Clinical Study-
Anti-SARS-CoV-2 Rapid Test

1. Research purpose

This study aims to evaluate the clinical performance of the Anti-SARS-CoV-2 Rapid Test kit in Autobio.

2. Materials for performance evaluation

Evaluation reagent：Anti-SARS-CoV-2 Rapid Test (Lateral Flow Method), which is manufactured by Autobio Diagnostics Co., Ltd.

Control reagent: SARS-CoV-2 Antibody Test (Lateral Flow Method), manufactured by Guangzhou Wondfo Biotech Co.,Ltd., which has been approved by CFDA.

3. Protocol

For Serum/Plasma samples:

68 positive samples which had been diagnosed as SARS-CoV-2 virus infection were tested with Autobio reagent and the control reagent at Henan Centers for Disease Control. And 312 negative samples were tested with Autobio reagent and the control reagent at Autobio Diagnostics Co., Ltd.

For Whole blood samples:

15 positive samples which had been diagnosed as SARS-CoV-2 virus infection were tested with Autobio reagent and the control reagent at Henan Centers for Disease Control. And 15 negative samples were tested with Autobio reagent and the control reagent at Autobio Diagnostics Co., Ltd.

All the positive samples were confirmed by NAT test.

Test the samples by Autobio and Wondfo tests in parallel, and calculate the coincidence rate

For Autobio test, IgG and IgM reactive could be recognized, either IgM or IgG or both IgM and IgG reactive are considered as reactive.

For Wondfo test, IgG and IgM reactive could not be distinguished, it should be reported as reactive when the control line and test line are identified.

4. Results

4.1 Results of serum/plasma samples

Table 1 Results of serum/plasma samples

Evaluation reagent		Control reagent		Sum
		Reactive	Nonreactive	
Autobio	Reactive	38	13	51

	Nonreactive	1	328	329
Sum		39	341	380
Reactive coincidence rate		97.4%		
Nonreactive coincidence rate		96.2%		
Total coincidence rate		96.3%		

Conclusion: After kappa analysis of the results above, kappa value was 0.824, p value was $<$ 0.001. There was substantial consistency between Anti-SARS-CoV-2 Rapid Test (Autobio) and the control reagent.

The raw data was in appendix A.

4.2 Results of whole blood samples

Table 2 Results of whole blood samples

No. of positive samples	Autobio	Control reagent	No. of negative samples	Autobio	Control reagent
P1	+	+	N1	-	-
P2	+	+	N2	-	-
P3	+	+	N3	-	-
P4	+	+	N4	-	-
P5	+	+	N5	-	-
P6	+	+	N6	-	-
P7	+	+	N7	-	-
P8	+	+	N8	-	-
P9	±	±	N9	-	-
P10	+	+	N10	-	-
P11	+	+	N11	-	-
P12	+	+	N12	-	-
P13	±	±	N13	-	-
P14	+	+	N14	-	-
P15	+	+	N15	-	-

Note: "+" means reactive; "±" means weak reactive; "-"means unreactive.

Conclusion: According to the results above, the filtration performance of whole blood erythrocytes was acceptable. And there was perfect consistency between Anti-SARS-CoV-2 Rapid Test (Autobio) and the control reagent. Due to the specificity of collecting clinical

positive whole blood samples, clinical study of whole blood samples maybe further performed.

5. Discussion

Anti-SARS-CoV-2 Rapid Test (Autobio) is based on a colloidal gold method for the rapid, qualitative determination of Anti-SARS-CoV-2 (IgG/IgM antibodies of Severe Acute Respiratory Syndrome Coronavirus 2) in human serum, plasma or whole blood. It can give the reactive report of Anti-SARS-CoV-2 IgG/IgM antibodies separately or simultaneously. Then it will give an aid in identifying the early or late stages of patient infection in conjunction with clinical examination, patient's medical history and other test results. And about the strong reactive samples, Anti-SARS-CoV-2 Rapid Test can give the report within three or four minutes. However, comparing to NAT test method, there was a longer window period of Anti-SARS-CoV-2 Rapid Test. It can be used as a supplementary detection indicator for SARS-CoV-2 virus infection but not for the diagnosis and exclusion of the virus.

