Technical Product Report

For

All*Check* COVID-19 IgG/IgM

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Revision history

Rev. No.	Revised date on	Revised contents
0	2020. 05.15	Established
1	2020.07.02	Addition of extra clinical performance results

Responsibility

Prepared by	Reviewed by	Approved by
2020/07/02	20. 7. 2	20. 7. 2
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A. Product description

A.1. Product name

All*Check* COVID-19 IgG/IgM

A.2. Intended use

All*Check* COVID-19 IgG/IgM is a rapid immunochromatographic test for the qualitative detection of IgM and IgG antibodies to the SARS-CoV-2 in human serum, plasma, venous or capillary whole blood. Results from the All*Check* COVID-19 IgG/IgM System should not be used as the sole basis for diagnosis.

A.3. Explanation of the test

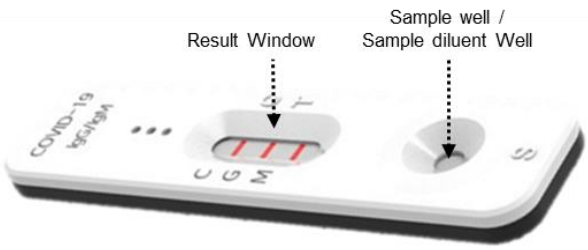
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by 2019-nCoV, a new strain of coronavirus that has not been previously identified in humans. The disease is primarily spread between people via respiratory droplets from infected individuals when they cough or sneeze. Time from exposure to onset of symptoms is generally between 2 and 14 days. The disease may initially present with few or no symptoms, or may develop into fever, coughing, shortness of breath, pain in the muscles and tiredness.

Detection of 2019-nCoV IgM and IgG antibodies in human blood can be used as an auxiliary means for early screening of COVID-19.

2019-nCoV IgM antibody could be detected in patient blood in 3-5 days after onset and IgG could be detected in 7 days after onset. However, the trend of IgM and IgG changes in different cases is not exactly the same. As it is a novel disease diagnosis and treatment of which are being explored, please refer to the latest guidelines for diagnosis and treatment of COVID-19.

A.7. External and specification

A.7.1. Externals – Appearance



20 mm x 77 mm x 5mm (L x W x H)

