Clinical Agreement Study for
One Step Test for
SARS-CoV-2 Total Antibody /Neutralizing Antibody
(Colloidal Gold)

CONTENTS

1. Purpose

One Step Test for SARS-CoV-2 Total Antibody /Neutralizing Antibody (Colloidal Gold) is developed by Getein Biotech, Inc. The test is intended for the qualitative detection of anti-SARS-CoV-2 total antibodies and neutralizing antibodies in serum, plasma or whole blood samples. One Step Test for SARS-CoV-2 Total Antibody /Neutralizing Antibody (Colloidal Gold) 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 One Step Test for SARS-CoV-2 Total Antibody /Neutralizing Antibody (Colloidal Gold) with EUA-authorized tests.

2. Experimental Materials

2.1 Trial reagent

Name: One Step Test for SARS-CoV-2 Total Antibody /Neutralizing Antibody (Colloidal Gold)
Specification: 25 tests per box
Lot no.: SN210001W (Manufacturing date: January 05, 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)

Name: Elecsys Anti-SARS-CoV-2
Specifications: 200 Tests
Manufacturer: Roche Diagnostics

3. Experimental sample

3.1 Sample source and amount

A total of 409 samples were tested using One Step Test for SARS-CoV-2 Total Antibody /Neutralizing Antibody (Colloidal Gold). 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 from 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 and Roche's Elecsys Anti-SARS-CoV-2 for SARS-CoV-2 total antibody. In this study, the GenScript Biotech Co., Ltd testing positive samples were considered as positive, the testing negative samples were considered as negative. the Roche testing positive samples were considered as positive, the testing negative samples were considered as negative. All samples were numbered and recorded.

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		
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	Serum	Nanjing Jiangbei People's Hospital
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
132	S520221	Female	24

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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 One Step Test for SARS-CoV-2 Total Antibody /Neutralizing Antibody (Colloidal Gold) 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 One Step Test for SARS-CoV-2 Total Antibody /Neutralizing Antibody (Colloidal Gold) and two comparator reagents (Elecsys Anti-SARS-CoV-2 and cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit). Overall study results are shown in Table 4 below. Results stratified by total antibodies and neutralization antibodies are shown in Tables 5 and 6.

Table 4 The test result of clinical agreement study

Sample ID	Roche	GenScript	Getein	
	Total Antibody	Neutralizing Antibody	Total Antibody	Neutralizing Antibody
S473573	0.05	12%	-	-
S563651	48.92	71%	+	+
S479693	0.30	11%	-	-
S473240	0.34	11%	-	-
S514023	10.61	93%	+	+
S472240	0.60	0%	-	-
S503466	47.82	57%	+	+
S473112	0.60	0%	-	-
S479578	0.35	6%	-	-
S479962	0.53	7%	-	-
S473104	0.27	0%	-	-
S516760	0.25	7%	-	-
S479358	0.52	4%	-	-
S471124	0.52	1%	-	-
S501627	42.65	47%	+	+
S564136	25.69	56%	+	+
S543837	0.34	13%	-	-
S473558	0.15	12%	-	-
S477258	0.23	0%	-	-
S555978	50.57	75%	+	+
S532124	45.67	68%	+	+

S566038	17.73	49%	+	+
S477935	0.31	18%	-	-
S478071	0.06	11%	-	-
S563778	9.89	80%	+	+
S473817	0.20	0%	-	-
S475595	0.43	0%	+	-
S475000	0.08	11%	-	-
S477997	0.54	1%	-	-
S470056	0.06	7%	-	-
S510608	27.9	66%	+	+
S475023	0.28	18%	-	-
S473643	0.46	0%	-	-
S472104	0.35	4%	-	-
S477376	0.25	4%	-	-
S470313	0.21	4%	-	-
S470609	0.40	14%	-	-
S476855	0.42	7%	-	-
S476493	0.22	18%	-	-
S536878	34.31	41%	+	+
S472752	0.59	2%	-	-
S472559	0.46	16%	-	-
S476318	0.50	15%	-	-
S476234	0.12	0%	-	-
S471025	0.42	14%	-	-

