Clinical Agreement Study for SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay)

CONTENTS

1. Purpose

SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay) is developed by Getein Biotech, Inc. The test is intended for the qualitative detection of anti-SARS-CoV-2 neutralizing antibodies in serum, plasma or whole blood samples. SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay) is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection and should not be used to diagnose acute SARS-CoV-2 infection.

The aim of the clinical agreement study was to compare and evaluate the clinical performance of SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay) with EUA-authorized tests.

2. Experimental Materials

2.1 Trial reagent

Name: SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay)
Specification: 25 tests per box
Lot no.: YXGN210001W (Manufacturing date: January 06, 2021)
Manufacturer: Getein Biotech, Inc.

2.2 Comparator reagent

Name: cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit (EUA Approved)
Specifications: 96 Tests
Manufacturer: GenScript Biotech Co., Ltd.
Lot no.: A201209 (Expiration date: December 20, 2021)

3. Experimental sample

3.1 Sample source and amount

A total of 409 samples were tested using SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay). The combined cohort was consisted of healthy people (n=257, RT-PCR negative) and volunteers who have been immunized by injecting two doses of vaccine against SARS-CoV-2 (n=152). Serum samples of vaccine group were collected at 28 days after the second dose of vaccine.

Samples of serum were collected. The healthy people samples were consented and collected from Nanjing Jiangbei People's Hospital and the volunteer’s samples by injecting vaccine were collected from Getein Biotech, Inc. and Nanjing Jiangbei People's Hospital based on the sample inclusion criteria. The studies were performed at January 2021.

3.2 Sample information

The samples were tested with GenScript Biotech Co., Ltd's cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit for SARS-CoV-2 neutralization antibody. In this study, the GenScript Biotech Co., Ltd testing positive samples were considered as positive, the testing negative samples were considered as negative.

3.2.1 Samples of Clinical agreement study

A total of 409 samples were used for the Clinical Agreement Study. The detailed sample information is as the following:

The detailed information of 257 healthy people samples data and sources are listed below in the Table 1.

Table 1 The 257 healthy people samples information of clinical agreement study from the Nanjing Jiangbei People's Hospital

No.	Sample ID	Gender	Age	Sample type	Sample source
1	S470025	Male	17	Serum	Nanjing Jiangbei People's Hospital
2	S470008	Female	14		
3	S473257	Male	57		
4	S476254	Male	79		
5	S470125	Female	24		
6	S476354	Male	57		
7	S471025	Female	75		
8	S473156	Female	48		
9	S472104	Male	66		
10	S472531	Female	78		
11	S470075	Male	14		
12	S471034	Female	20		
13	S471124	Male	41		
14	S470313	Female	8		
15	S477739	Male	33		
16	S471641	Female	76		
17	S476291	Male	34		
18	S477613	Male	7		
19	S477547	Male	9		
20	S472570	Female	7		
21	S477639	Male	37		
22	S478189	Male	43		

23	S475576	Female	11		
24	S476956	Male	32		
25	S477568	Male	12		
26	S476940	Female	58		
27	S471619	Female	92		
28	S476493	Male	43		
29	S471454	Male	52		
30	S474205	Male	26		
31	S470007	Female	41		
32	S479521	Male	24		
33	S472826	Female	34		
34	S473021	Male	8		
35	S474966	Male	12		
36	S475023	Male	56		
37	S475722	Female	54		
38	S472016	Male	84		
39	S477837	Female	75		
40	S472647	Female	14		
41	S472163	Male	58		
42	S474983	Male	42		
43	S479566	Female	79		
44	S479141	Male	39		
45	S476713	Female	21		
46	S473363	Male	21		
47	S473338	Female	77		
48	S471304	Male	24		
49	S477205	Male	15		
50	S478990	Female	82		
51	S473027	Male	76		
52	S479358	Female	19		
53	S476855	Female	29		
54	S474914	Male	34		
55	S477793	Male	31		
56	S476871	Male	52		

