



**Clinical Study Report of
ACCU-TELL® COVID-19 IgG/IgM Cassette
(Whole Blood/Serum/Plasma)
No.CSR-B352-BT01/03**

Purpose :

Evaluate the diagnostic value in SARS-COV-2 infection (COVID-19) with ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)

Material:

ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)

REF.: ABT-IDT-B352

Lot No.: 2020030601

Samples Information:

For Site A:

The study is testing 100 samples from patient infections SARS-COV-2(COVID-19) and 150 samples from the excluded cases.

For Site B:

The study is testing 70 samples from confirmed infected patients, and 10 samples from the excluded cases.

Comment:

- **Site A** indicate Jiangsu Provincial Center for Disease Control and prevention
- **Site B** indicate Hubei Center for Disease Control and Prevention
- Clinical agreement sample size reference ***In Vitro Diagnostics EUA from FDA (U.S. FOOD & DRUG) Website***

Method:

Read the entire manual and bring the test and specimens to reach room temperature (15-30°C) before use.

Remove from the test cassette from the sealed pouch and use it within 1hour.

- 1) Place the test cassette on a clean and level surface, hold the dropper vertically, draw the specimen up to the fill line (approximately 10µl), and transfer the specimen to the sample(S) of the test cassette, then add 2 drops of buffer (approximately 80µl) the buffer.
- 2) The colored line(s)to appear, the test result should be read at 10minutes, do not interpret the result after 20 minutes

Testing Results:

Relative Sensitivity

Relative Sensitivity of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) was evaluated using clinical samples collected from symptomatic subjects. All subjects were confirmed positive for COVID-19 by Nucleic Acid Test (RT-PCR) or clinical diagnosis.

Relative Specificity

Relative Specificity of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) was evaluated using clinical samples collected from symptomatic subjects. Samples were collected during the COVID-19 pandemic and all were excluded for COVID-19 by Nucleic Acid Test (RT-PCR) or clinical diagnosis.

The positive and/or negative population consisted of the following subjects.

The results show that the Relative Sensitivity of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) is 93.5%, the Relative Specificity is 97.5% and the Accuracy is 95.5%.

- Living in site A during the COVID-19 pandemic.
- Living in site B during the COVID-19 pandemic.

Method		PCR Positive (Confirmed Cases)	PCR Negative (Excluded Cases)	Total
Site A	IgG+ and IgM+	84	1	85
	IgM+ and IgG-	9	3	12
	IgM- and IgG+	2	0	2
	IgM- and IgG-	5	146	151
Site B	IgG+ and IgM+	58	0	58
	IgM+ and IgG-	5	0	5
	IgM- and IgG+	1	0	1
	IgM- and IgG-	6	10	16
Total		170	160	330
Agreement		$(95+64)/(100+70)$ =93.5% (95%CI:88.7%-96.7%)	$(146+10)/(150+10)$ =97.5% (95%CI:93.7%-99.3%)	$(95+64+146+10)/(100+70+150+10)$ =95.5% (95%CI:93.7%-99.3%)

Relative Sensitivity: $(95+64)/(100+70) = 93.5\%$ (95%CI:88.7%-96.7%)

Relative Specificity: $(146+10)/(150+10) = 97.5\%$ (95%CI:93.7%-99.3%)

Accuracy: $(95+64+146+10)/(100+70+150+10) = 95.5\%$ (95%CI:93.7%-99.3%)

CI means confidence interval



For Site A:

Perform the 100 Definitive Diagnosed samples with ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)

Comment: To protect the privacy of patients, the patient's name is numbered B1,B2,B3 etc.

