

CLINICAL STUDY REPORT

1. Synopsis

The clinical study is to evaluate the clinical sensitivity and specificity of One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette.

Catalogue number: 2700320

2. Background

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

3. Intended use

One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette is an in vitro diagnostic test device intended for the rapid detection of 2019-nCoV antigen in nasopharyngeal and oropharyngeal swab from patients with suspected 2019-nCoV infection, patients with suspected clustering cases, and others who need to diagnose or differentially diagnose 2019-Novel Coronavirus (2019-nCoV).

4. Material

4.1 Investigational Product name, lot number and study period.

One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette

Lot No.: 20201001

Study period: 13.10.2020-02.11.2020

4.2 Comparison method:

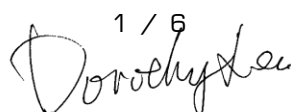
2019-nCoV RNA (Multiple PCR-Fluorescence Probing), manufactured by Guangdong Huayin Medicine Science Co., Ltd.

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

5. Methods

5.1 Demands for the Samples

500 clinical nasal swabs were collected from patients who were suspected of COVID-19 (within 7 days of onset). All samples were unaltered clinical specimens and confirmed with

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RT-PCR. Each sample was blindly labeled by a nonparticipant. Separate sets of the blind coded were assigned. Samples were also randomized prior to testing.

5.2 Each sample was run in 1 test and read the result at 15-20 minutes.

5.3 Interpretation of Results

Negative: Only one color line appears on the control region.

Positive: Two bands are appeared in the test line (T) and control line (C).

Invalid: No visible line at all, or there is a visible line only in the test region and not in the control region.

6. Acceptance Criteria:

Total Sensitivity: $\geq 90\%$

Total Specificity: $\geq 97\%$

7. Results

Test Cassette	RT-PCR		
	positive	negative	total
Positive	106	3	109
Negative	4	387	391
Total	110	390	500

8. Conclusions:

The sensitivity and specificity for One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette meet the acceptance criteria.

	Performance	95%CI
Sensitivity	96.4%	91.0-98.6%
Specificity	99.2%	97.8-99.7%

9. Raw data

Evaluated kits: One Step 2019-Novel Coronavirus (2019-nCoV) Antigen Test Cassette								
Lot Number: 20201001								
Sample No.	RT PCR	Test Cassette	Sample No.	RT PCR	Test Cassette	Sample No.	RT PCR	Test Cassette
1	Negative	Negative	168	Ct:31	Positive	335	Negative	Negative
2	Negative	Negative	169	Negative	Negative	336	Negative	Negative
3	Negative	Negative	170	Ct:29	Positive	337	Negative	Negative
4	Negative	Negative	171	Negative	Negative	338	Ct:34	Positive