57	S477591	Female	30		
58	S477625	Male	75		
59	S478298	Female	14		
60	S476990	Male	68		
61	S473915	Male	53		
62	S475388	Female	72		
63	S479392	Male	79		
64	S472070	Male	14		
65	S479543	Male	53		
66	S476304	Female	23		
67	S478389	Male	77		
68	S473500	Female	38		
69	S475104	Male	41		
70	S475595	Female	48		
71	S475617	Male	74		
72	S476163	Male	34		
73	S474991	Female	51		
74	S478618	Male	16		
75	S478292	Male	57		
76	S473196	Female	64		
77	S477450	Male	73		
78	S477701	Male	14		
79	S479113	Male	61		
80	S472751	Female	43		
81	S477686	Female	49		
82	S479780	Male	69		
83	S472855	Male	27		
84	S470629	Male	20		
85	S479106	Female	51		
86	S479186	Male	36		
87	S475911	Male	32		
88	S479254	Female	62		
89	S471417	Female	64		
90	S470609	Male	30		

91	S470273	Male	36		
92	S470785	Male	27		
93	S472317	Female	49		
94	S479124	Male	33		
95	S474178	Male	75		
96	S478444	Female	63		
97	S471263	Female	69		
98	S470143	Male	33		
99	S470447	Male	27		
100	S471040	Male	62		
101	S474369	Female	80		
102	S475657	Female	15		
103	S477997	Male	54		
104	S470290	Male	35		
105	S476907	Female	76		
106	S473240	Male	55		
107	S474737	Male	36		
108	S473218	Female	82		
109	S478393	Male	65		
110	S479487	Female	77		
111	S472566	Male	81		
112	S473558	Male	48		
113	S478069	Female	37		
114	S477800	Male	22		
115	S476683	Male	18		
116	S475643	Female	19		
117	S472399	Male	42		
118	S470593	Female	68		
119	S474765	Female	39		
120	S477504	Male	20		
121	S473573	Male	36		
122	S473024	Female	59		
123	S479962	Female	46		
124	S479693	Female	75		

125	S471024	Male	49		
126	S476201	Male	64		
127	S477744	Male	54		
128	S470056	Male	52		
129	S475161	Male	45		
130	S472397	Male	19		
131	S470870	Female	63		
132	S475873	Female	39		
133	S474936	Female	67		
134	S476410	Male	72		
135	S478448	Male	25		
136	S476554	Male	22		
137	S477258	Female	65		
138	S475946	Male	64		
139	S478071	Male	73		
140	S473364	Female	63		
141	S476119	Male	79		
142	S479002	Female	65		
143	S470807	Male	37		
144	S477336	Male	19		
145	S475990	Female	28		
146	S475687	Female	29		
147	S473752	Male	65		
148	S475451	Male	14		
149	S476955	Male	78		
150	S472230	Female	61		
151	S477513	Female	38		
152	S470387	Male	6		
153	S475938	Male	71		
154	S475500	Female	81		
155	S474886	Female	42		
156	S475042	Male	70		
157	S477940	Male	57		
158	S470355	Female	57		

159	S470900	Female	79		
160	S477572	Male	62		
161	S473643	Female	68		
162	S478650	Male	19		
163	S476116	Female	26		
164	S475810	Male	67		
165	S476986	Male	71		
166	S477199	Male	79		
167	S477935	Female	18		
168	S479357	Male	47		
169	S473104	Male	59		
170	S472752	Female	27		
171	S475556	Male	63		
172	S478734	Male	15		
173	S472941	Male	66		
174	S472240	Male	60		
175	S475000	Female	27		
176	S477376	Female	68		
177	S475735	Male	62		
178	S473474	Male	22		
179	S476234	Male	17		
180	S470368	Male	54		
181	S477938	Female	6		
182	S472433	Male	42		
183	S477965	Female	65		
184	S479301	Male	54		
185	S476584	Female	64		
186	S475542	Male	72		
187	S479578	Male	11		
188	S479223	Female	69		
189	S479668	Female	74		
190	S479394	Female	43		
191	S478014	Male	20		
192	S475919	Male	15		

