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Performance Characteristics Study

Product Name:
Rapid 2019-nCoV IgG/IgM Combo Test Card

Part Number: 1N38C2

Principle:
Rapid 2019-nCoV IgG/IgM Combo Test Card utilizes the principle of Immuno-chromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgM line in the test window is closer to the sample well and followed by IgG line. As the test sample flows through the membrane within the test device, the colored–2019-nCoV antigen-colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) of 2019 novel coronavirus, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti-2019 novel coronavirus antibodies in the specimen.

Intended Use:
Rapid 2019-nCoV IgG/IgM Combo Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of IgG and IgM antibodies to 2019 novel coronavirus (2019-nCoV, SARS-CoV-2) in human serum, plasma, or whole blood. Rapid 2019-nCoV IgG/IgM Combo Test Card is a fabulous supplement detection for COVID-19 suspected infected patients besides nucleic acid test, which could greatly raise the accuracy of the detection for COVID-19.

Performance Characteristics Study:
Performance Characteristics Study of 2019-nCoV IgG/IgM Combo Test is composed of the following experiments:
1. Analytical sensitivity and precision
2. Specificity
3. Interference
4. Accuracy
5. Stability

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Analytical Sensitivity and Precision Study

To demonstrate the sensitivity of 2019-nCoV IgG/IgM combo test device is determined properly and the precision performances of the subject devices to evaluate the visual error effect, the following sensitivity studies were performed.

(I) Sample Preparation

Three in–house controls were used in the sensitivity and precision study: Negative, weak positive and positive. Each control level—tested by 3 lots, duplicated by three technicians within a day; all three lots are tested and interpreted by same person.

Controls and acceptance criteria are listed below:

Control Level	Lot number	Expected results	Acceptance %
Negative	Q20020101	N	≥ 85
Weak Positive	Q20020102	P	≥ 85
Positive	Q20020103	P	≥ 85

(II) Procedure

1. Testing devices lot: 3 lots total.
2. Operators: 3 lab technicians (equivalent to Professional use setting) Each technician performs test on all three lots.
3. Testing Controls: Three Blinded control levels are performed; controls are brought to room temperature, thawed and mixed well prior to testing, daily.
4. Testing Intervals: 2 replicates per control level, per day, for 10 consecutive working days.
5. Study is performed by 3 operators and results are interpreted by the same operator/observer, to evaluate the visual error effect. All of the three lots per format, per control level, must be performed and interpreted by same operators.
6. Results are interpreted 15 minutes, after the addition of blinded labeled controls.

(III) Results

The results of the sensitivity and precision study are summarized as shown below, results at 15 minutes.

Lot 1 20020110	Control Level	No.	Expected results	No. of Tested		No. of Negative		No. of Positive		% Agreement	
				IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
Tested by Xiaoyong Zhuang	Neg.	1	N	20	20	20	20	0	0	100	100
	Weak Pos.	2	P	20	20	0	0	20	20	100	100
	Pos.	3	P	20	20	0	0	20	20	100	100
Tested by Zhijuan Jia	Neg.	1	N	20	20	20	20	0	0	100	100
	Weak Pos.	2	P	20	20	0	0	20	20	100	100
	Pos.	3	P	20	20	0	0	20	20	100	100
Tested by Xuehong Chen	Neg.	1	N	20	20	20	20	0	0	100	100
	Weak Pos.	2	P	20	20	0	0	20	20	100	100
	Pos.	3	P	20	20	0	0	20	20	100	100

Lot 2 20020111	Control Level	No.	Expected results	No. of Tested		No. of Negative		No. of Positive		% Agreement	
				IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
Tested by Xiaoyong Zhuang	Neg.	1	N	20	20	20	20	0	0	100	100
	Weak Pos.	2	P	20	20	0	0	20	20	100	100
	Pos.	3	P	20	20	0	0	20	20	100	100
Tested by Zhijuan Jia	Neg.	1	N	20	20	20	20	0	0	100	100
	Weak Pos.	2	P	20	20	0	0	20	20	100	100
	Pos.	3	P	20	20	0	0	20	20	100	100
Tested by Xuehong Chen	Neg.	1	N	20	20	20	20	0	0	100	100
	Weak Pos.	2	P	20	20	0	0	20	20	100	100
	Pos.	3	P	20	20	0	0	20	20	100	100