Item No.	Experiment No.	Sex	Age	Type of Sample	Diagnostic Result	Testing Result		Clinical Symptom
						IgM	IgG	
1	B1	Male	49	Serum	Confirmed Case	+	+	Feeble, Headache, Fever, Dry cough, Expectoration, Chill
2	B2	Male	30	Serum	Confirmed Case	+	+	Fever, Dry cough, Chill
3	B3	Male	59	Serum	Confirmed Case	+	+	Headache, Fever, Expectoration, Chill, Other
4	B4	Female	36	Serum	Confirmed Case	+	+	Headache, Fever, Expectoration, Chill, Other, Feeble
5	B5	Male	43	Serum	Confirmed Case	+	+	Feeble, Fever, Expectoration,
6	B6	Female	50	Serum	Confirmed Case	+	+	Headache, Fever, Other
7	B7	Male	31	Serum	Confirmed Case	+	+	Fever, Dry cough, Expectoration
8	B8	Male	34	Serum	Confirmed Case	+	-	Fever, Dry cough, Chill,
9	B9	Male	34	Serum	Confirmed Case	+	+	Fever,
10	B10	Male	61	Serum	Confirmed Case	-	-	Fever, Dry cough, Muscle pain,
11	B11	Male	39	Serum	Confirmed Case	+	+	Feeble, Fever Chill
12	B12	Male	23	Serum	Confirmed Case	+	+	Feeble, Fever, Dry cough, Expectoration, Chill, Muscle pain
13	B13	Male	30	Serum	Confirmed Case	+	-	Fever, Dry cough, Chill
14	B14	Female	37	Serum	Confirmed Case	+	+	Pharyngalgia
15	B15	Male	30	Serum	Confirmed Case	-	-	Running Nose
16	B16	Female	42	Serum	Confirmed Case	+	+	Feeble, Dry cough, Expectoration, Chill
17	B17	Female	33	Serum	Confirmed Case	+	+	Other
18	B18	Male	1	Serum	Confirmed Case	+	+	Other
19	B19	Female	64	Serum	Confirmed Case	+	+	Dry cough, Expectoration
20	B20	Male	31	Serum	Confirmed Case	+	+	Headache, Fever, Dry cough,
21	B21	Male	45	Serum	Confirmed Case	+	+	Expectoration,



22	B22	Female	36	Serum	Confirmed Case	+	-	Fever, Dry cough
23	B23	Male	48	Serum	Confirmed Case	+	+	Headache, Fever, Dry cough, Chill, Muscle pain
24	B24	Male	33	Serum	Confirmed Case	+	+	Headache, Fever, Chill, Muscle pain,
25	B25	Male	25	Serum	Confirmed Case	+	+	Dry cough
26	B26	Male	38	Serum	Confirmed Case	+	+	Fever, Dry cough,
27	B27	Female	57	Serum	Confirmed Case	+	+	Expectoration
28	B28	Male	36	Serum	Confirmed Case	+	+	Fever, Dry cough, Other
29	B29	Male	47	Serum	Confirmed Case	+	+	Expectoration
30	B30	Male	23	Serum	Confirmed Case	+	+	Fever
31	B31	Female	52	Serum	Confirmed Case	+	+	Expectoration
32	B32	Male	22	Serum	Confirmed Case	+	+	Headache, Fever, Dry cough, Expectoration, Chill
33	B33	Female	51	Serum	Confirmed Case	+	+	Fever
34	B34	Female	56	Serum	Confirmed Case	+	+	Other
35	B35	Male	31	Serum	Confirmed Case	+	-	Fever, Dry cough, Expectoration
36	B36	Female	20	Serum	Confirmed Case	-	-	Fever
37	B37	Female	20	Serum	Confirmed Case	-	-	Fever
38	B38	Male	23	Serum	Confirmed Case	+	+	Fever Expectoration
39	B39	Male	55	Serum	Confirmed Case	+	-	Other
40	B40	Male	66	Serum	Confirmed Case	+	+	Fever, Dry cough
41	B41	Female	53	Serum	Confirmed Case	+	+	Fever, Expectoration
42	B42	Female	31	Serum	Confirmed Case	+	+	Fever
43	B43	Male	43	Serum	Confirmed Case	+	+	Fever
44	B44	Female	46	Serum	Confirmed Case	+	+	Fever, Expectoration
45	B45	Male	46	Serum	Confirmed Case	+	+	Other
46	B46	Male	31	Serum	Confirmed Case	+	+	Fever, Dry cough, Expectoration
47	B47	Male	49	Serum	Confirmed Case	+	+	Fever, Dry cough
48	B48	Female	51	Serum	Confirmed Case	+	+	Fever, Dry cough, Diarrhea