193	S472559	Male	38		
194	S478549	Female	50		
195	S474195	Male	43		
196	S474360	Female	76		
197	S478008	Male	35		
198	S472337	Male	54		
199	S472157	Female	58		
200	S477991	Male	53		
201	S470583	Female	27		
202	S471125	Male	12		
203	S472829	Female	78		
204	S470403	Male	35		
205	S471872	Female	21		
206	S471044	Male	37		
207	S477221	Female	44		
208	S470621	Female	21		
209	S473087	Male	32		
210	S478046	Female	6		
211	S470750	Male	9		
212	S479133	Female	28		
213	S471601	Male	64		
214	S472510	Female	74		
215	S470598	Female	65		
216	S473639	Male	47		
217	S472975	Male	36		
218	S471681	Male	61		
219	S474568	Female	32		
220	S474417	Female	25		
221	S476386	Male	63		
222	S472151	Male	41		
223	S477558	Female	22		
224	S477759	Male	36		
225	S474535	Female	79		
226	S478397	Female	25		

227	S473088	Male	12		
228	S470739	Male	36		
229	S470556	Male	41		
230	S475313	Female	68		
231	S476196	Male	60		
232	S471383	Male	56		
233	S471969	Female	75		
234	S476392	Female	48		
235	S478093	Male	15		
236	S475441	Male	10		
237	S477819	Female	15		
238	S476663	Male	37		
239	S474724	Female	44		
240	S470163	Male	24		
241	S473374	Female	76		
242	S472014	Male	20		
243	S473722	Female	60		
244	S470924	Female	72		
245	S478073	Female	60		
246	S476318	Male	12		
247	S479875	Female	33		
248	S477760	Female	47		
249	S471033	Male	71		
250	S479257	Female	18		
251	S473112	Female	60		
252	S471613	Male	38		
253	S473817	Female	31		
254	S475208	Female	59		
255	S470698	Male	62		
256	S473414	Male	10		
257	S471552	Female	21		

The detailed information of 152 volunteers (who have been immunized by injecting two doses of vaccine against SARS-CoV-2) samples data and sources are listed below in the Table 2.

Table 2 The sample information of 152 volunteers' samples

No.	Sample ID	Gender	Age	Sample type	Volunteer source
1	S513164	Female	36	Serum	Nanjing Jiangbei People's Hospital
2	S550045	Female	47		
3	S511159	Male	49		
4	S514157	Female	20		
5	S535624	Male	44		
6	S542825	Female	49		
7	S518563	Male	22		
8	S539775	Male	35		
9	S524989	Female	29		
10	S503466	Female	23		
11	S553136	Male	39		
12	S549251	Male	27		
13	S547035	Female	31		
14	S536878	Female	45		
15	S547249	Female	44		
16	S506840	Male	28		
17	S507842	Female	36		
18	S566038	Female	30		
19	S506292	Male	33		
20	S557506	Male	46		
21	S547257	Male	46		
22	S501290	Female	21		
23	S534916	Female	36		
24	S555978	Female	30		
25	S531674	Male	34		
26	S521406	Female	45		
27	S522183	Male	37		
28	S557341	Female	49		
29	S557566	Female	50		
30	S502151	Male	46		
31	S564978	Female	33		
32	S527532	Male	37		

33	S567357	Female	40		
34	S569672	Male	45		
35	S557509	Female	22		
36	S512594	Male	49		
37	S552563	Female	28		
38	S559789	Male	20		
39	S530763	Female	36		
40	S511158	Male	24		
41	S539063	Female	41		
42	S524045	Female	21		
43	S563778	Male	23		
44	S558088	Female	21		
45	S514071	Male	38		
46	S562071	Female	48		
47	S533450	Female	26		
48	S560602	Male	21		
49	S539696	Female	34		
50	S513867	Male	29		
51	S506056	Male	44		
52	S567823	Female	34		
53	S532216	Male	25		
54	S541848	Female	22		
55	S565421	Female	45		
56	S531101	Male	20		
57	S509082	Female	28		
58	S520230	Female	33		
59	S505999	Male	48		
60	S542741	Female	38		
61	S564448	Male	30		
62	S500522	Female	49		
63	S554527	Male	41		
64	S551319	Female	20		
65	S508357	Male	25		
66	S560772	Female	21		

