



2019-nCoV Antigen Screen Test (Cassette)

Performance Study Report

Reagent Name:

2019-nCoV Antigen Screen Test (Cassette)

Product Code:

7270681

Format:

20 tests / box (individual packing in aluminum pouch)

Test Specimen:

Nasal swab

Main Researcher:



Hongwei Wu, Hong Feng

Study Period:

01/12/2021 - 02/05/2021

Reporting Date:

02/05/2021

Prepared by:	Hongwei Wu	Date: Feb 05, 2021	Signature: 
Checked by:	Hong Feng	Date: Feb 05, 2021	Signature: 





1. Synopsis

The performance study is to evaluate the clinical sensitivity and specificity of 2019-nCoV Antigen Screen Test (Cassette) when using nasal swab as a test specimen and its cross-reactivity and interference.

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

2019-nCoV Antigen Screen Test (Cassette) is an in vitro diagnostic test device intended for the rapid detection of 2019-nCoV nucleocapsid protein antigen in nasal swab samples 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). The test kit only detects the N protein, and cannot detect the S protein and its mutation structure.

Purpose: The 2019-nCoV Antigen Screen Test (Cassette) is intended for professional in-vitro diagnostics only and serves as an aid to diagnose a Covid-19 infection.

4. Material

4.1 Investigational product name and lot number

2019-nCoV Antigen Screen Test (Cassette)

Lot No.: 20201101

4.2 Comparison method:

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

Nasal swab vs Nasopharyngeal RT-PCR

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

5. Method and Result of Nasal Swab vs Nasopharyngeal RT-PCR

5.1 Method

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 Nasopharyngeal 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.

5.4 Acceptance criteria:

Total Sensitivity: ≥90%

Total Specificity: ≥97%

5.5 Result

Test Cassette	Nasopharyngeal RT-PCR		
	Positive	Negative	Total
Positive	111	3	114
Negative	9	377	386
Total	120	380	500
Sensitivity	92.5% (95%CI: 86.4% - 96.0%)		
Specificity	99.2% (95%CI: 97.7% - 99.7%)		

The sensitivity and specificity of 2019-nCoV Antigen Screen Test (Cassette) when using nasal swab as a test specimen meet the acceptance criteria.

Nasal Swab vs Nasopharyngeal RT-PCR	Performance	95%CI	Ct Values
Sensitivity	92.5%	86.4% – 96.0%	≤ 37
Specificity	99.2%	97.7% – 99.7%	/

6. Cross-reactivity

Cross-reactivity with SARS-CoV-1 has been observed. However, no cross-reactivity with the following viruses was detected:

Interfering substances	Concentration	Results
Influenza A (H1N1)	2x 10 ⁵ TCID50/ml	Negative
Influenza A (H3N2)	3x 10 ⁵ TCID50/ml	Negative
Influenza A (H5N1)	2.5x 10 ⁵ TCID50/ml	Negative
Influenza A (H7N9)	3x 10 ⁵ TCID50/ml	Negative
Influenza B	2x 10 ⁵ TCID50/ml	Negative
MERS-Coronavirus	2x 10 ⁴ TCID50/ml	Negative
Human Coronavirus (NL63)	3x 10 ⁴ TCID50/ml	Negative
Human Coronavirus (229E)	1x 10 ⁵ TCID50/ml	Negative



Human Coronavirus (OC43)	1x 10 ⁵ TCID50/ml	Negative
Respiratory Syncytial Virus (Type A)	3x 10 ⁵ TCID50/ml	Negative
Adenovirus (Type 1)	3x 10 ⁵ TCID50/ml	Negative
Enterovirus (Type 68)	1x 10 ⁵ TCID50/ml	Negative
EB-Virus	1x 10 ⁵ TCID50/ml	Negative
Measles Virus	1x 10 ⁵ TCID50/ml	Negative
Human Cytomegalovirus	3x 10 ⁵ TCID50/ml	Negative
Norovirus	1x 10 ⁵ TCID50/ml	Negative
Rubulavirus	2x 10 ⁵ TCID50/ml	Negative
Varicella-Zoster-Virus	1x 10 ⁵ TCID50/ml	Negative
Mycoplasma pneumoniae	4x 10 ⁴ TCID50/ml	Negative

7. Interference

There was no interference with the following substances proven:

Interfering substances	Concentration	Results
Phenylephrine	15% v/v	Negative
Nasal Gel Sodium Chloride	5% v/v	Negative
Cromolyn	15% v/v	Negative
Oxymetazoline	15% v/v	Negative
Fluconazole	5% w/v	Negative
Throat Lozenge Benzocaine	0.15% w/v	Negative
Sabadilla	20% w/v	Negative
Zincum gluconium	5% w/v	Negative
Alkalol	10% v/v	Negative
Fluticasone Propionate	5% v/v	Negative
Phenol	15% v/v	Negative
Tamiflu	0.5% w/v	Negative
Nasal Ointment Mupirocin	0.25% w/v	Negative
Systemic Tobramycin	0.0004% w/v	Negative