49	B49	Female	55	Serum	Confirmed Case	+	+	Fever
50	B50	Male	33	Serum	Confirmed Case	+	+	Fever, Dry cough
51	B51	Male	56	Serum	Confirmed Case	+	+	Headache, Fever
52	B52	Male	29	Serum	Confirmed Case	+	-	Fever, Expectoration
53	B53	Male	46	Serum	Confirmed Case	+	+	Other
54	B54	Female	49	Serum	Confirmed Case	+	+	Other
55	B55	Male	59	Serum	Confirmed Case	+	+	Dry cough, Pharyngalgia
56	B56	Female	12	Serum	Confirmed Case	+	+	Other
57	B57	Female	51	Serum	Confirmed Case	+	+	Fever, Dry cough, Expectoration, Pharyngalgia
58	B58	Female	6	Serum	Confirmed Case	+	+	Other
59	B59	Male	27	Serum	Confirmed Case	+	+	Fever, Expectoration
60	B60	Male	31	Serum	Confirmed Case	+	+	Dry cough
61	B61	Female	31	Serum	Confirmed Case	+	+	Fever, Expectoration
62	B62	Male	52	Serum	Confirmed Case	+	+	Fever, Expectoration
63	B63	Female	49	Serum	Confirmed Case	+	+	Fever, Dry cough, Expectoration, Vomiting, Diarrhea
64	B64	Female	61	Serum	Confirmed Case	+	+	Fever
65	B65	Female	22	Serum	Confirmed Case	+	-	Dry cough
66	B66	Male	39	Serum	Confirmed Case	+	+	Fever
67	B67	Male	48	Serum	Confirmed Case	+	+	Fever
68	B68	Female	40	Serum	Confirmed Case	+	+	Feeble
69	B69	Male	25	Serum	Confirmed Case	+	+	Fever, Dry cough
70	B70	Male	57	Serum	Confirmed Case	+	+	Fever, Dry cough
71	B71	Male	54	Serum	Confirmed Case	-	-	Other
72	B72	Female	25	Serum	Confirmed Case	+	+	Dry cough
73	B73	Female	56	Serum	Confirmed Case	+	+	Expectoration



74	B74	Male	66	Serum	Confirmed Case	+	+	Fever, Dry cough
75	B75	Female	53	Serum	Confirmed Case	+	+	Fever, Expectoration
76	B76	Female	31	Serum	Confirmed Case	+	+	Fever
77	B77	Male	43	Serum	Confirmed Case	+	+	Fever
78	B78	Male	57	Serum	Confirmed Case	+	+	Fever, Dry cough,
79	B79	Female	31	Serum	Confirmed Case	+	+	Other
80	B80	Male	48	Serum	Confirmed Case	+	+	Other
81	B81	Male	56	Serum	Confirmed Case	-	+	Expectoration
82	B82	Female	75	Serum	Confirmed Case	+	-	Other
83	B83	Male	31	Serum	Confirmed Case	+	+	Dry cough
84	B84	Female	31	Serum	Confirmed Case	+	+	Fever, , Expectoration
85	B85	Female	31	Serum	Confirmed Case	+	+	Other
86	B86	Male	38	Serum	Confirmed Case	+	+	Expectoration, Running Nose, Pharyngalgia, Fever
87	B87	Male	25	Serum	Confirmed Case	+	-	Fever
88	B88	Female	12	Serum	Confirmed Case	+	+	Other
89	B89	Female	6	Serum	Confirmed Case	+	+	Other
90	B90	Male	57	Serum	Confirmed Case	+	+	Fever, Dry Cough, Chest Distress, Other
91	B91	Female	25	Serum	Confirmed Case	+	+	Fever
92	B92	Female	60	Serum	Confirmed Case	+	+	Fever
93	B93	Female	56	Serum	Confirmed Case	+	+	Other
94	B94	Female	56	Serum	Confirmed Case	+	+	Pharyngalgia
95	B95	Female	65	Serum	Confirmed Case	+	+	Fever
96	B96	Female	38	Serum	Confirmed Case	-	+	Other
97	B97	Female	67	Serum	Confirmed Case	+	+	Other
98	B98	Female	47	Serum	Confirmed Case	+	+	Other
99	B99	Female	62	Serum	Confirmed Case	+	+	Other
100	B100	Female	57	Serum	Confirmed Case	+	+	Fever, , Expectoration, Dry cough