67	S548614	Male	29		
68	S504628	Female	24		
69	S501627	Male	47		
70	S540914	Female	33		
71	S565909	Male	44		
72	S535245	Male	36		
73	S554291	Male	42		
74	S567922	Female	22		
75	S514891	Female	38		
76	S532124	Male	40		
77	S567144	Male	34		
78	S514023	Male	38		
79	S502824	Female	34		
80	S537643	Male	27		
81	S533744	Male	38		
82	S552009	Female	50		
83	S500910	Male	43		
84	S550233	Female	38		
85	S529420	Female	34		
86	S568011	Male	20		
87	S568154	Male	42		
88	S557460	Male	30		
89	S518685	Female	27		
90	S563651	Female	46		
91	S557285	Female	42		
92	S555810	Female	47		
93	S538188	Female	34		
94	S519000	Male	39		
95	S516304	Male	32		
96	S545710	Female	45		
97	S521281	Female	25		
98	S530823	Female	32		
99	S565364	Male	47		
100	S562458	Male	50		

101	S555117	Female	48		
102	S542380	Male	44		
103	S511206	Male	48		
104	S557798	Female	49		
105	S552736	Male	41		
106	S533004	Male	25		
107	S511162	Male	43		
108	S510089	Male	42		
109	S532254	Female	49		
110	S506297	Female	50		
111	S557476	Female	34		
112	S551231	Male	31		
113	S520068	Female	36		
114	S552794	Male	38		
115	S545502	Male	27		
116	S557538	Female	34		
117	S507353	Male	35		
118	S530192	Female	43		
119	S523997	Male	43		
120	S530458	Female	37		
121	S523242	Female	26		
122	S550714	Male	33		
123	S527507	Male	45		
124	S510608	Male	23		
125	S555694	Female	34		
126	S564136	Female	22		
127	S555403	Male	37		
128	S539594	Female	47		
129	S534609	Female	32		
130	S500909	Male	36		
131	S556215	Female	44		Getein Biotech, Inc.
132	S520221	Female	24		
133	S520093	Female	48		
134	S553199	Female	44		

135	S526734	Male	26		
136	S501436	Female	27		
137	S511877	Male	50		
138	S516012	Male	29		
139	S540804	Female	27		
140	S511845	Male	20		
141	S510532	Female	22		
142	S527460	Female	39		
143	S535409	Male	34		
144	S541180	Female	38		
145	S505230	Male	43		
146	S567996	Female	44		
147	S509345	Male	47		
148	S500710	Male	21		
149	S516760	Female	27		
150	S543837	Female	34		
151	S577513	Female	38		
152	S564542	Male	47		

4. Test process

The clinical agreement study of SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay) was evaluated by testing a total of 409 clinical samples from individual patients: The study was a double-blind and randomization experiment. A is responsible for the collection and numbering of all samples, and performing the comparator reagent testing. B is responsible for performing the trial reagent only (Note: A and B should not reveal the testing results to each other so to ensure the study was double-blinded). C is responsible for reveal and compare the testing results from A and B. D is responsible for the statistical analysis of the data.

5. Statistical methods

5.1 Calculation method of positive, negative and total percent agreement

Table 3 The test results of trial reagent and comparator reagent

Experiment	comparator reagent

		positive	negative
Trial reagent	positive	a	b
	negative	c	d

Calculation with the following formula:
Positive percent agreement = a / (a+c) ×100%
Negative percent agreement = d / (b+d) ×100%
Total percent agreement = (a+d) / (a+b+c+d) ×100%

5.2 Calculation method of 95% confidence interval

(1) The formula for calculating 95% confidence interval of total coincidence rate

[100% (Q1－Q2) /Q3， 100% (Q1＋Q2) / Q3]

$Q1=2\ (a+d)+1.96^2$

$Q2=1.96\sqrt{1.96^2+4\ (a+d)\ (b+c)/n}$

$Q3=2\ (n+1.96^2)$

(2) The formula for calculating 95% confidence interval of PPA

[100% (Q1, ppa－Q2, ppa) / Q3, 100% (Q1, ppa＋Q2, ppa) / Q3, ppa]