8. Raw Data

Evaluated kits: 2019-nCoV Antigen Screen Test (Cassette)								
Lot Number: 20201101								
Sample No.	Nasopharyngeal RT-PCR	Test Cassette	Sample No.	Nasopharyngeal RT-PCR	Test Cassette	Sample No.	Nasopharyngeal RT-PCR	Test Cassette
1	Negative	Negative	168	Negative	Negative	335	Negative	Negative
2	Negative	Negative	169	Negative	Negative	336	Negative	Negative
3	Ct:32	Positive	170	Negative	Negative	337	Negative	Negative
4	Ct:25	Positive	171	Negative	Negative	338	Negative	Negative



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



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48	Negative	Negative	215	Negative	Negative	382	Negative	Negative
49	Ct:30	Positive	216	Negative	Negative	383	Ct:27	Positive
50	Ct:29	Positive	217	Ct:24	Positive	384	Negative	Negative
51	Ct:27	Positive	218	Ct:27	Positive	385	Ct:34	Negative
52	Negative	Negative	219	Ct:32	Positive	386	Negative	Negative
53	Negative	Negative	220	Ct:36	Positive	387	Ct:33	Positive
54	Negative	Negative	221	Negative	Negative	388	Negative	Negative
55	Negative	Negative	222	Negative	Negative	389	Negative	Negative
56	Negative	Negative	223	Ct:37	Negative	390	Negative	Negative
57	Negative	Negative	224	Negative	Negative	391	Negative	Negative
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	Ct:27	Positive	228	Negative	Negative	395	Negative	Negative
62	Ct:30	Positive	229	Ct:35	Positive	396	Negative	Negative
63	Negative	Negative	230	Negative	Negative	397	Negative	Negative
64	Ct:31	Positive	231	Negative	Negative	398	Negative	Negative
65	Negative	Negative	232	Negative	Negative	399	Negative	Negative
66	Negative	Negative	233	Negative	Negative	400	Negative	Negative
67	Negative	Negative	234	Negative	Negative	401	Negative	Negative
68	Negative	Negative	235	Negative	Negative	402	Ct:26	Positive
69	Negative	Negative	236	Ct:35	Positive	403	Ct:26	Positive
70	Negative	Negative	237	Negative	Negative	404	Ct:24	Positive
71	Negative	Negative	238	Ct:24	Positive	405	Negative	Negative
72	Negative	Negative	239	Negative	Negative	406	Negative	Negative
73	Ct:26	Positive	240	Negative	Negative	407	Ct:34	Positive
74	Negative	Negative	241	Negative	Negative	408	Ct:36	Positive
75	Negative	Negative	242	Negative	Negative	409	Negative	Negative
76	Negative	Negative	243	Negative	Negative	410	Negative	Negative
77	Negative	Negative	244	Negative	Negative	411	Negative	Negative
78	Negative	Negative	245	Negative	Negative	412	Negative	Negative
79	Negative	Negative	246	Ct:27	Positive	413	Negative	Negative
80	Negative	Negative	247	Negative	Negative	414	Negative	Negative
81	Negative	Negative	248	Negative	Negative	415	Negative	Negative
82	Negative	Negative	249	Ct:37	Positive	416	Negative	Negative
83	Ct:30	Positive	250	Negative	Negative	417	Negative	Negative
84	Negative	Negative	251	Ct:29	Positive	418	Negative	Negative
85	Negative	Negative	252	Ct:30	Positive	419	Negative	Negative
86	Negative	Negative	253	Negative	Negative	420	Negative	Negative
87	Negative	Negative	254	Negative	Negative	421	Negative	Negative
88	Negative	Negative	255	Ct:34	Positive	422	Negative	Negative
89	Negative	Negative	256	Negative	Negative	423	Negative	Negative
90	Ct:32	Positive	257	Negative	Negative	424	Ct:28	Positive