Appendix A - Raw data of serum/plasma samples results

No.	SARS-CoV-2 IgM (Autobio)	SARS-CoV-2 IgG (Autobio)	Control reagent	No.	SARS-CoV-2 IgM (Autobio)	SARS-CoV-2 IgG (Autobio)	Control reagent
1	+	+	+	191	—	—	—
2	+	—	+	192	—	—	—
3	+	—	—	193	—	—	—
4	+	+	+	194	—	—	—
5	+	—	+	195	—	—	—
6	—	—	—	196	—	—	—
7	+	—	+	197	—	—	—
8	+	+	+	198	—	—	—
9	—	—	—	199	—	—	—
10	+	—	+	200	—	—	—
11	+	+	+	201	—	—	—
12	+	+	+	202	—	—	—
13	+	+	—	203	—	—	—
14	+	—	+	204	—	—	—
15	—	+	+	205	—	—	—
16	+	—	+	206	—	—	—
17	+	+	—	207	—	—	—
18	—	+	+	208	—	—	—
19	+	+	+	209	—	—	—
20	—	+	+	210	—	—	—
21	+	+	—	211	—	—	—
22	+	+	+	212	—	—	—
23	+	—	+	213	—	—	—
24	+	—	+	214	—	—	—
25	—	—	—	215	—	—	—
26	+	+	+	216	—	—	—
27	—	+	+	217	—	—	—
28	+	—	—	218	—	—	—
29	—	+	+	219	—	—	—
30	+	+	+	220	—	—	—
31	+	+	+	221	—	—	—
32	—	+	+	222	—	—	—
33	+	—	+	223	—	—	—
34	—	+	+	224	—	—	—
35	+	+	+	225	—	—	—

36	—	+	+	226	—	—	—
37	—	—	—	227	—	—	—
38	—	+	+	228	—	—	—
39	—	+	+	229	—	—	—
40	+	+	—	230	—	—	—
41	+	+	—	231	—	—	—
42	+	+	+	232	—	—	—
43	—	+	—	233	—	—	—
44	+	—	+	234	—	—	—
45	+	—	+	235	—	—	—
46	+	+	—	236	—	—	—
47	+	+	+	237	—	—	—
48	—	+	—	238	—	—	—
49	+	—	+	239	—	—	—
50	—	+	—	240	—	—	—
51	+	+	+	241	—	—	—
52	—	+	+	242	—	—	—
53	+	+	—	243	—	—	—
54	+	+	+	244	—	—	—
55	+	—	+	245	—	—	—
56	—	—	—	246	—	—	—
57	—	—	—	247	—	—	—
58	—	—	—	248	—	—	—
59	—	—	—	249	—	—	—
60	—	—	—	250	—	—	—
61	—	—	—	251	—	—	—
62	—	—	—	252	—	—	—
63	—	—	—	253	—	—	—
64	—	—	—	254	—	—	—
65	—	—	—	255	—	—	—
66	—	—	—	256	—	—	—
67	—	—	—	257	—	—	—
68	—	—	—	258	—	—	—
69	—	—	—	259	—	—	—
70	—	—	—	260	—	—	—
71	—	—	—	261	—	—	—
72	—	—	—	262	—	—	—
73	—	—	—	263	—	—	—
74	—	—	—	264	—	—	—