$Q1,\ ppa=2a+1.96^2$

$Q2,\ ppa=1.96\sqrt{1.96^2+4ac/(a+c)}$

$Q3,\ ppa=2\ (a+c+1.96^2)$

(3) The formula for calculating 95% confidence interval of NPA

[100%*(Q1, npa－Q2, npa) / Q3, npa, 100%*(Q1, npa＋Q2, npa) / Q3, npa]

$Q1,\ npa=2d+1.96^2$

$Q2,\ npa=1.96\sqrt{1.96^2+4bd/(b+d)}$

$Q3,\ npa=2\ (b+d+1.96^2)$

6. Test results

6.1 Clinical agreement study result

Across all study sites, a total of 257 healthy people samples and 152 volunteer's samples in serum collected at 28 days after the second dose of vaccine were tested with SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay) and one comparator reagent (cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit). Overall study results are shown in Table 4 below.

Table 4 The test result of clinical agreement study

Sample ID	GenScript	Getein	Sample ID	GenScript	Getein
S502151	58%	67.4%	S472070	1%	< 10.0%
S473088	3%	< 10.0%	S473364	14%	25.8%
S501627	47%	58.2%	S475313	0%	< 10.0%
S564542	0%	< 10.0%	S567357	52%	58.7%
S506297	76%	84.8%	S502824	36%	37.6%
S479002	5%	12.6%	S470007	1%	< 10.0%
S547035	73%	74.6%	S474360	4%	< 10.0%
S477572	6%	< 10.0%	S562458	82%	80.8%
S477547	1%	< 10.0%	S472829	9%	< 10.0%
S476683	7%	25.6%	S477760	17%	< 10.0%
S471044	13%	22.3%	S474936	18%	< 10.0%
S564136	56%	52.2%	S511162	37%	32.9%
S563778	80%	81.8%	S477759	6%	< 10.0%
S471613	18%	< 10.0%	S470870	0%	< 10.0%
S478008	7%	< 10.0%	S559789	55%	69.3%
S472016	5%	12.7%	S472104	4%	< 10.0%
S476990	0%	< 10.0%	S557538	78%	76.1%
S545710	33%	38.0%	S473087	11%	< 10.0%
S471969	4%	< 10.0%	S478071	11%	< 10.0%
S526734	15%	12.6%	S560772	60%	71.5%
S557509	61%	58.7%	S472163	5%	34.6%
S505999	36%	36.9%	S475595	0%	< 10.0%

S553136	39%	47.7%	S473218	0%	15.6%
S569672	48%	57.9%	S470629	10%	11.6%
S473643	0%	< 10.0%	S541180	6%	< 10.0%
S470403	8%	< 10.0%	S473500	16%	< 10.0%
S479875	1%	< 10.0%	S557341	61%	54.3%
S478650	0%	< 10.0%	S474568	13%	< 10.0%
S475873	14%	< 10.0%	S475451	7%	< 10.0%
S543837	13%	21.7%	S511206	55%	57.2%
S478014	0%	< 10.0%	S475938	15%	< 10.0%
S471417	1%	20.1%	S531101	78%	69.7%
S471034	9%	< 10.0%	S477793	11%	< 10.0%
S475023	18%	< 10.0%	S523997	37%	37.5%
S474195	14%	15.5%	S470387	0%	12.6%
S527532	69%	60.4%	S524045	89%	81.6%
S470593	12%	< 10.0%	S479141	0%	< 10.0%
S471619	12%	< 10.0%	S478618	9%	14.6%
S473104	0%	< 10.0%	S567996	4%	< 10.0%
S506292	87%	90.9%	S479223	0%	< 10.0%
S477558	0%	< 10.0%	S475617	7%	< 10.0%
S472570	7%	< 10.0%	S477336	8%	< 10.0%
S478990	8%	24.4%	S536878	41%	41.6%
S478549	0%	< 10.0%	S470583	12%	22.3%
S473752	17%	11.2%	S507842	45%	49.5%
S470368	10%	< 10.0%	S512594	40%	49.8%

