Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1023959	03/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Carlos A Regalado Md Pa	2121 E Griffin Pwy Suite 1, Mission, TX	

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
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 review of manufacturer's instructions, review of patient test records, review of personnel records, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions to (I) distribute patient fact sheets for 5 of 5 patients reviewed, and (II) ensure 2 of 2 testing persons are trained for performance and resulting of COVID-19 testing using the Clarity Diagnostics brand test kit. The findings included: I. Distribution of patient fact sheets 1. Review of the manufacturer's instructions (REF: CLA-COV19AG-VIS) for the Clarity Diagnostics COVID-19 antigen test stated, "A. Authorized laboratories* using your product must include, with test result reports, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 2. Review of patient records found that for 5 of 5 patient results reviewed that was no documentation of the laboratory distributing the patient fact sheets. Patient 1 (name redacted) Date of Birth: February 3 (year redacted) Date Tested: 01-11-2022 COVID-19 Result: Positive Patient 2 (name redacted) Date of Birth: November 9 (year redacted) Date Tested: 01-22-2022 COVID-19 Result: Negative Patient 3 (name redacted) Date of Birth: April 27 (year redacted) Date Tested: 01-19-2022 COVID-19 Result: Negative Patient 4 (name redacted) Date of Birth: July 20 (year redacted) Date Tested: 01-11-2022 COVID-19 Result: Positive Patient 5 (name redacted) Date of Birth: April 29 (year redacted) Date Tested: 01-11-2022 COVID-19 Result: Positive 3. Review of the patient test records found not evidence that the laboratory followed the manufacturer's instructions to distribute the patient fact sheets provided by the manufacturer. 4. An interview with

	testing personnel #1 (as listed on Form CMS-209) on March 9, 2002 at 10:20 hours in the break room confirmed the findings. II. Documentation of training Based on review of manufacturer's instructions, review of personnel records, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions to ensure 2 of 2 operators are appropriately trained in performing and interpreting results for COVID-19 testing using the Clarity Diagnostics brand test kit. The findings included: 1. Review of the manufacturer's instructions (REF: CLA-COV19AG-VIS) for the Clarity Diagnostics COVID-19 antigen test stated, "F. All operators using your product must be appropriately trained in performing and interpreting the results of your product. Use appropriate personal protective equipment when handling this kit,and use your product in accordance with the labeling." 2. Review of personnel records for 2 of 2 testing persons found no documentation of training as required by the manufacturer. 3. An interview with testing personnel #1 (as listed on Form CMS-209) on March 9, 2002 at 10:20 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services