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91	Negative	Negative	258	Negative	Negative	425	Negative	Negative
92	Negative	Negative	259	Ct:25	Positive	426	Negative	Negative
93	Negative	Negative	260	Negative	Negative	427	Negative	Negative
94	Negative	Negative	261	Negative	Negative	428	Negative	Negative
95	Negative	Negative	262	Negative	Negative	429	Negative	Negative
96	Ct:33	Positive	263	Negative	Negative	430	Negative	Negative
97	Negative	Negative	264	Ct:28	Positive	431	Negative	Negative
98	Negative	Negative	265	Negative	Negative	432	Negative	Negative
99	Negative	Negative	266	Negative	Negative	433	Negative	Negative
100	Negative	Negative	267	Ct:23	Positive	434	Negative	Negative
101	Ct:29	Positive	268	Negative	Negative	435	Negative	Negative
102	Negative	Negative	269	Negative	Negative	436	Negative	Negative
103	Negative	Negative	270	Ct:23	Positive	437	Negative	Negative
104	Negative	Negative	271	Ct:26	Positive	438	Ct:29	Positive
105	Negative	Negative	272	Negative	Negative	439	Negative	Negative
106	Negative	Negative	273	Ct:30	Positive	440	Negative	Negative
107	Negative	Negative	274	Negative	Negative	441	Ct:30	Positive
108	Negative	Negative	275	Negative	Negative	442	Negative	Negative
109	Ct:35	Negative	276	Ct:24	Positive	443	Ct:31	Positive
110	Negative	Negative	277	Ct:27	Positive	444	Ct:29	Positive
111	Negative	Negative	278	Negative	Negative	445	Ct:33	Positive
112	Negative	Negative	279	Negative	Negative	446	Negative	Negative
113	Negative	Negative	280	Negative	Negative	447	Negative	Negative
114	Negative	Negative	281	Ct:29	Positive	448	Ct:33	Positive
115	Negative	Negative	282	Negative	Negative	449	Negative	Negative
116	Negative	Negative	283	Negative	Negative	450	Negative	Negative
117	Negative	Negative	284	Ct:28	Positive	451	Negative	Positive
118	Negative	Negative	285	Negative	Negative	452	Negative	Negative
119	Negative	Negative	286	Ct:23	Positive	453	Negative	Negative
120	Ct:29	Positive	287	Negative	Negative	454	Negative	Negative
121	Negative	Negative	288	Negative	Negative	455	Ct:29	Positive
122	Ct:29	Positive	289	Negative	Negative	456	Ct:35	Negative
123	Negative	Negative	290	Ct:30	Positive	457	Negative	Negative
124	Negative	Negative	291	Ct:32	Positive	458	Negative	Negative
125	Ct:36	Positive	292	Negative	Negative	459	Negative	Negative
126	Negative	Negative	293	Negative	Negative	460	Negative	Negative
127	Ct:31	Positive	294	Negative	Negative	461	Negative	Negative
128	Ct:24	Positive	295	Negative	Negative	462	Negative	Negative
129	Negative	Negative	296	Negative	Negative	463	Negative	Negative
130	Ct:33	Negative	297	Ct:26	Positive	464	Negative	Negative
131	Negative	Negative	298	Ct:31	Positive	465	Negative	Negative
132	Negative	Negative	299	Negative	Negative	466	Ct:31	Positive
133	Negative	Negative	300	Ct:28	Positive	467	Negative	Negative



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134	Negative	Negative	301	Negative	Negative	468	Negative	Negative
135	Negative	Negative	302	Negative	Negative	469	Ct:25	Positive
136	Negative	Negative	303	Negative	Negative	470	Negative	Negative
137	Negative	Negative	304	Negative	Negative	471	Ct:31	Positive
138	Negative	Negative	305	Ct:32	Negative	472	Ct:33	Positive
139	Negative	Negative	306	Negative	Negative	473	Negative	Negative
140	Negative	Negative	307	Negative	Negative	474	Negative	Negative
141	Negative	Negative	308	Ct:31	Positive	475	Ct:25	Positive
142	Ct:27	Positive	309	Negative	Negative	476	Negative	Negative
143	Ct:33	Positive	310	Negative	Negative	477	Negative	Negative
144	Ct:27	Positive	311	Negative	Negative	478	Ct:27	Positive
145	Ct:29	Positive	312	Negative	Negative	479	Negative	Negative
146	Negative	Negative	313	Ct:23	Positive	480	Negative	Negative
147	Negative	Negative	314	Negative	Negative	481	Negative	Negative
148	Negative	Negative	315	Negative	Negative	482	Negative	Negative
149	Negative	Negative	316	Negative	Negative	483	Ct:24	Positive
150	Negative	Negative	317	Negative	Negative	484	Negative	Negative
151	Ct:34	Positive	318	Negative	Negative	485	Ct:25	Positive
152	Negative	Negative	319	Ct:31	Positive	486	Negative	Negative
153	Negative	Negative	320	Negative	Negative	487	Ct:31	Negative
154	Negative	Negative	321	Negative	Negative	488	Negative	Negative
155	Negative	Negative	322	Negative	Negative	489	Negative	Negative
156	Negative	Negative	323	Negative	Negative	490	Negative	Negative
157	Negative	Negative	324	Negative	Negative	491	Ct:34	Positive
158	Negative	Positive	325	Negative	Negative	492	Negative	Negative
159	Negative	Negative	326	Ct:35	Positive	493	Negative	Negative
160	Ct:28	Positive	327	Negative	Negative	494	Ct:28	Positive
161	Negative	Negative	328	Negative	Negative	495	Negative	Negative
162	Negative	Negative	329	Ct:30	Positive	496	Negative	Negative
163	Negative	Negative	330	Negative	Negative	497	Negative	Negative
164	Negative	Negative	331	Negative	Negative	498	Negative	Negative
165	Ct:27	Positive	332	Negative	Negative	499	Negative	Negative
166	Negative	Negative	333	Negative	Negative	500	Negative	Negative
167	Ct:29	Positive	334	Ct:26	Positive			

Ct: Cycle threshold

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