S476196	8%	18.7%	S537643	45%	25.9%
S539696	68%	83.1%	S473240	11%	14.3%
S557476	41%	37.8%	S473374	5%	< 10.0%
S473817	0%	21.8%	S478448	7%	19.7%
S475919	18%	19.2%	S518685	64%	59.0%
S513164	63%	49.3%	S533450	71%	59.2%
S539063	57%	68.4%	S477744	16%	19.4%
S504628	45%	41.1%	S471304	4%	< 10.0%
S479394	8%	16.2%	S557798	61%	61.3%
S550233	47%	41.9%	S560602	80%	86.2%
S472855	16%	12.3%	S500909	55%	44.2%
S477625	4%	< 10.0%	S470143	15%	< 10.0%
S470556	11%	< 10.0%	S500522	52%	63.6%
S530823	83%	77.8%	S564978	57%	49.5%
S557460	90%	93.5%	S520068	47%	57.9%
S530763	88%	86.7%	S474983	12%	16.7%
S473024	5%	14.0%	S472752	2%	< 10.0%
S475657	7%	< 10.0%	S520230	68%	86.3%
S565421	74%	85.1%	S510532	0%	< 10.0%
S473021	16%	< 10.0%	S476254	1%	< 10.0%
S472433	14%	< 10.0%	S477935	18%	< 10.0%
S475500	6%	< 10.0%	S479962	7%	16.3%
S476554	0%	< 10.0%	S506056	35%	20.1%
S476119	4%	< 10.0%	S534916	59%	64.4%

S551231	69%	84.2%	S470025	0%	16.3%
S470900	1%	< 10.0%	S470924	5%	< 10.0%
S471025	14%	< 10.0%	S563651	71%	57.7%
S516760	7%	< 10.0%	S564448	78%	96.7%
S473722	0%	< 10.0%	S557285	65%	73.2%
S550045	52%	47.5%	S503466	57%	68.2%
S471872	7%	< 10.0%	S472531	4%	< 10.0%
S475104	0%	< 10.0%	S476201	11%	< 10.0%
S473573	12%	< 10.0%	S477376	4%	10.8%
S474914	12%	< 10.0%	S478734	19%	< 10.0%
S511845	7%	< 10.0%	S475990	9%	26.3%
S470785	14%	< 10.0%	S547249	60%	67.3%
S477940	12%	< 10.0%	S531674	38%	46.6%
S555694	73%	65.3%	S470355	3%	< 10.0%
S474178	0%	< 10.0%	S541848	58%	61.9%
S523242	58%	69.8%	S477221	6%	< 10.0%
S470008	10%	10.4%	S475161	1%	< 10.0%
S514023	93%	82.6%	S518563	52%	46.1%
S532254	47%	47.8%	S478046	15%	< 10.0%
S476940	15%	15.2%	S552794	60%	73.9%
S524989	57%	49.5%	S470609	14%	< 10.0%
S476956	15%	< 10.0%	S476386	1%	< 10.0%
S540914	88%	89.6%	S500910	47%	45.7%
S477613	3%	< 10.0%	S514071	68%	71.5%

S473156	6%	12.1%	S471552	7%	< 10.0%
S533744	47%	51.8%	S565364	41%	40.6%
S477739	18%	< 10.0%	S478397	9%	< 10.0%
S477205	8%	< 10.0%	S473338	4%	19.4%
S477837	12%	< 10.0%	S473257	2%	12.9%
S479186	3%	24.4%	S475542	4%	< 10.0%
S511159	92%	95.9%	S476986	1%	< 10.0%
S479521	17%	< 10.0%	S478389	15%	26.0%
S554527	88%	83.0%	S478393	0%	< 10.0%
S557566	52%	59.2%	S470075	18%	< 10.0%
S477591	3%	22.3%	S471124	1%	15.2%
S475000	11%	< 10.0%	S470807	1%	< 10.0%
S476163	14%	11.6%	S540804	15%	14.3%
S555978	75%	93.0%	S567922	80%	86.9%
S477568	0%	< 10.0%	S533004	66%	59.8%
S479693	11%	< 10.0%	S565909	58%	59.5%
S474535	9%	< 10.0%	S470056	7%	15.3%
S551319	95%	75.7%	S474966	13%	< 10.0%
S472826	1%	16.2%	S479133	6%	21.3%
S479254	3%	< 10.0%	S552009	34%	36.1%
S479566	5%	< 10.0%	S475388	2%	< 10.0%
S527507	49%	46.9%	S479106	12%	< 10.0%
S472941	10%	< 10.0%	S476955	0%	14.9%
S516012	14%	< 10.0%	S476234	0%	< 10.0%