Lot 3 20020113	Control Level	No.	Expected results	No. of Tested		No. of Negative		No. of Positive		% Agreement	
				IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
Tested by Xiaoyong Zhuang	Neg.	1	N	20	20	20	20	0	0	100	100
	Weak Pos.	2	P	20	20	0	0	20	20	100	100
	Pos.	3	P	20	20	0	0	20	20	100	100
Tested by Zhijuan Jia	Neg.	1	N	20	20	20	20	0	0	100	100
	Weak Pos.	2	P	20	20	0	0	20	20	100	100
	Pos.	3	P	20	20	0	0	20	20	100	100
Tested by Xuehong Chen	Neg.	1	N	20	20	20	20	0	0	100	100
	Weak Pos.	2	P	20	20	0	0	20	20	100	100
	Pos.	3	P	20	20	0	0	20	20	100	100

Summary table for intra-assay results

Control Level	Expected results	No. of Tested		No. of Negative		No. of Positive		% Agreement	
		IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
Neg.	N	180	180	180	180	0	0	100	100
Weak Pos.	P	180	180	0	0	180	180	100	100
Pos.	P	180	180	0	0	180	180	100	100

(IV) Conclusion

1. With the 100% agreement performance on all control levels, which meets the acceptance criteria, study results demonstrate that the 2019-nCoV IgG/IgM combo test sensitivity is accurate and determined properly.

2. Based on the precision and reproducibility study summarized above, the results indicate high agreements of with-in-day, between-day, between lots and between human visual effects.

3. With the fact that no invalid result was reported, human error has been minimized so that 2019-nCoV IgG/IgM combo test can be used easily.

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Specificity Study

(I) Purpose

To evaluate the specificity of 2019-nCoV IgG/IgM combo test device.

(II) Sample Preparation

Samples infected by the following diseases were used in the specificity study: Influenza A Virus, Influenza B Virus, Adenovirus, Rotavirus and Mycoplasma Pneumoniae. Each sample was tested in three triplicates by using one lot of 2019-nCoV IgG/IgM combo tests.

(III) Procedure

Each sample was tested in three triplicates by using one lot of 2019-nCoV IgG/IgM combo tests. Read results at 15 minutes.

(IV) Results

Rapid 2019-nCoV IgG/IgM Combo Test

Part# 1N38C2 Lot# 20020110

Sample Type	Number of samples tested	Negative		Positive	
		IgG	IgM	IgG	IgM
Samples infected by Influenza A Virus	3	3	3	0	0
Samples infected by Influenza B Virus	3	3	3	0	0
Samples infected by Adenovirus	3	3	3	0	0
Samples infected by Rotavirus	3	3	3	0	0
Samples infected by Mycoplasma Pneumoniae	3	3	3	0	0

(V) Conclusion

All the samples showed no affect on the specificity of 2019-nCoV IgG/IgM combo test device.

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Interference Study

(I) Purpose

To evaluate the interference compounds commonly appeared in human blood specimens.

(II) Sample Preparation

All compounds were prepared in three levels of 2019-nCoV IgG/IgM controls to defined concentration. Each compound in each level of controls was tested in three triplicates by using one lot of 2019-nCoV IgG/IgM combo tests.

(III) Procedure

Add the following substances to negative, weak positive and positive controls, to reach the defined concentration.

Substances	Concentration
Rheumatoid Factor	80 IU/ml
Bilirubin	342 μmol/L
Triglyceride	37 mmol/L
Hemoglobin	10 mg/mL

Acceptance criteria: No effect of listed substances at defined concentration in blood samples. If a compound shows interference that either cause negative to become positive or positive to become negative, do 2-fold dilution until the expected result is obtained. The non-interference concentration is set as the lowest concentration that gives expected result.

(IV) Results

Rapid 2019-nCoV IgG/IgM Combo Test

Part# 1N38C2 Lot# 20020110

Substance	Concentration Tested	Negative		Weak Positive		Positive		Interfere (Y/N)
		IgG	IgM	IgG	IgM	IgG	IgM	
Rheumatoid Factor	80 IU/ml	N	N	P	P	P	P	N
Bilirubin	342 μmol/L	N	N	P	P	P	P	N
Triglyceride	37 mmol/L	N	N	P	P	P	P	N
Hemoglobin	10 mg/mL	N	N	P	P	P	P	N

(V) Conclusion

The tested compounds were found not to interfere when tested at the desired concentrations.

