



Clinical Study for SARS-CoV-2 Antigen Rapid Test

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I. Instruction

The SARS-CoV-2 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-Cov-2 nucleocapsid antigens in nasal swab specimens. It is intended to be used by professionals as a screening test in the diagnosis of infection with Novel coronavirus.

II. Study Objective

To perform a clinical sensitivity, specificity study.

III. Material:

SARS-CoV-2 Antigen Rapid Test, Lot# 202009001

Comparison method: RT-PCR, Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing), manufactured by Sansure BioTech Inc.

Extraction Buffer, Lot#:202008001

Nasal swab samples from infected patients and non-infected patients.

IV .Method:

- 1) 304 clinical nasal swabs were collected from patients who were suspected of COVID-19 (within 7 days of onset). All the samples were confirmed with RT-PCR.
- 2) Each sample was run in 1 test and read the result at 15-20 minutes.
- 3) Read the result as positive or negative.

Acceptance Criteria:

Total Sensitivity: $\geq 85\%$

Total Specificity: $\geq 99\%$

VI. Test Results:

Sample No.	RT-PCR	Result	Sample No.	RT-PCR	Result	Sample No.	RT-PCR	Result	Sample No.	RT-PCR	Result
1	+	-	81	-	-	161	+	+	241	-	-
2	-	-	82	-	-	162	-	-	242	-	-
3	-	-	83	-	-	163	-	-	243	-	-
4	-	-	84	-	-	164	-	-	244	-	-
5	+	+	85	-	-	165	+	+	245	-	-
6	-	-	86	-	-	166	-	-	246	+	+
7	-	-	87	+	+	167	-	-	247	-	-
8	-	-	88	-	-	168	-	-	248	-	-
9	+	+	89	-	-	169	-	-	249	-	-
10	-	-	90	+	+	170	+	+	250	-	-
11	-	-	91	-	-	171	-	-	251	-	-
12	-	-	92	-	-	172	-	-	252	+	+
13	-	-	93	-	-	173	+	+	253	-	-
14	-	-	94	-	-	174	-	-	254	-	-
15	-	-	95	-	-	175	-	-	255	-	-
16	-	-	96	-	-	176	-	-	256	-	-
17	-	-	97	-	-	177	-	-	257	-	-

18	-	-	98	-	-	178	-	-	258	-	-
19	-	-	99	+	+	179	-	-	259	-	-
20	+	+	100	-	-	180	-	-	260	-	-
21	-	-	101	-	-	181	-	-	261	-	-
22	-	-	102	-	-	182	+	+	262	-	-
23	-	-	103	-	-	183	-	-	263	-	-
24	-	-	104	-	-	184	-	-	264	-	-
25	-	-	105	-	-	185	-	-	265	-	-
26	-	-	106	-	-	186	-	-	266	-	-
27	-	-	107	-	-	187	-	-	267	-	-
28	-	-	108	+	+	188	-	-	268	+	+
29	-	-	109	-	-	189	-	-	269	-	-
30	-	-	110	-	-	190	-	-	270	-	-
31	-	-	111	-	-	191	-	-	271	-	-
32	-	-	112	-	-	192	-	-	272	-	-
33	-	-	113	-	-	193	-	-	273	-	-
34	-	-	114	-	-	194	-	-	274	-	-
35	-	-	115	-	-	195	-	-	275	-	-
36	-	-	116	-	-	196	-	-	276	-	-
37	-	-	117	+	+	197	-	-	277	-	-
38	-	-	118	-	-	198	-	-	278	-	-
39	+	+	119	+	+	199	-	-	279	-	-
40	-	-	120	-	-	200	-	-	280	-	-
41	-	-	121	-	-	201	-	-	281	-	-
42	-	-	122	-	-	202	-	-	282	-	-
43	-	-	123	-	-	203	+	+	283	-	-
44	-	-	124	+	+	204	-	-	284	-	-
45	-	-	125	+	+	205	-	-	285	-	-
46	-	-	126	-	-	206	-	-	286	-	-
47	-	-	127	-	-	207	-	-	287	+	+
48	-	-	128	-	-	208	+	+	288	-	-
49	-	-	129	-	-	209	-	-	289	-	-
50	-	-	130	-	-	210	-	-	290	-	-
51	-	-	131	-	-	211	-	-	291	-	-
52	-	-	132	-	-	212	-	-	292	-	-
53	-	-	133	-	-	213	-	-	293	-	-
54	-	-	134	-	-	214	-	-	294	-	-
55	-	-	135	-	-	215	-	-	295	-	-
56	-	-	136	-	-	216	-	-	296	-	-
57	+	+	137	-	-	217	-	-	297	-	-
58	-	-	138	-	-	218	-	-	298	-	-
59	-	-	139	-	-	219	+	+	299	-	-
60	-	-	140	-	-	220	-	-	300	-	-
61	-	-	141	-	-	221	-	-	301	+	+
62	-	-	142	-	-	222	-	-	302	-	-
63	-	-	143	-	-	223	+	+	303	-	-
64	-	-	144	-	-	224	-	-	304	-	-
65	-	-	145	+	+	225	+	+	/	/	/
66	-	-	146	-	-	226	-	-	/	/	/

67	-	-	147	-	-	227	-	-	/	/	/
68	-	-	148	-	-	228	-	-	/	/	/
69	-	-	149	-	-	229	-	-	/	/	/
70	-	-	150	-	-	230	-	-	/	/	/
71	-	-	151	-	-	231	+	+	/	/	/
72	-	+	152	+	+	232	-	-	/	/	/
73	-	-	153	-	-	233	-	-	/	/	/
74	-	-	154	-	-	234	-	-	/	/	/
75	-	-	155	-	-	235	-	-	/	/	/
76	-	-	156	-	-	236	+	+	/	/	/
77	-	-	157	-	-	237	-	-	/	/	/
78	-	-	158	-	-	238	+	+	/	/	/
79	-	-	159	-	-	239	-	-	/	/	/
80	-	-	160	-	-	240	-	-	/	/	/

Summary:

Method		RT-PCR		Total Results	
SARS-CoV-2 Antigen Rapid Test	Results	Negative	Positive		
		Negative	269	1	270
		Positive	1	33	34
Total Results		270	34	304	

Conclusions:

The sensitivity, specificity and accuracy for SARS-CoV-2 Antigen Rapid Test meet the acceptance criteria.

	Performance	95%CI
Sensitivity	97.1%	83.8%-99.9%
Specificity	99.6%	97.7%-99.9%
Accuracy	99.3%	97.5%-99.9%