S520221	21.34	54%	+	+
S560602	32.97	80%	+	+
S470785	0.36	14%	-	-
S475687	0.07	17%	-	-
S470629	0.16	10%	-	-
S477991	0.41	0%	-	-
S477793	0.23	11%	-	-
S475938	0.56	15%	-	-
S471383	0.40	0%	-	-
S470025	0.09	0%	-	-
S479357	0.46	0%	-	-
S472531	0.46	4%	-	-
S557506	14.7	87%	+	+
S506292	17.24	87%	+	+
S506056	43.68	35%	+	+
S557566	45.37	52%	+	+
S516012	0.30	14%	-	-
S524045	31.81	89%	+	+
S476713	0.54	16%	-	-
S553136	11.21	39%	+	+
S477205	0.45	8%	-	-
S477558	0.14	0%	-	-
S473414	0.13	10%	-	-
S474369	0.07	14%	-	-

S550233	9.17	47%	+	+
S534609	41.57	44%	+	+
S545502	47.93	47%	+	+
S477336	0.43	8%	-	-
S524989	30.06	57%	+	+
S470750	0.22	18%	-	-
S520230	13.84	68%	+	+
S471044	0.29	13%	-	-
S541848	53.11	58%	+	+
S530763	17.72	88%	+	+
S474205	0.50	7%	-	-
S533004	44.41	66%	+	+
S478093	0.53	1%	-	-
S477221	0.22	6%	-	-
S478292	0.29	13%	-	-
S554527	16.84	88%	+	+
S477199	0.10	9%	-	-
S472337	0.57	18%	-	-
S471969	0.09	4%	-	-
S471304	0.29	4%	-	-
S479254	0.16	3%	-	-
S473338	0.16	4%	-	-
S477800	0.56	0%	-	-
S470924	0.41	5%	-	-

S471613	0.06	18%	-	-
S479543	0.30	17%	-	-
S549251	6.35	38%	+	+
S514071	25.82	68%	+	+
S476986	0.31	1%	-	-
S557509	37.07	61%	+	+
S473087	0.15	11%	-	-
S530192	53.53	67%	+	+
S562071	7.03	23%	+	-
S557538	17.26	78%	+	+
S555403	21.08	69%	+	+
S477547	0.27	1%	-	-
S473722	0.06	0%	-	-
S470125	0.40	5%	-	-
S529420	41.27	34%	+	+
S477938	0.04	19%	-	-
S476907	0.36	0%	-	-
S535409	0.09	0%	-	-
S479124	0.34	14%	-	-
S479394	0.58	8%	-	-
S470900	0.48	1%	-	-
S470273	0.28	6%	-	-
S471619	0.59	12%	-	-
S539775	44.42	57%	+	+

S477686	0.56	14%	-	-
S523997	5.95	37%	+	+
S477568	0.06	0%	-	-
S470593	0.05	12%	-	-
S475735	0.16	16%	-	-
S479002	0.38	5%	-	-
S475556	0.12	8%	-	-
S527460	0.47	5%	-	-
S502824	12.81	36%	+	+
S470583	0.39	12%	-	-
S475946	0.04	11%	-	-
S477819	0.04	16%	-	-
S542741	52.76	53%	+	+
S522183	53.46	45%	+	+
S500522	29.12	52%	+	+
S474991	0.27	4%	-	-
S472433	0.58	14%	-	-
S475657	0.08	7%	-	-
S514157	6.61	59%	+	+
S479301	0.36	5%	-	-
S542380	12.27	37%	+	+
S472829	0.54	9%	-	-
S477759	0.31	6%	-	-
S476410	0.55	11%	-	-

S507353	46.17	65%	+	+
S477591	0.33	3%	-	-
S470447	0.27	13%	-	-
S474195	0.56	14%	-	-
S565421	47.22	74%	+	+
S474914	0.33	12%	-	-
S562458	49.51	82%	+	+
S537643	2.09	45%	-	-
S470290	0.06	6%	-	-
S518685	36.56	64%	+	+
S506297	30.53	76%	+	+
S475313	0.24	0%	-	-
S478393	0.34	0%	-	-
S565364	50.94	41%	+	+
S475617	0.31	7%	-	-
S557285	36.43	65%	+	+
S473218	0.30	0%	-	-
S548614	14.15	46%	+	+
S564542	0.60	0%	-	-
S477625	0.11	4%	-	-
S475722	0.21	9%	-	-
S473257	0.16	2%	-	-
S476196	0.06	8%	-	-
S565909	20.26	58%	+	+