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Interference Study

(I) Purpose

To evaluate the interference compounds commonly appeared in common drugs.

(II) Sample Preparation

All compounds were prepared in three levels of 2019-nCoV IgG/IgM controls. Each compound in each level of controls was tested in three triplicates by using one lot of 2019-nCoV IgG/IgM combo tests.

(III) Procedure

Add the following substances to negative, weak positive and positive controls.

Histamine Hydrochloride	Oseltamivir	Arbidol	Meropenem
Interferon-α	Peramivir	Levofloxacin	Tobramycin
Zanamivir	Lopinavir	Azithromycin	
Ribavirin	Ritonavir	Ceftriaxone	

(IV) Results

Rapid 2019-nCoV IgG/IgM Combo Test

Part# 1N38C2 Lot# 20020110

Substance	Negative		Weak Positive		Positive		Interfere (Y/N)
	IgG	IgM	IgG	IgM	IgG	IgM	
Histamine Hydrochloride	N	N	P	P	P	P	N
Interferon-α	N	N	P	P	P	P	N
Zanamivir	N	N	P	P	P	P	N
Ribavirin	N	N	P	P	P	P	N
Oseltamivir	N	N	P	P	P	P	N
Peramivir	N	N	P	P	P	P	N
Lopinavir	N	N	P	P	P	P	N
Ritonavir	N	N	P	P	P	P	N
Arbidol	N	N	P	P	P	P	N
Levofloxacin	N	N	P	P	P	P	N
Azithromycin	N	N	P	P	P	P	N
Ceftriaxone	N	N	P	P	P	P	N
Meropenem	N	N	P	P	P	P	N
Tobramycin	N	N	P	P	P	P	N

(V) Conclusion

The tested compounds were found not to interfere when tested.

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Accuracy Study

(I) Materials

1. Three hundred and five specimens from healthy persons.
2. Seventy four specimens from COVID-19 confirmed patients.
3. Rapid 2019-nCoV IgG/IgM combo Tests (Part number: 1N38C2)

(II) Method and Report

1. Test the three hundred and five specimens from healthy persons with the provided 2019-nCoV IgG/IgM combo tests according to the instructions for use.
2. Test the seventy four specimens from COVID-19 confirmed patients with the provided 2019-nCoV IgG/IgM combo tests according to the instructions for use.
3. Record the results at 15 minutes.

(III) Acceptance Criteria

Clinical sensitivity: ≥ 85%
Clinical specificity: ≥ 85%

(IV) Results and Calculation

Rapid 2019-nCoV IgG/IgM Combo Test

Part# 1N38C2 Lot# 20020110

Table I. Three hundred and five specimens from healthy persons.

Sample No.	Test 1		Test 2		Comments
	IgG	IgM	IgG	IgM	
1	N	N	N	N	
2	N	N	N	N	
3	N	N	N	N	
4	N	N	N	N	
5	P	N	P	N	Positive on IgG
6	N	N	N	N	
7	N	N	N	N	
8	N	N	N	N	
9	N	N	N	N	
10	N	N	N	N	
11	N	N	N	N	
12	N	N	N	N	
13	N	N	N	N	
14	N	N	N	N	
15	N	N	N	N	
16	N	N	N	N	
17	N	N	N	N	
18	N	N	N	N	
19	N	N	N	N	
20	N	N	N	N	
21	N	N	N	N	
22	N	N	N	N	