150 Excluded Samples Results:

Item No.	Experiment No.	Sex	Age	Type of Sample	Diagnostic Result	Background	Testing Result	
							IgM	IgG
1	B101	Male	27	Serum	Excluded	Suspicious patient	-	-
2	B102	Female	17	Serum	Excluded	Suspicious patient	-	-
3	B103	Male	21	Serum	Excluded	Suspicious patient	-	-
4	B104	Female	59	Serum	Excluded	Suspicious patient	-	-
5	B105	Male	52	Serum	Excluded	Suspicious patient	-	-
6	B106	Male	2	Serum	Excluded	Suspicious patient	-	-
7	B107	Female	52	Serum	Excluded	Suspicious patient	-	-
8	B108	Male	56	Serum	Excluded	Suspicious patient	-	-
9	B109	Female	52	Serum	Excluded	Suspicious patient	-	-
10	B110	Male	36	Serum	Excluded	Suspicious patient	-	-
11	B111	Male	12	Serum	Excluded	Suspicious patient	-	-
12	B112	Female	31	Serum	Excluded	Suspicious patient	-	-
13	B113	Male	56	Serum	Excluded	Suspicious patient	-	-
14	B114	Female	55	Serum	Excluded	Suspicious patient	-	-
15	B115	Female	32	Serum	Excluded	Suspicious patient	-	-
16	B116	Female	24	Serum	Excluded	Suspicious patient	-	-
17	B117	Male	68	Serum	Excluded	Suspicious patient	-	-
18	B118	Male	42	Serum	Excluded	Suspicious patient	-	-
19	B119	Female	8	Serum	Excluded	Suspicious patient	-	-
20	B120	Female	35	Serum	Excluded	Suspicious patient	-	-
21	B121	Female	71	Serum	Excluded	Suspicious patient	-	-
22	B122	Male	43	Serum	Excluded	Suspicious patient	-	-
23	B123	Female	38	Serum	Excluded	Suspicious patient	-	-
24	B124	Male	7	Serum	Excluded	Suspicious patient	-	-
25	B125	Male	64	Serum	Excluded	Suspicious patient	-	-
26	B126	Male	26	Serum	Excluded	Suspicious patient	-	-
27	B127	Male	26	Serum	Excluded	Suspicious patient	-	-
28	B128	Female	75	Serum	Excluded	Suspicious patient	+	+
29	B129	Male	30	Serum	Excluded	Suspicious patient	-	-
30	B130	Male	30	Serum	Excluded	Suspicious patient	-	-
31	B131	Male	30	Serum	Excluded	Suspicious patient	-	-
32	B132	Male	34	Serum	Excluded	Suspicious patient	+	-
33	B133	Female	30	Serum	Excluded	Suspicious patient	-	-
34	B134	Male	27	Serum	Excluded	Suspicious patient	-	-
35	B135	Female	15	Serum	Excluded	Suspicious patient	-	-



36	B136	Male	31	Serum	Excluded	Suspicious patient	-	-
37	B137	Female	16	Serum	Excluded	Suspicious patient	-	-
38	B138	Female	33	Serum	Excluded	Suspicious patient	-	-
39	B139	Female	34	Serum	Excluded	Suspicious patient	-	-
40	B140	Female	33	Serum	Excluded	Suspicious patient	-	-
41	B141	Female	20	Serum	Excluded	Suspicious patient	-	-
42	B142	Female	35	Serum	Excluded	Suspicious patient	-	-
43	B143	Male	30	Serum	Excluded	Suspicious patient	-	-
44	B144	Male	26	Serum	Excluded	Suspicious patient	-	-
45	B145	Female	35	Serum	Excluded	Suspicious patient	-	-
46	B146	Female	27	Serum	Excluded	Suspicious patient	-	-
47	B147	Male	68	Serum	Excluded	Suspicious patient	-	-
48	B148	Female	61	Serum	Excluded	Suspicious patient	-	-
49	B149	Female	70	Serum	Excluded	Suspicious patient	-	-
50	B150	Male	31	Serum	Excluded	Suspicious patient	-	-
51	B151	Female	62	Serum	Excluded	Suspicious patient	-	-
52	B152	Male	63	Serum	Excluded	Suspicious patient	-	-
53	B153	Male	3	Serum	Excluded	Suspicious patient	-	-
54	B154	Female	9	Serum	Excluded	Suspicious patient	-	-
55	B155	Male	57	Serum	Excluded	Suspicious patient	-	-
56	B156	Male	28	Serum	Excluded	Suspicious patient	-	-
57	B157	Male	27	Serum	Excluded	Suspicious patient	-	-
58	B158	Female	54	Serum	Excluded	Suspicious patient	-	-
59	B159	Male	38	Serum	Excluded	Suspicious patient	-	-
60	B160	Male	29	Serum	Excluded	Suspicious patient	-	-
61	B161	Male	27	Serum	Excluded	Suspicious patient	-	-
62	B162	Female	26	Serum	Excluded	Suspicious patient	-	-
63	B163	Male	29	Serum	Excluded	Suspicious patient	-	-
64	B164	Male	22	Serum	Excluded	Suspicious patient	-	-
65	B165	Male	59	Serum	Excluded	Suspicious patient	-	-
66	B166	Female	55	Serum	Excluded	Suspicious patient	-	-
67	B167	Male	22	Serum	Excluded	Suspicious patient	-	-
68	B168	Female	37	Serum	Excluded	Suspicious patient	-	-
69	B169	Female	72	Serum	Excluded	Suspicious patient	-	-
70	B170	Male	35	Serum	Excluded	Suspicious patient	-	-
71	B171	Male	80	Serum	Excluded	Suspicious patient	-	-
72	B172	Female	20	Serum	Excluded	Suspicious patient	+	-
73	B173	Female	25	Serum	Excluded	Suspicious patient	-	-