S472647	14%	< 10.0%	S566038	49%	47.0%
S470313	4%	< 10.0%	S476871	16%	< 10.0%
S521281	77%	84.4%	S476304	5%	< 10.0%
S479392	0%	14.6%	S472337	18%	17.0%
S479668	4%	< 10.0%	S475643	9%	< 10.0%
S473027	17%	< 10.0%	S477686	14%	26.6%
S532124	68%	63.2%	S471681	0%	< 10.0%
S478093	1%	13.8%	S505230	21%	< 10.0%
S552736	93%	79.5%	S568011	66%	73.0%
S479357	0%	15.3%	S472751	2%	< 10.0%
S476584	16%	< 10.0%	S556215	49%	51.4%
S501436	11%	< 10.0%	S522183	45%	39.9%
S479487	3%	< 10.0%	S471383	0%	< 10.0%
S477258	0%	13.9%	S474765	12%	< 10.0%
S473558	12%	11.30%	S473639	0%	< 10.0%
S473112	0%	< 10.0%	S472510	8%	< 10.0%
S477997	1%	10.4%	S567144	91%	83.4%
S548614	46%	52.9%	S577513	0%	< 10.0%
S470698	17%	< 10.0%	S535409	0%	18.8%
S478444	11%	12.6%	S477800	0%	< 10.0%
S510608	66%	73.6%	S478073	2%	16.4%
S475810	5%	< 10.0%	S471601	10%	22.3%
S470739	2%	15.3%	S475042	19%	< 10.0%
S535624	65%	61.5%	S473196	0%	< 10.0%

S477513	17%	< 10.0%	S552563	53%	50.6%
S555403	69%	60.7%	S470621	6%	12.3%
S476855	7%	< 10.0%	S539775	57%	55.0%
S477819	16%	< 10.0%	S530458	76%	67.8%
S475946	11%	< 10.0%	S539594	35%	37.2%
S477701	2%	< 10.0%	S477991	0%	< 10.0%
S479358	4%	< 10.0%	S475556	8%	< 10.0%
S508357	60%	63.3%	S477938	19%	20.0%
S474417	13%	23.0%	S479543	17%	< 10.0%
S477504	1%	14.4%	S562071	23%	11.2%
S470163	7%	19.7%	S510089	34%	32.9%
S535245	45%	39.2%	S514157	59%	50.2%
S475735	16%	< 10.0%	S478189	10%	< 10.0%
S554291	70%	76.4%	S470750	18%	< 10.0%
S472399	11%	20.1%	S476354	14%	< 10.0%
S547257	84%	78.4%	S474886	3%	< 10.0%
S475722	9%	< 10.0%	S471641	0%	< 10.0%
S478069	8%	< 10.0%	S479124	14%	20.1%
S477199	9%	< 10.0%	S478298	6%	< 10.0%
S542380	37%	39.5%	S472566	12%	25.0%
S473915	9%	19.2%	S474724	10%	< 10.0%
S477965	18%	< 10.0%	S538188	65%	60.0%
S474991	4%	< 10.0%	S474205	7%	20.7%
S553199	11%	16.2%	S545502	47%	43.0%