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23	N	N	N	N	
24	N	N	N	N	
25	N	N	N	N	
26	N	N	N	N	
27	N	N	N	N	
28	N	N	N	N	
29	N	N	N	N	
30	N	N	N	N	
31	N	N	N	N	
32	N	N	N	N	
33	N	N	N	N	
34	N	N	N	N	
35	N	N	N	N	
36	N	N	N	N	
37	N	N	N	N	
38	N	N	N	N	
39	N	N	N	N	
40	N	N	N	N	
41	N	N	N	N	
42	N	N	N	N	
43	N	N	N	N	
44	N	N	N	N	
45	N	N	N	N	
46	N	N	N	N	
47	N	N	N	N	
48	N	N	N	N	
49	N	N	N	N	
50	N	N	N	N	
51	N	N	N	N	
52	N	N	N	N	
53	N	N	N	N	
54	N	N	N	N	
55	N	N	N	N	
56	N	N	N	N	
57	N	N	N	N	
58	N	N	N	N	
59	N	N	N	N	
60	N	N	N	N	
61	N	N	N	N	
62	N	N	N	N	
63	N	N	N	N	
64	N	N	N	N	
65	N	N	N	N	
66	N	N	N	N	
67	N	N	N	N	
68	N	N	N	N	
69	N	N	N	N	
70	N	N	N	N	
71	N	N	N	N	
72	N	N	N	N	
73	N	N	N	N	
74	N	N	N	N	
75	N	N	N	N	
76	N	N	N	N	
77	N	N	N	N	
78	N	N	N	N	
79	N	N	N	N	

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80	N	N	N	N	
81	N	N	N	N	
82	N	N	N	N	
83	N	N	N	N	
84	N	N	N	N	
85	N	N	N	N	
86	N	N	N	N	
87	N	N	N	N	
88	N	N	N	N	
89	N	N	N	N	
90	N	N	N	N	
91	N	N	N	N	
92	N	N	N	N	
93	N	N	N	N	
94	N	N	N	N	
95	P	N	P	N	Positive on IgG
96	N	N	N	N	
97	N	N	N	N	
98	N	N	N	N	
99	N	N	N	N	
100	N	N	N	N	
101	N	N	N	N	
102	N	N	N	N	
103	N	N	N	N	
104	N	N	N	N	
105	N	N	N	N	
106	N	N	N	N	
107	N	N	N	N	
108	N	N	N	N	
109	N	N	N	N	
110	N	N	N	N	
111	N	N	N	N	
112	N	N	N	N	
113	N	N	N	N	
114	N	N	N	N	
115	N	N	N	N	
116	N	N	N	N	
117	N	N	N	N	
118	N	N	N	N	
119	N	N	N	N	
120	N	N	N	N	
121	N	N	N	N	
122	N	N	N	N	
123	N	N	N	N	
124	N	N	N	N	
125	N	N	N	N	
126	N	N	N	N	
127	N	N	N	N	
128	N	N	N	N	
129	N	N	N	N	
130	N	N	N	N	
131	N	N	N	N	
132	N	N	N	N	
133	N	N	N	N	
134	N	N	N	N	
135	N	N	N	N	
136	N	N	N	N	

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137	N	N	N	N	
138	N	N	N	N	
139	N	N	N	N	
140	N	N	N	N	
141	N	N	N	N	
142	N	N	N	N	
143	N	N	N	N	
144	N	N	N	N	
145	N	N	N	N	
146	N	N	N	N	
147	N	N	N	N	
148	N	N	N	N	
149	N	N	N	N	
150	N	N	N	N	
151	N	N	N	N	
152	N	N	N	N	
153	N	N	N	N	
154	N	N	N	N	
155	N	N	N	N	
156	N	N	N	N	
157	N	N	N	N	
158	N	N	N	N	
159	N	N	N	N	
160	N	N	N	N	
161	N	N	N	N	
162	N	N	N	N	
163	N	N	N	N	
164	N	N	N	N	
165	N	N	N	N	
166	N	N	N	N	
167	N	N	N	N	
168	N	N	N	N	
169	N	N	N	N	
170	N	N	N	N	
171	N	N	N	N	
172	N	N	N	N	
173	N	N	N	N	
174	N	N	N	N	
175	N	N	N	N	
176	N	N	N	N	
177	N	N	N	N	
178	N	N	N	N	
179	N	N	N	N	
180	N	N	N	N	
181	N	N	N	N	
182	N	N	N	N	
183	N	N	N	N	
184	N	N	N	N	
185	N	N	N	N	
186	N	N	N	N	
187	N	N	N	N	
188	N	N	N	N	
189	N	N	N	N	
190	N	N	N	N	
191	N	N	N	N	
192	N	N	N	N	
193	N	N	N	N	