74	B174	Male	33	Serum	Excluded	Suspicious patient	-	-
75	B175	Male	34	Serum	Excluded	Suspicious patient	-	-
76	B176	Male	42	Serum	Excluded	Suspicious patient	-	-
77	B177	Female	64	Serum	Excluded	Suspicious patient	-	-
78	B178	Female	86	Serum	Excluded	Suspicious patient	-	-
79	B179	Male	57	Serum	Excluded	Suspicious patient	-	-
80	B180	Female	34	Serum	Excluded	Suspicious patient	-	-
81	B181	Male	53	Serum	Excluded	Suspicious patient	-	-
82	B182	Female	10	Serum	Excluded	Suspicious patient	-	-
83	B183	Male	35	Serum	Excluded	Suspicious patient	-	-
84	B184	Female	21	Serum	Excluded	Suspicious patient	-	-
85	B185	Female	44	Serum	Excluded	Suspicious patient	-	-
86	B186	Female	/	Serum	Excluded	Suspicious patient	-	-
87	B187	Male	31	Serum	Excluded	Suspicious patient	-	-
88	B188	Female	33	Serum	Excluded	Suspicious patient	-	-
89	B189	Female	3	Serum	Excluded	Suspicious patient	-	-
90	B190	Female	50	Serum	Excluded	Suspicious patient	-	-
91	B191	Male	6	Serum	Excluded	Suspicious patient	-	-
92	B192	Female	8	Serum	Excluded	Suspicious patient	-	-
93	B193	Female	10	Serum	Excluded	Suspicious patient	-	-
94	B194	Male	30	Serum	Excluded	Suspicious patient	-	-
95	B195	Male	30	Serum	Excluded	Suspicious patient	-	-
96	B196	Female	32	Serum	Excluded	Suspicious patient	-	-
97	B197	Female	56	Serum	Excluded	Suspicious patient	-	-
98	B198	Female	24	Serum	Excluded	Suspicious patient	-	-
99	B199	Female	10	Serum	Excluded	Suspicious patient	-	-
100	B200	Male	38	Serum	Excluded	Suspicious patient	-	-
101	B201	Female	35	Serum	Excluded	Suspicious patient	-	-
102	B202	Female	53	Serum	Excluded	Suspicious patient	-	-
103	B203	Female	46	Serum	Excluded	Suspicious patient	-	-
104	B204	Female	44	Serum	Excluded	Suspicious patient	-	-
105	B205	Male	78	Serum	Excluded	Suspicious patient	-	-
106	B206	Male	36	Serum	Excluded	Suspicious patient	-	-
107	B207	Female	34	Serum	Excluded	Suspicious patient	-	-
108	B208	Female	17	Serum	Excluded	Suspicious patient	-	-
109	B209	Female	10	Serum	Excluded	Suspicious patient	-	-
110	B210	Male	38	Serum	Excluded	Suspicious patient	-	-
111	B211	Female	49	Serum	Excluded	Suspicious patient	-	-



