

Clinical Validation Report on IVD Kits

Product Name: SARS-CoV-2 (COVID-19) Antibody Test Kit (GICA)

Model and Specifications: 20 tests/kit, packed independently

Type of Clinical Tests: clinical validation

Date of Commence of Clinical Tests: February 14, 2020

Date of Completion of Clinical Tests: February 18, 2020

Validated by: Beijing Aipuyi Medical Inspection Center

V Results and Analysis of Clinical Tests

In total, 220 test samples (125 for male and 95 for female) are included for the unit and all test samples included are tested. Statistics on test results and those of the product tested are as follows:

Table 1: Statistics on Serum IgG Test Results of the Product Tested and the Reference Product

	Positive Reference Product	Negative Reference Product	Total
Positive product tested	92	1	93
Negative product tested	0	127	127
Total	92	128	220

Item	Formula	Results	95%-L	95%-H
Coincidence rate of negative (%)	$a/(a+c)*100\%$	100.00%	100.00%	100.00%
Coincidence rate of positive (%)	$d/(b+d)*100\%$	99.22%	98.06%	99.88%
Total coincidence rate (%)	$(a+d)/(a+b+c+d)*100\%$	99.55%	98.66%	100.18%
Theoretical coincidence rate Pe:	$[(a+b)(a+c)+(c+d)(b+d)]/(a+b+c+d)^2$	0.620		
Kappa	$(PA-Pe)/(1-Pe)$	0.988		

According to Table 1, among the 93 samples of the positive group, 92 are proven positive in the test results of the product tested, and 1 is proven negative. Among the 127 samples of the negative group, 127 are proven negative in the test results of the product tested and 0 is proven positive. Both the coincidence rate of positive/negative and the total coincidence rate are more than 90%, indicating favorable consistency with the reference product. According to the table, the Kappa coefficient = 0.988 (>0.8) in the results of Kappa inspection and analysis, indicating favorable and high consistency of two methods and equivalence of two such systems.