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194	N	N	N	N	
195	N	N	N	N	
196	N	N	N	N	
197	N	N	N	N	
198	N	N	N	N	
199	N	N	N	N	
200	N	N	N	N	
201	N	N	N	N	
202	N	N	N	N	
203	N	N	N	N	
204	N	N	N	N	
205	N	N	N	N	
206	N	N	N	N	
207	N	N	N	N	
208	N	N	N	N	
209	N	N	N	N	
210	N	P	N	P	Positive on IgM
211	N	N	N	N	
212	N	N	N	N	
213	N	N	N	N	
214	N	N	N	N	
215	N	N	N	N	
216	N	N	N	N	
217	N	N	N	N	
218	N	N	N	N	
219	N	N	N	N	
220	N	N	N	N	
221	N	N	N	N	
222	N	N	N	N	
223	N	N	N	N	
224	N	N	N	N	
225	N	N	N	N	
226	N	N	N	N	
227	N	N	N	N	
228	N	N	N	N	
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235	N	N	N	N	
236	N	N	N	N	
237	N	N	N	N	
238	N	N	N	N	
239	N	N	N	N	
240	N	N	N	N	
241	N	N	N	N	
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248	N	N	N	N	
249	N	N	N	N	
250	N	N	N	N	

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251	N	N	N	N	
252	N	N	N	N	
253	N	N	N	N	
254	N	N	N	N	
255	N	N	N	N	
256	N	N	N	N	
257	N	N	N	N	
258	N	N	N	N	
259	N	N	N	N	
260	N	N	N	N	
261	N	N	N	N	
262	N	N	N	N	
263	N	N	N	N	
264	N	N	N	N	
265	N	N	N	N	
266	N	N	N	N	
267	N	N	N	N	
268	N	N	N	N	
269	N	N	N	N	
270	N	N	N	N	
271	N	N	N	N	
272	N	N	N	N	
273	N	N	N	N	
274	N	N	N	N	
275	N	N	N	N	
276	N	N	N	N	
277	N	N	N	N	
278	N	N	N	N	
279	N	N	N	N	
280	N	N	N	N	
281	N	N	N	N	
282	N	N	N	N	
283	N	N	N	N	
284	N	N	N	N	
285	N	N	N	N	
286	N	N	N	N	
287	N	N	N	N	
288	N	N	N	N	
289	N	N	N	N	
290	N	N	N	N	
291	N	N	N	N	
292	N	N	N	N	
293	N	N	N	N	
294	N	N	N	N	
295	N	N	N	N	
296	N	N	N	N	
297	N	N	N	N	
298	N	N	N	N	
299	N	N	N	N	
300	N	N	N	N	
301	N	N	N	N	
302	N	N	N	N	
303	N	N	N	N	
304	N	N	N	N	
305	N	N	N	N	

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Calculation:
Specificity of IgG = IgG negative/ total number of samples= (305-2) / 305 *100% =99.3%
Specificity of IgM = IgM negative/ total number of samples= (305-1) / 305 *100% =99.7%
Both IgG and IgM specificity meet the acceptance criteria.

Table II. Seventy four specimens from COVID-19 confirmed patients.

Sample No.	Test 1		Test 2		Comments
	IgG	IgM	IgG	IgM	
1	N	P	N	P	
2	N	N	N	N	Negative on IgM and IgG
3	P	P	P	P	
4	N	P	N	P	
5	N	P	N	P	
6	P	P	P	P	
7	P	N	P	N	
8	N	P	N	P	
9	N	P	N	P	
10	P	P	P	P	
11	N	P	N	P	
12	N	P	N	P	
13	N	P	N	P	
14	N	N	N	N	Negative on IgM and IgG
15	N	P	N	P	
16	N	P	N	P	
17	N	P	N	P	
18	P	P	P	P	
19	N	P	N	P	
20	N	P	N	P	
21	N	P	N	P	
22	N	P	N	P	
23	P	P	P	P	
24	N	P	N	P	
25	N	P	N	P	
26	P	P	P	P	
27	N	N	N	N	Negative on IgM and IgG
28	P	P	P	P	
29	P	P	P	P	
30	N	P	N	P	
31	P	P	P	P	
32	N	P	N	P	
33	P	P	P	P	
34	N	P	N	P	
35	N	P	N	P	
36	P	P	P	P	
37	N	N	N	N	Negative on IgM and IgG
38	P	P	P	P	
39	P	P	P	P	
40	N	P	N	P	
41	P	P	P	P	
42	N	P	N	P	
43	N	P	N	P	
44	P	N	P	N	