112	B212	Male	49	Serum	Excluded	Suspicious patient	-	-
113	B213	Female	39	Serum	Excluded	Suspicious patient	-	-
114	B214	Female	9	Serum	Excluded	Suspicious patient	-	-
115	B215	Female	24	Serum	Excluded	Suspicious patient	-	-
116	B216	Female	29	Serum	Excluded	Suspicious patient	-	-
117	B217	Male	44	Serum	Excluded	Suspicious patient	-	-
118	B218	Male	13	Serum	Excluded	Suspicious patient	-	-
119	B219	Female	41	Serum	Excluded	Suspicious patient	-	-
120	B220	Male	46	Serum	Excluded	Suspicious patient	-	-
121	B221	Female	47	Serum	Excluded	Suspicious patient	-	-
122	B222	Male	26	Serum	Excluded	Suspicious patient	-	-
123	B223	Female	41	Serum	Excluded	Suspicious patient	-	-
124	B224	Male	18	Serum	Excluded	Suspicious patient	-	-
125	B225	Male	43	Serum	Excluded	Suspicious patient	-	-
126	B226	Male	33	Serum	Excluded	Suspicious patient	-	-
127	B227	Male	11	Serum	Excluded	Suspicious patient	-	-
128	B228	Female	33	Serum	Excluded	Suspicious patient	-	-
129	B229	Female	4	Serum	Excluded	Suspicious patient	-	-
130	B230	Female	32	Serum	Excluded	Suspicious patient	-	-
131	B231	Male	38	Serum	Excluded	Suspicious patient	-	-
132	B232	Male	46	Serum	Excluded	Suspicious patient	-	-
133	B233	Female	50	Serum	Excluded	Suspicious patient	-	-
134	B234	Male	36	Serum	Excluded	Suspicious patient	-	-
135	B235	Female	61	Serum	Excluded	Suspicious patient	-	-
136	B236	Male	75	Serum	Excluded	Suspicious patient	-	-
137	B237	Female	52	Serum	Excluded	Suspicious patient	-	-
138	B238	Female	75	Serum	Excluded	Suspicious patient	-	-
139	B239	Male	74	Serum	Excluded	Suspicious patient	-	-
140	B240	Male	44	Serum	Excluded	Suspicious patient	-	-
141	B241	Female	44	Serum	Excluded	Suspicious patient	-	-
142	B242	Male	22	Serum	Excluded	Suspicious patient	-	-
143	B243	Female	65	Serum	Excluded	Suspicious patient	-	-
144	B244	Female	40	Serum	Excluded	Suspicious patient	-	-
145	B245	Male	40	Serum	Excluded	Suspicious patient	-	-
146	B246	Male	13	Serum	Excluded	Suspicious patient	-	-
147	B247	Female	4	Serum	Excluded	Suspicious patient	+	-
148	B248	Male	44	Serum	Excluded	Suspicious patient	-	-
149	B249	Male	18	Serum	Excluded	Suspicious patient	-	-
150	B250	Female	10	Serum	Excluded	Suspicious patient	-	-



For Site B:

Perform the 70 Definitive Diagnosed samples with ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma)

Comment: To protect the privacy of patients, the patient's name is numbered .

Item No.	Experiment No.	Type of Sample	Diagnostic Result	Testing Result	
				IgM	IgG
1	20021700002	Serum	Confirmed Case	+	+
2	200208513	Serum	Confirmed Case	+	+
3	200208183	Serum	Confirmed Case	+	+
4	200208187	Serum	Confirmed Case	+	+
5	200208429	Serum	Confirmed Case	+	+
6	200208196	Serum	Confirmed Case	+	+
7	200208452	Serum	Confirmed Case	-	-
8	200208410	Serum	Confirmed Case	+	+
9	200208259	Serum	Confirmed Case	+	+
10	200208428	Serum	Confirmed Case	+	+
11	200208185	Serum	Confirmed Case	+	+
12	200208193	Serum	Confirmed Case	+	+
13	200208325	Serum	Confirmed Case	+	+
14	200208399	Serum	Confirmed Case	+	+
15	200208538	Serum	Confirmed Case	-	+
16	200208247	Serum	Confirmed Case	+	+
17	200208272	Serum	Confirmed Case	+	+
18	200208283	Serum	Confirmed Case	+	+
19	200208278	Serum	Confirmed Case	-	-
20	200208551	Serum	Confirmed Case	+	+
21	200208456	Serum	Confirmed Case	+	+
22	200208244	Serum	Confirmed Case	+	+
23	200208615	Serum	Confirmed Case	+	+
24	200208957	Serum	Confirmed Case	+	+
25	200208941	Serum	Confirmed Case	+	+
26	200208964	Serum	Confirmed Case	+	+
27	200208948	Serum	Confirmed Case	-	-
28	200208674	Serum	Confirmed Case	+	+
29	200208593	Serum	Confirmed Case	+	+
30	200208873	Serum	Confirmed Case	+	+
31	200208666	Serum	Confirmed Case	+	+