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5	Ct:23	Positive	172	Ct:33	Negative	339	Negative	Negative
6	Ct:30	Positive	173	Negative	Negative	340	Ct:30	Positive
7	Negative	Negative	174	Negative	Negative	341	Negative	Negative
8	Negative	Negative	175	Negative	Negative	342	Ct:35	Positive
9	Negative	Negative	176	Negative	Negative	343	Negative	Negative
10	Negative	Negative	177	Negative	Negative	344	Negative	Negative
11	Negative	Negative	178	Negative	Negative	345	Negative	Negative
12	Negative	Negative	179	Negative	Negative	346	Negative	Negative
13	Ct:23	Positive	180	Negative	Negative	347	Negative	Negative
14	Ct:32	Positive	181	Ct:33	Positive	348	Negative	Negative
15	Negative	Negative	182	Negative	Negative	349	Negative	Negative
16	Negative	Negative	183	Negative	Negative	350	Negative	Negative
17	Negative	Negative	184	Negative	Negative	351	Ct:32	Positive
18	Negative	Negative	185	Negative	Negative	352	Negative	Negative
19	Ct:30	Positive	186	Negative	Negative	353	Negative	Negative
20	Negative	Negative	187	Negative	Negative	354	Negative	Negative
21	Negative	Negative	188	Ct:26	Positive	355	Negative	Negative
22	Negative	Negative	189	Negative	Negative	356	Negative	Negative
23	Negative	Negative	190	Negative	Negative	357	Negative	Negative
24	Ct:27	Positive	191	Negative	Negative	358	Ct:32	Positive
25	Negative	Negative	192	Ct:28	Positive	359	Negative	Negative
26	Negative	Negative	193	Ct:32	Negative	360	Negative	Negative
27	Negative	Negative	194	Ct:31	Positive	361	Negative	Negative
28	Negative	Negative	195	Negative	Negative	362	Ct:27	Positive
29	Negative	Negative	196	Negative	Negative	363	Negative	Negative
30	Negative	Negative	197	Negative	Negative	364	Negative	Negative
31	Ct:31	Positive	198	Negative	Negative	365	Negative	Negative
32	Negative	Negative	199	Negative	Negative	366	Ct:27	Positive
33	Negative	Negative	200	Negative	Negative	367	Ct:28	Positive
34	Negative	Negative	201	Negative	Negative	368	Negative	Negative
35	Negative	Negative	202	Negative	Negative	369	Ct:29	Positive
36	Negative	Negative	203	Negative	Negative	370	Negative	Negative
37	Negative	Negative	204	Negative	Negative	371	Negative	Negative
38	Ct:31	Positive	205	Negative	Negative	372	Negative	Negative
39	Negative	Negative	206	Negative	Negative	373	Negative	Negative
40	Negative	Negative	207	Negative	Negative	374	Negative	Negative
41	Negative	Negative	208	Negative	Negative	375	Negative	Negative
42	Negative	Negative	209	Ct:37	Positive	376	Negative	Negative
43	Negative	Negative	210	Ct:28	Positive	377	Negative	Negative
44	Negative	Negative	211	Negative	Negative	378	Ct:29	Positive
45	Negative	Negative	212	Negative	Negative	379	Ct:32	Positive
46	Ct:29	Positive	213	Negative	Negative	380	Ct:29	Positive
47	Negative	Negative	214	Negative	Negative	381	Negative	Negative
48	Ct:28	Positive	215	Negative	Negative	382	Negative	Negative