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45	N	N	N	N	Negative on IgM and IgG
46	P	P	P	P	
47	N	P	N	P	
48	N	P	N	P	
49	P	P	P	P	
50	N	N	N	N	Negative on IgM and IgG
51	P	P	P	P	
52	N	P	N	P	
53	N	P	N	P	
54	N	P	N	P	
55	P	P	P	P	
56	N	N	N	N	Negative on IgM and IgG
57	P	P	P	P	
58	N	P	N	P	
59	N	P	N	P	
60	P	P	P	P	
61	N	P	N	P	
62	N	P	N	P	
63	P	N	P	N	
64	N	N	N	N	Negative on IgM and IgG
65	N	P	N	P	
66	P	P	P	P	
67	N	P	N	P	
68	N	P	N	P	
69	N	P	N	P	
70	N	P	N	P	
71	N	N	N	N	Negative on IgM and IgG
72	N	P	N	P	
73	N	P	N	P	
74	P	N	P	N	

Calculation:
Sensitivity of IgG/IgM = IgG/IgM positive/ total number of samples= (74-9) / 74 *100% =87.8%
Sensitivity of IgG/IgM meet the acceptance criteria.

(V) Conclusion

1. No invalid results were reported. Human error has been minimized so that 2019-nCoV IgG/IgM combo test can be used easily.
2. Based on the calculation that specificity of IgG is 99.3% and IgM is 99.7%, the study results demonstrate 2019-nCoV IgG/IgM combo tests meet the acceptance criteria and reach the high agreement with expected results.
3. With the facts that sensitivity of IgG/IgM is 87.8%, we conclude that 2019-nCoV IgG/IgM combo tests succeed in sensitivity performance with accurate results.

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Product Stability Study

The product stability was evaluated under the stability guideline, Product Stability Evaluation. To verify the recommended storage condition at 4-30°C, three stability studies were performed: real time study at refrigerated temperature (2-8°C) and room temperature (15 – 30°C) for 24 months, an accelerated study at 40°C for 10 weeks. Based on the European stability regulations, "In use" real time stability studies will be added to design protocol. "In use" real time stability study tests the performance of devices removed from pouches and exposed to ambient temperature and humidity. Duplicate tests were performed on each control level. The table lists the testing schedule and the acceptance criteria.

Temperature	Testing Period	Testing schedule and No. of lots	Expected results		
			Negative	Weak Positive	Positive
40°C	10 weeks	Per protocol	N	P	P
2-8°C	24 months	Per protocol	N	P	P
RT	24 months	Per protocol	N	P	P
RT without pouch	24 hours	Per protocol	N	P	P
Acceptance %			≥ 85	≥ 85	≥ 85

Product Lot Number List

Lot Number	2019-nCoV IgG/IgM Combo Test	Control Level	Lot number
Lot 1	20020110	Negative	Q20020101
Lot 2	20020111	Weak Positive	Q20020102
Lot 3	20020112	Positive	Q20020103

The summary result of each testing is tabulated and presented in the following tables:

Unopened pouch product

Table I. Accelerated Stability (40°C) (As of 03/12/2020)

Batch Tested	Control Levels	Expected Results	Total No. passed/Total No. Tested		Agreement %
			IgG	IgM	
Lot 1	Neg.	N	14/14	14/14	100
	Weak Pos.	P	14/14	14/14	100
	Pos.	P	14/14	14/14	100
Lot 2	Neg.	N	14/14	14/14	100
	Weak Pos.	P	14/14	14/14	100
	Pos.	P	14/14	14/14	100
Lot 3	Neg.	N	14/14	14/14	100
	Weak Pos.	P	14/14	14/14	100
	Pos.	P	14/14	14/14	100

Note: Accelerated temperature stability is still going on and will be completed by 04/10/2020. Report was summarized based on current data.

