log, emails, patient test logs, and interview with TC#2 (Technical Consultant #2), the laboratory failed to report negative SARS-CoV-2 test result to the New Mexico Department of Health within 24 hours as required by the Public Health Emergency requirements at 42 CFR part 400.200. The laboratory performed a total of 130 SARS-CoV-2 tests 11/11/2020 - 01 /11/2021. Findings are: A. Observation of laboratory equipment and supplies on 01/14

	/2021 at 08:00 am revealed the laboratory performed SARS-CoV-2 testing using the Abbott IDNow rapid antigen system. B. Review of the laboratory's patient test logs, ID NOW COVID-19 Positive Test Notification Log, fax logs and fax confirmations for 11/11/2020 - 01/11/2021 revealed the laboratory reported positive SARS-CoV-2 test results but not the negative results. The first day of patient testing was on 11/11 /2020. 1. November 2020: A total of 38 patients (PT#2-PT#39) were tested for SARS-CoV-2. 35 (PT#2-PT#15, PT#17-PT#23, PT#25-PT#28, PT#31- PT#39) of 38 (PT#2-PT#39 patients were not reported to the New Mexico Department of Health because they were negative for SARS-CoV-2. 2. December 2020: A total of 59 patients (PT#40-PT#99) were tested for SARS-CoV-2. 47 (PT#40, PT#41, PT#43-PT#71, PT#73-PT#90, PT#92-PT#94, PT#76-PT#84, PT#100-PT#102, PT#103-PT#107, PT#109, PT#111-PT#112, PT#115-PT#117, PT#119-PT#137) of 59 patients (PT#40-PT#99) were not reported to the New Mexico Department of Health because they were negative for SARS-CoV-2. 3. January 1 - 11, 2021: A total of 40 patients (PT #1, PT#100-PT#139) were tested for SARS-CoV-2. 33 (PT#100, 101, 103 -107, 109, 111, 112. 115, 116, 117, 119 -137, 139) of 40 (PT #1, PT#100-PT#139) patients were not reported to the New Mexico Department of Health because they were negative for SARS-CoV-2. C. During interview on 01/14/2021 at 01:30 pm, TC#2 stated that the main (hospital) laboratory takes the daily worksheet (positives only) and sends it to the New Mexico Department of Health. She also stated that Infection Control at the hospital is following state guidelines for weekly reporting and other than emails, there is no approved written policy. D. Review of the emails sent to TC#2 from Infection Control on 01/14/2021 at 12:17 pm indicated the following: Original email date Friday December 4, 2020 at 09:15 am "Please note that the NMDOH has created new number faxed number (sic) for positive Covids and Covid hospitalizations/transfers to be reported to (505) XXX-XXXX, and batch the negatives Covid results on a weekly basis to (505) XXX-XXXX." "Lab staff will fax a copy of all positive Covids lab results/face sheet and other reportable conditions to (505) XXX-XXXX, as the results are finalized." "Lab staff will fax all negative Covid results as a batch to (505) XXX-XXXX on a weekly basis (lab will decided (sic) which day of the week works best for them).
D5805	TEST REPORT CFR(s): 493.1291(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 the review of patient test records and interview with the TC #2 (Technical Consultant), the laboratory failed to identify the name and address of the laboratory where tests are performed. Findings are: A. Review of COVID19 test results for PT #1 (Patient #1) on 01/11/2021 revealed no documentation that the test was performed by the laboratory. The report was issued by the affiliated hospital laboratory. B. Review of CBC (Complete Blood Count) test results for PT#140 on 02/05/2020 revealed no documentation that the test was performed by the laboratory. The report

	was issued by the affiliated hospital laboratory. C. During interview on 01/14/2021 at 12:02 pm, TC#2 confirmed the laboratory reported test results under the affiliated hospital's CLIA (Clinical Laboratory Improvement Amendment of 1988) number and address.