S506840	26.76	95%	+	+
S471872	0.07	7%	-	-
S554291	39.68	70%	+	+
S474765	0.06	12%	-	-
S479487	0.31	3%	-	-
S474360	0.22	4%	-	-
S477701	0.10	2%	-	-
S530823	48.71	83%	+	+
S520093	0.47	5%	-	-
S476683	0.47	7%	-	-
S470007	0.33	1%	-	-
S475911	0.38	1%	-	-
S511206	11.57	55%	+	+
S479223	0.47	0%	-	-
S557476	27.85	41%	+	+
S539063	42.04	57%	+	+
S564448	6.1	78%	+	+
S478073	0.25	2%	-	-
S478618	0.23	9%	-	-
S473156	0.38	6%	-	-
S471024	0.52	0%	-	-
S477760	0.50	17%	-	-
S472016	0.29	5%	-	-
S547035	7.96	73%	+	+

S470621	0.35	6%	-	-
S479106	0.45	12%	-	-
S478008	0.38	7%	-	-
S479141	0.23	0%	-	-
S470598	0.05	16%	-	-
S518563	44.48	52%	+	+
S555810	24.08	66%	+	+
S473374	0.43	5%	-	-
S552009	24.38	34%	+	+
S470387	0.43	0%	-	-
S478069	0.05	8%	-	-
S475576	0.34	9%	-	-
S476956	0.39	15%	-	-
S470075	0.38	18%	-	-
S479113	0.48	0%	-	-
S476554	0.09	0%	-	-
S478444	0.45	11%	-	-
S567996	0.28	4%	-	-
S514891	51.84	58%	+	+
S476990	0.21	0%	-	-
S476584	0.60	16%	-	-
S509082	29.98	56%	+	+
S476955	0.38	0%	-	-
S472317	0.46	14%	-	-

S550045	48.61	52%	+	+
S470403	0.29	8%	-	-
S479133	0.47	6%	-	-
S476940	0.28	15%	-	-
S477965	0.18	18%	-	-
S479566	0.59	5%	-	-
S472751	0.42	2%	-	-
S511877	0.38	13%	-	-
S477639	0.39	6%	-	-
S532216	44.15	87%	+	+
S472855	0.55	16%	-	-
S470355	0.37	3%	-	-
S477504	0.32	1%	-	-
S475542	0.13	4%	-	-
S473088	0.14	3%	-	-
S478549	0.12	0%	-	-
S476354	0.41	14%	-	-
S473196	0.19	0%	-	-
S568154	8.2	82%	+	+
S521281	50.01	77%	+	+
S471417	0.24	1%	-	-
S473752	0.05	17%	-	-
S471125	0.13	16%	-	-
S552736	44.7	93%	+	+

S558088	42.6	81%	+	+
S478046	0.19	15%	-	-
S473474	0.27	15%	-	-
S569672	50.99	48%	+	+
S472163	0.39	5%	-	-
S478734	0.14	19%	-	-
S472975	0.41	0%	-	-
S557460	20.37	90%	+	+
S479392	0.26	0%	-	-
S470163	0.40	7%	-	-
S470698	0.26	17%	-	-
S477739	0.36	18%	-	-
S476119	0.29	4%	-	-
S523242	42.52	58%	+	+
S560772	47.82	60%	+	+
S533450	8.75	71%	+	+
S539696	7.41	68%	+	+
S478990	0.06	8%	-	-
S476201	0.16	11%	-	-
S476386	0.06	1%	-	-
S530458	54.19	76%	+	+
S474178	0.04	0%	-	-
S500909	30.24	55%	+	+
S479780	0.19	6%	-	-