A.7.2. Shelf-life

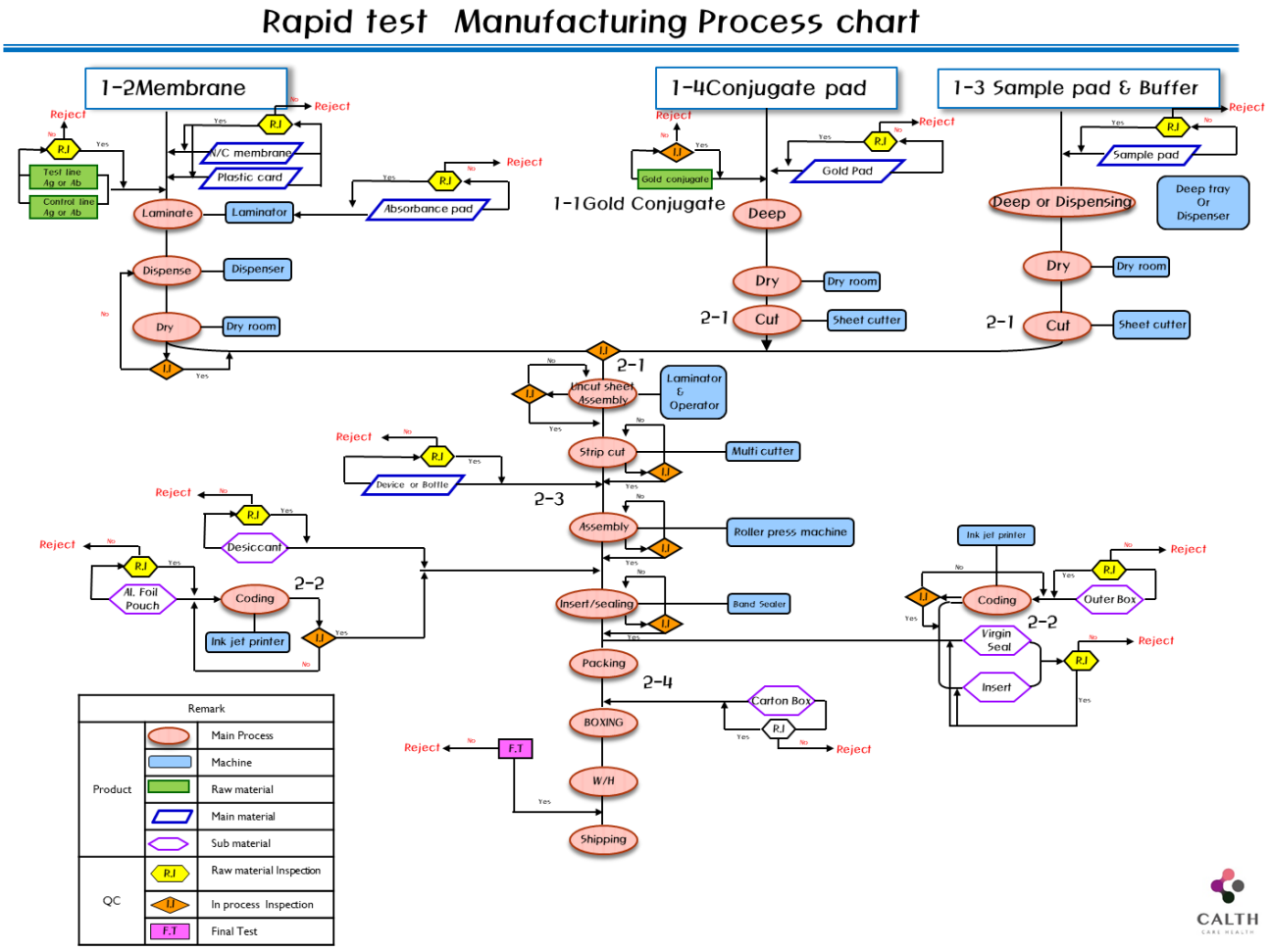
12 months from date of manufacture at 1~30 ℃ (34~86 ℉)

A.7.3. Contents

25 of COVID-19 Test devices, 1 of Dropping Bottle containing sample diluent, 25 of 10㎕ Capillary pipette, 1 of package insert

B. Development

B.1 Manufacturing Process



C. Analytical performance

C.1 Analytical Sensitivity (Limit of Detection)

The Limit of Detection (LoD) study was performed to establish the lowest concentration of SARS-CoV-2 that can be detected by All*Check* COVID-19 IgG/IgM at least 95% of the time. The study results showed that the LoD of All*Chec*k COVID-19 IgG/IgM are 1:40 for IgM and 1:80 for IgG.

	Dilution	Result	Positive Rate(%)
COVID-19 IgM	1:10	300(+)/300	100%
	1:20	300(+)/300	100%
	1:40	300(+)/300	100%
	1:80	150(+)/300	50%
	1:100	0(+)/300	0%

	Dilution	Result	Positive Rate(%)
COVID-19 IgG	1:10	300(+)/300	100%
	1:20	300(+)/300	100%
	1:40	300(+)/300	100%
	1:80	150(+)/300	50%
	1:100	0(+)/300	0%

C.2. Analytical specificity (cross reactivity and Interference)

C.2.1 Cross reactivity

It was tested three times with total 11 kinds of cross reacting substances spiked negatives.
It had no effect in below substances.

No.	Cross reacting substances
1	Human coronavirus NL63
2	Human coronavirus 229E
3	Human coronavirus HKU1(HCOV-HKU1)
4	Influenza A
5	Influenza B
6	Adenovirus
7	RSV-A
8	RSV-B
9	HCV Performance panel
10	HIV Performance panel
11	HBsAg Performance panel

C.2.2 Interference

It was tested three times with total 9 kinds of interfering substance spiked positives with 3 different titer and negatives.

It had no effect in below substances.