75	—	—	—	265	—	—	—
76	—	—	—	266	—	—	—
77	—	—	—	267	—	—	—
78	—	—	—	268	—	—	—
79	—	—	—	269	—	—	—
80	—	—	—	270	—	—	—
81	—	—	—	271	—	—	—
82	—	—	—	272	—	—	—
83	—	—	—	273	—	—	—
84	—	—	—	274	—	—	—
85	—	—	—	275	—	—	—
86	—	—	—	276	—	—	—
87	—	—	—	277	—	—	—
88	—	—	—	278	—	—	—
89	—	—	—	279	—	—	—
90	—	—	—	280	—	—	—
91	—	—	—	281	—	—	—
92	—	—	—	282	—	—	—
93	—	—	—	283	—	—	—
94	—	—	—	284	—	—	—
95	—	—	—	285	—	—	—
96	—	—	—	286	—	—	—
97	—	—	—	287	—	—	—
98	—	—	—	288	—	—	—
99	—	—	—	289	—	—	—
100	—	—	—	290	—	—	—
101	—	—	—	291	—	—	—
102	—	—	—	292	—	—	—
103	—	—	—	293	—	—	—
104	—	—	—	294	—	—	—
105	—	—	—	295	—	—	—
106	—	—	—	296	—	—	—
107	—	—	—	297	—	—	—
108	—	—	—	298	—	—	—
109	—	—	—	299	—	—	—
110	—	—	—	300	—	—	—
111	—	—	—	301	—	—	—
112	—	—	—	302	—	—	—
113	—	—	—	303	—	—	—

114	—	—	—	304	—	—	—
115	—	—	—	305	—	—	—
116	—	—	—	306	—	—	—
117	—	—	—	307	—	—	—
118	—	—	—	308	—	—	—
119	—	—	—	309	—	—	—
120	—	—	—	310	—	—	—
121	—	—	—	311	—	—	—
122	—	—	—	312	—	—	—
123	—	—	—	313	—	—	—
124	—	—	—	314	—	—	—
125	—	—	—	315	—	—	—
126	—	—	—	316	—	—	—
127	—	—	—	317	—	—	—
128	—	—	—	318	—	—	—
129	—	—	—	319	—	—	—
130	—	—	—	320	—	—	—
131	—	—	—	321	—	—	—
132	—	—	—	322	—	—	—
133	—	—	—	323	—	—	—
134	—	—	—	324	—	—	—
135	—	—	—	325	—	—	—
136	—	—	—	326	—	—	—
137	—	—	—	327	—	—	—
138	—	—	—	328	—	—	—
139	—	—	—	329	—	—	—
140	—	—	—	330	—	—	—
141	—	—	—	331	—	—	—
142	—	—	—	332	—	—	—
143	—	—	—	333	—	—	—
144	—	—	—	334	—	—	—
145	—	—	—	335	—	—	—
146	—	—	—	336	—	—	—
147	—	—	—	337	—	—	—
148	—	—	—	338	—	—	—
149	—	—	—	339	—	—	—
150	—	—	—	340	—	—	—
151	—	—	—	341	—	—	—
152	—	—	—	342	—	—	—

153	—	—	—	343	—	—	—
154	—	—	—	344	—	—	—
155	—	—	—	345	—	—	—
156	—	—	—	346	—	—	—
157	—	—	—	347	—	—	—
158	—	—	—	348	—	—	—
159	—	—	—	349	—	—	—
160	—	—	—	350	—	—	—
161	—	—	—	351	—	—	—
162	—	—	—	352	—	—	—
163	—	—	—	353	—	—	—
164	—	—	—	354	—	—	—
165	—	—	—	355	—	—	—
166	—	—	—	356	—	—	—
167	—	—	—	357	—	—	—
168	—	—	—	358	—	—	—
169	—	—	—	359	—	—	—
170	—	—	—	360	—	—	—
171	—	—	—	361	—	—	—
172	—	—	—	362	—	—	—
173	—	—	—	363	—	—	—
174	—	—	—	364	—	—	—
175	—	—	—	365	—	—	—
176	—	—	—	366	—	—	—
177	—	—	—	367	—	—	—
178	—	—	—	368	—	—	—
179	—	—	—	369	—	—	—
180	—	—	—	370	—	—	—
181	—	—	—	371	—	—	—
182	—	—	—	372	—	—	—
183	—	—	—	373	—	—	—
184	—	—	—	374	—	—	—
185	—	—	—	375	—	—	—
186	—	—	—	376	—	—	—
187	—	—	—	377	—	—	—
188	—	—	—	378	—	—	—
189	—	—	—	379	—	—	—
190	—	—	—	380	—	—	—

Note: "＋" means reactive; "-"means unreactive.

No. 1-No.68 are tested as positive samples which had been diagnosed as SARS-CoV-2 virus infection.

No. 69-No.380 are tested as negative samples.