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Table II. Room Temperature (15-30℃) (As of 03/12/2020)

Batch Tested	Control Levels	Expected Results	Total No. passed/Total No. Tested		Agreement %
			IgG	IgM	
Lot 1	Neg.	N	4/4	4/4	100
	Weak Pos.	P	4/4	4/4	100
	Pos.	P	4/4	4/4	100
Lot 2	Neg.	N	4/4	4/4	100
	Weak Pos.	P	4/4	4/4	100
	Pos.	P	4/4	4/4	100
Lot 3	Neg.	N	4/4	4/4	100
	Weak Pos.	P	4/4	4/4	100
	Pos.	P	4/4	4/4	100

Note: Room Temperature Stability is still going on and will be completed by 02/01/2022. Report was summarized by the current data.

Table III. Refrigerated Temperature (2-8℃)

Batch Tested	Control Levels	Expected Results	Total No. passed/Total No. Tested		Agreement %
			IgG	IgM	
Lot 1	Neg.	N	2/2	2/2	100
	Weak Pos.	P	2/2	2/2	100
	Pos.	P	2/2	2/2	100
Lot 2	Neg.	N	2/2	2/2	100
	Weak Pos.	P	2/2	2/2	100
	Pos.	P	2/2	2/2	100
Lot 3	Neg.	N	2/2	2/2	100
	Weak Pos.	P	2/2	2/2	100
	Pos.	P	2/2	2/2	100

Note: Refrigerated Temperature Stability is still going on and will be completed by 02/01/2022. Report was summarized by the current data.

Table IV. "In use" Real Time Un-pouched Stability

2019-nCoV IgG/IgM Combo tests PN#:1N38C2 Lot# 20020110

Interval		0 hour		2 hours		4 hours		8 hours		24 hours	
Control Level		Test 1	Test 2	Test 1	Test 2	Test 1	Test 2	Test 1	Test 2	Test 1	Test 2
Neg	IgG	N	N	N	N	N	N	N	N	N	N
	IgM	N	N	N	N	N	N	N	N	N	N
Weak Pos.	IgG	P	P	P	P	P	P	P	P	P	P
	IgM	P	P	P	P	P	P	P	P	P	P
Pos.	IgG	P	P	P	P	P	P	P	P	P	P
	IgM	P	P	P	P	P	P	P	P	P	P

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Control Level	Expected results	No. of Tested		No. of Negative		No. of Positive		% Agreement	
		IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
Neg.	N	10	10	10	10	0	0	100	100
Weak Pos.	P	10	10	0	0	10	10	100	100
Pos.	P	10	10	0	0	10	10	100	100

Table V. Specimen Stability

Specimen stability was evaluated by testing 2019-nCoV IgG/IgM controls at two storage conditions: refrigerate at 2-8ºC and frozen at -15--20ºC for seven consecutive working days. The summary result of each testing is tabulated and presented in the following table.

Condition	Control Levels	Expected Results	Total No. passed/Total No. Tested		Agreement %
			IgG	IgM	
2-8ºC	Neg.	N	14/14	14/14	100
	Weak Pos.	P	14/14	14/14	100
	Pos.	P	14/14	14/14	100
-15--20ºC	Neg.	N	14/14	14/14	100
	Weak Pos.	P	14/14	14/14	100
	Pos.	P	14/14	14/14	100

Conclusion: 2019-nCoV controls are stable at -20ºC or 2-8ºC for at least 7 days.

Conclusion:

1. Based on the stability data evaluated by 3 batches of 2019-nCoV IgG/IgM combo tests at 40ºC stressed environment, results showed 100% agreement performance on all control levels, which meets the acceptance criteria. Based on the Boson production pattern, we could predict that 2019-nCoV IgG/IgM combo test devices are stable in the defined time range and storage condition.
2. Room temperature stability study is still ongoing, and will be done by 02/01/2022. With current results, devices retained in room temperature are stable on performance with 100% agreement.
3. The first testing (month 6) of three lots stored in refrigerated temperature (2-8ºC) will be on 08/01/2020. No data available right now.
4. The ‘in use” Real time stability (un-pouched) results indicated that there were no significantly functional discrepancy between 2019-nCoV IgG/IgM combo test devices with pouch and without pouch, in the defined time range, twenty-four hours.
5. From the summary of specimen stability study, we concluded that the 2019-nCoV IgG/IgM controls are stable at two storage conditions: (1) 2-8 ºC for 7 days, (2) -20 ºC for at least 7 days.