No.	Interfering substance	Concentration	Reactivity
1	Conjugated Bilirubin	0.02mg/mL	-
2	Cholesterol	15mg/mL	-
3	Lipids	20mg/mL	-
4	Sodium Heparin	30mg/mL	-
5	Na citrate	10mg/mL	-
6	Na-EDTA	20mg/mL	-
7	Albumin	20mg/mL	-
8	Hemoglobin	50mg/mL	-
9	Glucose	1.2mg/mL	-

C.2.3 Precision Study

Repeatability test and reproducibility test were performed using positives with 3 different titers and negatives.

C.2.3.1 Repeatability

All results a total of 80 replicates were found to be “PASS”.

One tester repeated the test twice a day for 20 days, and after performing 2runs in one test, the positive result was positive (100%) and negative (100%) within 10 minutes of the reading time.

Target	Titer	Result	Positive Rate(%)
Negative sample		80(-)/80	0%
COVID-19 IgM	High	80(+)/80	100%
	Medium	80(+)/80	100%
	Low	80(+)/80	100%
COVID-19 IgG	High	80(+)/80	100%
	Medium	80(+)/80	100%
	Low	80(+)/80	100%

C.2.3.2 Reproducibility

All results a total of 180 replicates were found to be “PASS”.

Three testers repeated tests for 5 days twice a day in 3 different places (Lab 1, Lab 2, QC room), and after 2 runs of 1 test, positive within 10 minutes of reading time was positive (100%), Negative (100%) showed the same result.

Target	Titer	Result	Positive Rate(%)
Negative sample		180(-)/180	0%
COVID-19 IgM	High	180(+)/180	100%
	Medium	180(+)/180	100%
	Low	180(+)/180	100%
COVID-19 IgG	High	180(+)/180	100%
	Medium	180(+)/180	100%
	Low	180(+)/180	100%

D. Stability Performance Evaluation Study

D.1 Stability Study

Through accelerated stability test conducted at 50℃ and 55℃, it was confirmed that AllCheck COVID-19 IgG/IgM is stable for 12 months. Real-time tests and accelerated stability study are on-going as planned. Tests are repeated 3 times for 3 lots at weekly intervals under the following conditions.

Accelerated stability test Condition		Shelf-life	Claimed shelf-life At the present time
Setting Temperature	Acceptance criteria		
55℃	63 days	580 days	365 days 12 months
50℃	63 days	390 days	

It was confirmed that all 3 lots of AllCheck COVID-19 IgG/IgM are stable for at least 12 months at 1~30℃.

D.2 Transport Stability Study

The first group of test kits was stored at 5±3℃ and was subjected to transport condition at 45℃ for 3 or 7 days. Three lots were tested under these conditions.

Stress Condition Duration	Test Period	IgM	IgG	Negative
3 days	1 month	27(+)/27	27(+)/27	9(-)/9
	1 month + 3 days at 45℃	27(+)/27	27(+)/27	9(-)/9
	2 months	27(+)/27	27(+)/27	9(-)/9
7 days	1 month	27(+)/27	27(+)/27	9(-)/9
	1 month + 7 days at 45℃	27(+)/27	27(+)/27	9(-)/9
	2 months	27(+)/27	27(+)/27	9(-)/9

The second group of test kits was stored at 25±5℃ and was subjected to transport condition at 45℃ for 3 or 7 days Three lots were tested under these conditions.

Stress Condition Duration	Test Period	IgM	IgG	Negative
3 days	1 month	27(+)/27	27(+)/27	9(-)/9
	1 month + 3 days at 45℃	27(+)/27	27(+)/27	9(-)/9
	2 months	27(+)/27	27(+)/27	9(-)/9
7 days	1 month	27(+)/27	27(+)/27	9(-)/9
	1 month + 7 days at 45℃	27(+)/27	27(+)/27	9(-)/9
	2 months	27(+)/27	27(+)/27	9(-)/9

The transport stability study is still on-going but results up to date shows that AllC*heck* COVID-19 IgG/IgM is stable after undergoing stressful transport conditions.

E. Clinical Performance Evaluation Study

E.1 Clinical Evaluation 1

For the Clinical sensitivity,
31 positive serum samples were collected from individuals who tested positive with a RT-PCR method for SARS-CoV-2 infection and were collected within 8-40 days after onset of symptoms.
29 of 31 were found to be reactive with All*Check* COVID-19 IgG/IgM.