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49	Negative	Negative	216	Ct:31	Positive	383	Negative	Negative
50	Negative	Negative	217	Negative	Negative	384	Negative	Negative
51	Negative	Negative	218	Negative	Negative	385	Negative	Negative
52	Negative	Negative	219	Negative	Negative	386	Ct:27	Positive
53	Ct:31	Positive	220	Negative	Negative	387	Negative	Negative
54	Negative	Negative	221	Negative	Negative	388	Negative	Negative
55	Negative	Negative	222	Ct:30	Positive	389	Negative	Negative
56	Negative	Negative	223	Negative	Negative	390	Negative	Negative
57	Ct:27	Positive	224	Negative	Negative	391	Ct:31	Positive
58	Negative	Negative	225	Negative	Negative	392	Negative	Negative
59	Negative	Negative	226	Negative	Negative	393	Negative	Negative
60	Negative	Negative	227	Negative	Negative	394	Negative	Negative
61	Negative	Negative	228	Negative	Negative	395	Negative	Negative
62	Negative	Negative	229	Negative	Negative	396	Negative	Negative
63	Negative	Negative	230	Negative	Negative	397	Negative	Negative
64	Ct:30	Positive	231	Negative	Negative	398	Negative	Negative
65	Ct:34	Positive	232	Negative	Negative	399	Ct:37	Positive
66	Negative	Negative	233	Negative	Negative	400	Negative	Negative
67	Negative	Negative	234	Negative	Negative	401	Negative	Negative
68	Ct:32	Positive	235	Negative	Negative	402	Negative	Negative
69	Negative	Negative	236	Negative	Negative	403	Negative	Negative
70	Negative	Negative	237	Ct:28	Positive	404	Negative	Negative
71	Ct:31	Positive	238	Negative	Negative	405	Negative	Negative
72	Negative	Negative	239	Negative	Negative	406	Ct:27	Positive
73	Negative	Negative	240	Ct:28	Positive	407	Negative	Negative
74	Negative	Negative	241	Ct:26	Positive	408	Negative	Negative
75	Negative	Negative	242	Negative	Negative	409	Negative	Negative
76	Negative	Negative	243	Ct:30	Positive	410	Negative	Negative
77	Ct:29	Positive	244	Negative	Negative	411	Negative	Negative
78	Ct:26	Positive	245	Negative	Negative	412	Negative	Negative
79	Negative	Negative	246	Negative	Negative	413	Negative	Negative
80	Negative	Negative	247	Negative	Negative	414	Negative	Negative
81	Negative	Negative	248	Negative	Negative	415	Ct:30	Positive
82	Negative	Negative	249	Negative	Negative	416	Negative	Negative
83	Negative	Negative	250	Negative	Negative	417	Negative	Negative
84	Negative	Negative	251	Negative	Negative	418	Negative	Negative
85	Negative	Negative	252	Negative	Negative	419	Ct:26	Positive
86	Negative	Negative	253	Ct:36	Positive	420	Negative	Negative
87	Negative	Negative	254	Negative	Negative	421	Negative	Negative
88	Negative	Negative	255	Negative	Negative	422	Ct:26	Positive
89	Negative	Negative	256	Negative	Negative	423	Negative	Negative
90	Ct:35	Negative	257	Ct:31	Positive	424	Negative	Negative
91	Negative	Negative	258	Negative	Negative	425	Negative	Negative
92	Negative	Negative	259	Negative	Negative	426	Negative	Negative

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93	Negative	Negative	260	Ct:28	Positive	427	Negative	Negative
94	Ct:35	Positive	261	Negative	Negative	428	Ct:25	Positive
95	Negative	Negative	262	Negative	Negative	429	Ct:32	Positive
96	Negative	Negative	263	Negative	Negative	430	Negative	Negative
97	Negative	Negative	264	Negative	Negative	431	Negative	Negative
98	Negative	Negative	265	Negative	Negative	432	Negative	Negative
99	Negative	Negative	266	Ct:34	Positive	433	Negative	Negative
100	Ct:28	Positive	267	Negative	Negative	434	Negative	Negative
101	Negative	Negative	268	Negative	Negative	435	Ct:28	Positive
102	Ct:33	Positive	269	Ct:29	Positive	436	Negative	Negative
103	Negative	Negative	270	Negative	Negative	437	Negative	Negative
104	Negative	Negative	271	Negative	Negative	438	Negative	Negative
105	Negative	Negative	272	Ct:26	Positive	439	Negative	Negative
106	Negative	Negative	273	Negative	Negative	440	Ct:29	Positive
107	Negative	Negative	274	Ct:30	Positive	441	Negative	Negative
108	Negative	Negative	275	Ct:27	Positive	442	Negative	Negative
109	Ct:31	Positive	276	Negative	Negative	443	Ct:31	Positive
110	Negative	Negative	277	Negative	Negative	444	Negative	Negative
111	Ct:28	Positive	278	Negative	Negative	445	Ct:31	Negative
112	Negative	Negative	279	Negative	Negative	446	Negative	Negative
113	Negative	Negative	280	Negative	Negative	447	Negative	Negative
114	Negative	Negative	281	Negative	Negative	448	Ct:24	Positive
115	Negative	Negative	282	Negative	Negative	449	Negative	Positive
116	Ct:29	Positive	283	Negative	Negative	450	Negative	Negative
117	Negative	Negative	284	Negative	Negative	451	Ct:24	Positive
118	Ct:30	Positive	285	Negative	Negative	452	Negative	Negative
119	Negative	Negative	286	Ct:27	Positive	453	Negative	Negative
120	Negative	Negative	287	Ct:32	Positive	454	Negative	Negative
121	Negative	Negative	288	Negative	Negative	455	Negative	Negative
122	Negative	Negative	289	Negative	Negative	456	Negative	Negative
123	Negative	Negative	290	Negative	Negative	457	Ct:33	Positive
124	Negative	Negative	291	Negative	Negative	458	Negative	Negative
125	Ct:30	Positive	292	Negative	Negative	459	Negative	Negative
126	Negative	Negative	293	Negative	Negative	460	Negative	Negative
127	Negative	Negative	294	Negative	Negative	461	Negative	Negative
128	Negative	Negative	295	Negative	Negative	462	Ct:29	Positive
129	Negative	Negative	296	Negative	Negative	463	Negative	Negative
130	Negative	Negative	297	Negative	Negative	464	Negative	Negative
131	Negative	Negative	298	Negative	Negative	465	Negative	Negative
132	Negative	Negative	299	Negative	Negative	466	Ct:28	Positive
133	Ct:29	Positive	300	Negative	Negative	467	Negative	Negative
134	Ct:24	Positive	301	Negative	Negative	468	Negative	Negative
135	Negative	Negative	302	Negative	Negative	469	Negative	Negative
136	Negative	Negative	303	Ct:32	Positive	470	Ct:28	Positive

