Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2095721	03/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dr Karelys Rivera And Associates Pa	3126 Centerpoint Drive, Edinburg, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 from October 2020 to March 2021, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of following the manufacturer's instructions when performing Quidel Sofia SARS Antigen testing. The findings were: 1. Review of the manufacturer's instructions for the QUIDEL Sofia SARS Antigen stated, "All operators using your product must be appropriately trained in performing and interpreting the results of your product in accordance with the authorized labeling." 2. Review of patient test records October 2021 to March 2021 (see patient alias list) found the laboratory tested the patients when the laboratory failed to provide documentation of training operators. 3. The laboratory was asked to provide documentation of following the manufacturer's instructions to train operators in performing and interpreting results for Sofia SARS Antigen testing. No documentation was provided. 4. The results were confirmed in interview with the technical consultant on March 10, 2021 at 09:30 hours in the break room.