32	200208865	Serum	Confirmed Case	+	+
33	200208977	Serum	Confirmed Case	+	+
34	200208982	Serum	Confirmed Case	-	-
35	200208911	Serum	Confirmed Case	+	+
36	200208902	Serum	Confirmed Case	+	+
37	200208606	Serum	Confirmed Case	+	+
38	200208933	Serum	Confirmed Case	+	+
39	200208971	Serum	Confirmed Case	+	-
40	200208845	Serum	Confirmed Case	+	+
41	200208996	Serum	Confirmed Case	+	+
42	200208585	Serum	Confirmed Case	+	+
43	200208900	Serum	Confirmed Case	+	-
44	200208895	Serum	Confirmed Case	+	+
45	200208703	Serum	Confirmed Case	+	+
46	200208663	Serum	Confirmed Case	+	+
47	200208892	Serum	Confirmed Case	+	+
48	200208581	Serum	Confirmed Case	+	+
49	200208589	Serum	Confirmed Case	-	-
50	200208905	Serum	Confirmed Case	+	+
51	200208653	Serum	Confirmed Case	+	+
52	200208852	Serum	Confirmed Case	+	-
53	200208700	Serum	Confirmed Case	+	+
54	200208991	Serum	Confirmed Case	+	+
55	200208908	Serum	Confirmed Case	+	-
56	200208889	Serum	Confirmed Case	+	+
57	200209001	Serum	Confirmed Case	+	+
58	200208611	Serum	Confirmed Case	+	+
59	200208708	Serum	Confirmed Case	+	-
60	200208769	Serum	Confirmed Case	+	+
61	200208898	Serum	Confirmed Case	+	+
62	200209006	Serum	Confirmed Case	+	+
63	200208601	Serum	Confirmed Case	+	+
64	200208869	Serum	Confirmed Case	+	+
65	200208706	Serum	Confirmed Case	+	+
66	200209003	Serum	Confirmed Case	-	-
67	200208578	Serum	Confirmed Case	+	+
68	20021800001	Serum	Confirmed Case	+	+



69	20021800002	Serum	Confirmed Case	+	+
70	20021800005	Serum	Confirmed Case	+	+

10 Excluded Samples Results

Item No.	Experiment No.	Type of Sample	Diagnostic Result	Background	Testing Result	
					IgG	IgM
1	20021700001	Serum	Excluded	Suspicious patient	-	-
2	20021700003	Serum	Excluded	Suspicious patient	-	-
3	20021700004	Serum	Excluded	Suspicious patient	-	-
4	20021700005	Serum	Excluded	Suspicious patient	-	-
5	20021700006	Serum	Excluded	Suspicious patient	-	-
6	200208467	Serum	Excluded	Suspicious patient	-	-
7	200208462	Serum	Excluded	Suspicious patient	-	-
8	20021700011	Serum	Excluded	Suspicious patient	-	-
9	200208925	Serum	Excluded	Suspicious patient	-	-
10	200208914	Serum	Excluded	Suspicious patient	-	-

Conclusion:

330 samples in total were evaluated in the clinical trials. The results show that the Relative Sensitivity of ACCU-TELL® COVID-19 IgG/IgM Cassette (Whole Blood/Serum/Plasma) is 93.5%, the Relative Specificity is 97.5% and the Accuracy is 95.5%

For and on behalf of
ACCUBIOTECH CO., LTD.

.....
Authorized Signature(s)