

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  32D2186985	<b>(X3) Date Survey Completed</b>  05/13/2021
<b>Name of Provider or Supplier</b>  Southern Clinical Laboratory-Tricare Inc	<b>Street Address, City, State</b>  2525 S Telshor Blvd 14 Ste 102, Las Cruces, NM	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The following deficiency was cited as the result of an initial survey completed on 05 /13/21 for 42 CFR part 493 Laboratory Requirements.
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory policies and interviews with the Laboratory Supervisor and Laboratory Director, the laboratory failed to have written policies for A) reporting SARS-CoV-2 (COVID19) test results to the New Mexico Department of Health and B) providing the Patient Fact Sheets to patients as required by the manufacturer of the Aptima SARS-CoV-2 assay. Findings are: A. Review of the laboratory's "Infectious Disease Reporting Policy", revision date 11/2020, did not include any reference to the reporting of positive and negative SARS-CoV-2 results to the New Mexico Department of Health. 1. During interview on 05/13/21 at 3:00 pm, the Laboratory Supervisor confirmed that this was the only policy for reporting. B. During interview on 05/13/21 at 11:33 am, the Laboratory Supervisor stated that since this site did not see patients and collect patient samples, the laboratory did not provide the Patient Fact Sheets to the patients tested for COVID19. 1. During interview on 05 /13/21 at 11:46 am, the Laboratory Director stated that the Patient Fact Sheets were not provided because at least 8 different test systems are used to test patients within the laboratory system (various hospital laboratories and reference laboratories) it wasn't possible to provide the specific Patient Fact Sheet to a patient at the time of collection nor could the laboratory refer the patient to the laboratory website because the patient would not know which Patient Fact Sheet to choose. The Laboratory</p>

Director further stated she was not sure if there was a policy for providing the Patient Fact Sheets to patients. 2. Review of the manufacturer's instructions for the Aptima SARS-CoV-2 assay indicated: "The Aptima SARS-CoV-2 assay Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA [Food & Drug Administration] website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>. However, to assist clinical laboratories using the Aptima SARS-CoV-2 assay, the relevant Conditions of Authorization are listed below. Authorized laboratories using the Aptima SARS-CoV-2 assay will include with result reports of the Aptima SARS-CoV-2 assay, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media."