For Clinical specificity,
Of 40 negative serum samples were collected from individuals who tested negative with a RT-PCR method for SARS-CoV-2 infection, 37 were found to be non-reactive with All*Check* COVID-19 IgG/IgM.

Sensitivity

		Days after onset		Total
		8~14	15~40	
All*Check* COVID-19	IgM	40% (2/5)	61.54% (16/26)	58.06% (18/31)
	IgG	80% (4/5)	96.15% (25/26)	93.55% (29/31)
Total		80% (4/5)	96.15% (25/26)	93.55% (29/31)

A total of 31 tests were performed to detect IgG and IgM antibodies in 31 positive samples. Among these, IgG was detected in 18 of the 31 positive samples, and IgM was detected in 29 of the 31 positive samples. The positive tests were validated via RT-PCR so the presence of IgG and IgM was undetermined prior to testing. Thus, the positive samples may or may not have contained either IgG/IgM or both. In total, it was concluded that out of 31 tests, the sensitivity of detecting either IgG or IgM antibodies was 93.55%.

Specificity

		Negatives
All*Check* COVID-19	IgM	95.0% (38/40)
	IgG	97.5% (39/40)
Total		92.5% (37/40)

A total of 40 negative samples were used to determine the specificity of All*Check* COVID-19 IgG/IgM. Out of 40 negative samples, IgM was not detected in 38 samples while IgG was not detected in 39 samples. In total, it was concluded that out of 40 tests, the specificity of All*Check* COVID-19 IgG/IgM was 92.5%.

Total

		RT-PCR method		Total
		Positive	Negative	
All*Check* COVID-19	Positive	29	3	32
	Negative	2	37	39
Total		31	40	71

Sensitivity: 93.5%, Specificity: 92.5%

E.2 Clinical Evaluation 2

For the Clinical sensitivity,
80 positive serum samples were collected from individuals who tested positive with a RT-PCR method for SARS-CoV-2 infection and were collected from 8 days after onset of symptoms.
75 of 80 were found to be reactive with All*Check* COVID-19 IgG/IgM.

For Clinical specificity,
Of 80 negative serum samples were collected from individuals who tested negative with a RT-PCR method for SARS-CoV-2 infection, 75 were found to be non-reactive with All*Check* COVID-19 IgG/IgM.

Sensitivity

		Days after onset		Total
		8~14	15~	
All*Check* COVID-19	IgM	63.64% (21/33)	76.60% (36/47)	71.25% (57/80)
	IgG	72.73% (24/33)	97.87% (46/47)	87.50% (70/80)
Total		87.88% (29/33)	97.87% (46/47)	93.75% (75/80)

A total of 80 tests were performed to detect IgG and IgM antibodies in 80 positive samples. Among these, IgG was detected in 70 of the 80 positive samples, and IgM was detected in 57 of the 80 positive samples. The positive tests were validated via RT-PCR so the presence of IgG and IgM

was undetermined prior to testing. Thus, the positive samples may or may not have contained either IgG/IgM or both. In total, it was concluded that out of 80 tests, the sensitivity of detecting either IgG or IgM antibodies was 93.75%.

Specificity

		Negatives
All*Check* COVID-19	IgM	95.0% (76/80)
	IgG	98.75% (79/80)
Total		93.75% (75/80)

A total of 80 negative samples were used to determine the specificity of All*Check* COVID-19 IgG/IgM. Out of 80 negative samples, IgM was not detected in 76 samples while IgG was not detected in 79 samples. In total, it was concluded that out of 80 tests, the specificity of All*Check* COVID-19 IgG/IgM was 92.5%.

Total

		RT-PCR method		Total
		Positive	Negative	
All*Check* COVID-19	Positive	75	5	80
	Negative	5	75	80
Total		80	80	160

Sensitivity: 93.75%, Specificity: 93.75%

Totally, the sensitivity and specificity of All*Check* COVID-19 IgG/IgM from 2 different clinical evaluation were 93.69% and 93.33% respectively.

		RT-PCR method		Total
		Positive	Negative	
All*Check* COVID-19	Positive	104	8	112
	Negative	7	112	119
Total		111	120	231