S478298	0.06	6%	-	-
S473024	0.43	5%	-	-
S475208	0.05	4%	-	-
S475451	0.40	7%	-	-
S479875	0.26	1%	-	-
S475104	0.24	0%	-	-
S473500	0.39	16%	-	-
S474936	0.32	18%	-	-
S479186	0.05	3%	-	-
S567357	28.53	52%	+	+
S478014	0.15	0%	-	-
S477513	0.38	17%	-	-
S470556	0.44	11%	-	-
S477572	0.32	6%	-	-
S471454	0.57	17%	-	-
S470870	0.18	0%	-	-
S475873	0.20	14%	-	-
S472510	0.29	8%	-	-
S527532	14.53	69%	+	+
S477837	0.35	12%	-	-
S471681	0.52	0%	-	-
S470807	0.16	1%	-	-
S470143	0.30	15%	-	-
S478650	0.55	0%	-	-

S527507	20.08	49%	+	+
S556215	12.20	49%	+	+
S511162	54.59	37%	+	+
S478189	0.59	10%	-	-
S472399	0.56	11%	-	-
S520068	51.31	47%	+	+
S557798	8.03	61%	+	+
S476291	0.20	5%	-	-
S476116	0.55	15%	-	-
S475042	0.41	19%	-	-
S513164	22.07	63%	+	+
S501290	28.47	89%	+	+
S473915	0.33	9%	-	-
S519000	37.68	93%	+	+
S472151	0.08	16%	-	-
S552563	20.34	53%	+	+
S555117	40.14	61%	+	+
S550714	2.92	43%	+	+
S538188	52.16	65%	+	+
S471034	0.35	9%	-	-
S476663	0.11	11%	-	-
S474568	0.39	13%	-	-
S470368	0.14	10%	-	-
S540804	0.23	15%	-	-

S472941	0.09	10%	-	-
S564978	8.08	57%	+	+
S471263	0.35	6%	-	-
S475643	0.24	9%	-	-
S473639	0.54	0%	-	-
S502151	42.48	58%	+	+
S475441	0.14	13%	-	-
S478389	0.07	15%	-	-
S474886	0.57	3%	-	-
S511158	50.63	80%	+	+
S479257	0.04	12%	-	-
S547257	26.03	84%	+	+
S510532	0.49	0%	-	-
S475810	0.38	5%	-	-
S567823	53.27	82%	+	+
S472070	0.42	1%	-	-
S531674	7.98	38%	+	+
S471552	0.44	7%	-	-
S472397	0.17	0%	-	-
S512594	25.78	40%	+	+
S568011	17.2	66%	+	+
S474535	0.52	9%	-	-
S472566	0.07	12%	-	-
S471040	0.10	12%	-	-

S531101	44.1	78%	+	+
S516304	44.04	60%	+	+
S476163	0.06	14%	-	-
S557341	34.07	61%	+	+
S535624	33.09	65%	+	+
S474966	0.56	13%	-	-
S474983	0.31	12%	-	-
S542825	7.36	46%	+	+
S475919	0.13	18%	-	-
S532254	76.82	47%	+	+
S476304	0.57	5%	-	-
S479521	0.48	17%	-	-
S474417	0.09	13%	-	-
S500910	40.36	47%	+	+
S471033	0.10	7%	-	-
S511159	9.31	92%	+	+
S472570	0.38	7%	-	+
S472157	0.13	0%	-	-
S505999	4.54	36%	+	+
S509345	0.17	3%	-	-
S508357	23.42	60%	+	+
S471641	0.21	0%	-	-
S541180	0.26	6%	-	-
S533744	50.88	47%	+	+

S477450	0.46	13%	-	-
S567144	26.39	91%	+	+
S505230	0.35	21%	-	-
S513867	26.98	85%	+	+
S478448	0.19	7%	-	-
S470008	0.39	10%	-	-
S476871	0.43	16%	-	-
S535245	12.71	45%	+	+
S475990	0.10	9%	-	-
S472647	0.13	14%	-	-
S472230	0.22	18%	-	-
S474724	0.29	10%	-	-
S471601	0.45	10%	-	-
S473364	0.39	14%	-	-
S477744	0.25	16%	-	-
S547249	10.36	60%	+	+
S559789	44.54	55%	+	+
S474737	0.30	13%	-	-
S552794	49.6	60%	+	+
S521406	21.05	57%	+	+
S555694	28.81	73%	+	+
S475500	0.20	6%	-	-
S577513	0.36	0%	-	-
S540914	26.02	88%	+	+