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137	Negative	Negative	304	Negative	Negative	471	Negative	Negative
138	Negative	Negative	305	Negative	Negative	472	Negative	Negative
139	Ct:29	Positive	306	Negative	Negative	473	Negative	Negative
140	Ct:32	Positive	307	Negative	Negative	474	Negative	Negative
141	Negative	Negative	308	Negative	Negative	475	Ct:29	Positive
142	Negative	Negative	309	Negative	Negative	476	Ct:32	Positive
143	Negative	Negative	310	Negative	Negative	477	Negative	Negative
144	Negative	Negative	311	Negative	Negative	478	Negative	Negative
145	Negative	Negative	312	Negative	Negative	479	Negative	Negative
146	Ct:30	Positive	313	Negative	Negative	480	Ct:36	Positive
147	Negative	Negative	314	Negative	Negative	481	Negative	Negative
148	Negative	Negative	315	Ct:35	Positive	482	Negative	Negative
149	Negative	Negative	316	Negative	Negative	483	Negative	Negative
150	Ct:28	Positive	317	Negative	Negative	484	Negative	Negative
151	Ct:33	Positive	318	Ct:30	Positive	485	Negative	Negative
152	Ct:26	Positive	319	Ct:30	Positive	486	Negative	Negative
153	Negative	Negative	320	Negative	Positive	487	Ct:26	Positive
154	Negative	Negative	321	Negative	Negative	488	Negative	Negative
155	Ct:33	Positive	322	Negative	Negative	489	Ct:31	Positive
156	Negative	Negative	323	Ct:27	Positive	490	Negative	Negative
157	Negative	Positive	324	Negative	Negative	491	Negative	Negative
158	Ct:28	Positive	325	Negative	Negative	492	Negative	Negative
159	Negative	Negative	326	Negative	Negative	493	Ct:29	Positive
160	Negative	Negative	327	Ct:28	Positive	494	Negative	Negative
161	Negative	Negative	328	Negative	Negative	495	Negative	Negative
162	Ct:32	Positive	329	Negative	Negative	496	Negative	Negative
163	Negative	Negative	330	Negative	Negative	497	Negative	Negative
164	Negative	Negative	331	Negative	Negative	498	Negative	Negative
165	Ct:25	Positive	332	Negative	Negative	499	Ct:23	Positive
166	Negative	Negative	333	Ct:32	Positive	500	Negative	Negative
167	Negative	Negative	334	Negative	Negative			

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