S506840	95%	90.0%	S519000	93%	78.1%
S507353	65%	54.3%	S534609	44%	38.7%
S473414	10%	< 10.0%	S509082	56%	59.1%
S472151	16%	< 10.0%	S474369	14%	15.4%
S476116	15%	< 10.0%	S520093	5%	< 10.0%
S475687	17%	< 10.0%	S479578	6%	21.5%
S476493	18%	< 10.0%	S470290	6%	< 10.0%
S477450	13%	15.0%	S514891	58%	61.9%
S472230	18%	< 10.0%	S532216	87%	87.2%
S555117	61%	57.9%	S527460	5%	< 10.0%
S472559	16%	< 10.0%	S473474	15%	< 10.0%
S473363	2%	< 10.0%	S477639	6%	15.0%
S471033	7%	12.6%	S511158	80%	77.4%
S479780	6%	< 10.0%	S472397	0%	25.6%
S520221	54%	62.0%	S500710	11%	< 10.0%
S470598	16%	10.80%	S511877	13%	< 10.0%
S470125	5%	13.1%	S471454	17%	< 10.0%
S501290	89%	83.5%	S509345	3%	11.9%
S472014	7%	< 10.0%	S471263	6%	11.1%
S549251	38%	41.5%	S475208	4%	< 10.0%
S470273	6%	< 10.0%	S472157	0%	< 10.0%
S474737	13%	< 10.0%	S471024	0%	21.2%
S475911	1%	< 10.0%	S521406	57%	58.2%
S530192	67%	63.6%	S550714	43%	37.6%

S476410	11%	< 10.0%	S476663	11%	20.2%
S516304	60%	54.8%	S513867	85%	83.8%
S479257	12%	< 10.0%	S476291	5%	26.1%
S476318	15%	< 10.0%	S479301	5%	< 10.0%
S555810	66%	56.6%	S479113	0%	< 10.0%
S568154	82%	80.6%	S478292	13%	< 10.0%
S471125	16%	< 10.0%	S476713	16%	< 10.0%
S470447	13%	18.0%	S476392	1%	< 10.0%
S567823	82%	90.4%	S472240	0%	< 10.0%
S472317	14%	< 10.0%	S476907	0%	12.6%
S529420	34%	35.5%	S471040	12%	< 10.0%
S475576	9%	12.6%	S542741	53%	51.5%
S472975	0%	17.4%	S542825	46%	38.9%
S558088	81%	77.2%	S475441	13%	< 10.0%
S557506	87%	98.2%			

Note：For GenScript Biotech Co., Ltd cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit, the test result is displayed numerically in terms of inhibition ratio. Test result is negative if inhibition rate is <30%, and positive if inhibition rate is ≥ 30%.
For Getein Biotech, Inc. SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay), Test result is negative if inhibition rate is <30%, and positive if inhibition rate is ≥ 30%.

7. Statistical analysis

7.1 Clinical agreement study results analysis

According to the statistical methods, the results of clinical agreement study were as follows.
Correlation analysis of SARS-CoV-2 neutralizing antibody
The test results were summarized as follows.

Table 5 Overall clinical study results for SARS-CoV-2 neutralizing antibody

SARS-CoV-2 Neutralizing Antibody	Comparator reagent （GenScript）

		positive	negative
Trail reagent	positive	130	0
	negative	1	278

Compared to GenScript neutralizing antibody (cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit):
Positive Percent Agreement = 130/ (130+1) × 100%=99.2% (95%CI: 95.80% - 99.87%)
Negative Percent Agreement =278/ (278+0) × 100%=100.0% (95%CI: 98.64% - 100.00%)
Total percent agreement= (130+278)/ (130+0+1+278) ×100%=99.8% (95%CI: 98.63% - 99.96%)

8. Conclusion

In this study, the trail regent is SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay), developed by Getein Biotech, Inc. The the comparator reagent is cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit *for detecting SARS-CoV-2* neutralizing antibodies developed by GenScript Biotech Co., Ltd. A total of 409 individual patient samples, with 257 healthy people and 152 volunteers who have been immunized by injecting two doses of vaccine against SARS-CoV-2, were tested with the trial reagent to evaluate the clinical agreement with the comparator.
According to the results of clinical agreement study, 409 clinical patients were tested. For SARS-CoV-2 Neutralizing Antibody tested by trial reagents, the positive percent agreement was 99.2%, the 95% confidence interval of the positive percent agreement was [95.80%,99.87%], the negative percent agreement was 100.0%, the 95% confidence interval of the negative percent agreement was [98.64%,100.00%], the total percent agreement is 99.8%, the 95% confidence interval of the total percent agreement was [98.63%,99.96%].