S478397	0.25	9%	-	-
S476392	0.30	1%	-	-
S473363	0.55	2%	-	-
S477940	0.32	12%	-	-
S511845	0.06	7%	-	-
S501436	0.15	11%	-	-
S475388	0.07	2%	-	-
S526734	0.54	15%	-	-
S551319	26.06	95%	+	+
S475161	0.14	1%	-	-
S472826	0.17	1%	-	-
S476254	0.47	1%	-	-
S470739	0.19	2%	-	-
S567922	3.58	80%	+	+
S553199	0.08	11%	-	-
S477613	0.06	3%	-	-
S504628	41.02	45%	+	+
S545710	3.65	33%	+	-
S510089	3.45	34%	+	+
S500710	0.22	11%	-	-
S507842	14.41	45%	+	+
S473021	0.28	16%	-	-
S534916	49.94	59%	+	+
S539594	9.49	35%	+	+

S551231	49.84	69%	+	+
S473027	0.14	17%	-	-
S479668	0.27	4%	-	-
S472014	0.20	7%	-	-

Note：For Roche Elecsys Anti-SARS-CoV-2, the test result is displayed numerically in terms of cut-off index (COI) value. Test result is negative if COI is <1.00, and positive if COI is ≥ 1.00.

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. One Step Test for SARS-CoV-2 Total Antibody /Neutralizing Antibody (Colloidal Gold), "-" means test result is negative; "+" means test result is positive.

7. Statistical analysis

7.1 Clinical agreement study results analysis

According to the statistical methods, the results of clinical agreement study were as follows.

(1) Correlation analysis of SARS-CoV-2 total antibody

The test results were summarized as follows

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

Total Antibody		Comparator reagent （Roche）	
		positive	negative
Trail reagent	positive	131	1
	negative	1	276

Compared to Roche total antibody (Elecsys Anti-SARS-CoV-2):

Positive Percent Agreement = 131 / (131+1) × 100%=99.2% (95%CI: 95.83% - 99.87%)

Negative Percent Agreement =276/ (1+276) × 100%=99.6% (95%CI: 97.98% - 99.94%)

Total Percent Agreement = (131+276)/ (131+1+1+276) ×100%=99.5% (95%CI: 98.23% - 99.87%)

(2) Correlation analysis of SARS-CoV-2 neutralizing antibody

The test results were summarized as follows

Table 6 Overall clinical study results for SARS-CoV-2 neutralizing antibody

Neutralizing Antibody	Comparator reagent （GenScript）

		positive	negative
Trail reagent	positive	129	1
	negative	2	277

Compared to GenScript neutralizing antibody (cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit):

Positive Percent Agreement = 129 / (129+2) × 100%=98.5% (95%CI: 94.60% - 99.58%)

Negative Percent Agreement =277/ (277+1) × 100%=99.6% (95%CI: 97.99% - 99.94%)

Total Percent Agreement = (129+277)/ (129+1+2+277) ×100%=99.3% (95%CI: 97.87% - 99.75%)

8. Conclusion

In this study, the trail regent is One Step Test for SARS-CoV-2 Total Antibody /Neutralizing Antibody (Colloidal Gold), developed by Getein Biotech, Inc. The comparator reagent is Elecsys Anti-SARS-CoV-2 *for detecting SARS-CoV-2* total antibodies, developed by Roche Diagnostics, and 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 Total Antibody tested by trial reagents, the positive percent agreement was 99.2%, the 95% confidence interval of the positive percent agreement was [95.83%,99.87%], the negative percent agreement was 99.6%, the 95% confidence interval of the negative percent agreement was [97.98%,99.94%], the total percent agreement is 99.5%, the 95% confidence interval of the total percent agreement was [98.23%,99.87%].

For SARS-CoV-2 Neutralizing Antibody tested by trial reagents, the positive percent agreement was 98.5%, the 95% confidence interval of the positive percent agreement was [94.60%,99.58%], the negative percent agreement was 99.6%, the 95% confidence interval of the negative percent agreement was [97.99%,99.94%], the total percent agreement is 99.3%, the 95% confidence interval of the total percent agreement was [97.87%,99.75%].