Clinical Sensitivity and Specificity Study Report

The "COVID-19 IgG/IgM Rapid Test" developed by Hangzhou Clongene Biotech Co.,Ltd .is for qualitative detection of antibodies (IgG and IgM) to Novel coronavirus in human Whole Blood/Serum/Plasma. By studying on the statistical coincident rate,we could validate if it could be used for detection of antibodies (IgG and IgM) to Novel coronavirus in human Whole Blood/Serum/Plasma.

1. Method

Regarding the IgM test, Testing was performed on approximately 167 clinical specimens from Professional Point of Care sites, Regarding the IgM test, the result was compared to RT-PCR.Regarding the IgG test, we have counted the positive rate of the 77 patients during the convalescence period.

2. Result

2.1 COVID-19 IgM

Agreement with RT-PCR

COVID-19 IgM		RT-PCR		Total
		Positive	Negative	
Hangzhou Clungene Biotech	Positive	67	1	68
	Negative	10	89	99
Total		77	90	167

Clinical Sensitivity（%）=67/（67+10）*100%=87.01%
Clinical Specificity（%）= 89/（1+89）*100%=98.89%
Total Coincidence Rate（%）=[（67+89）/（67+10+1+89）]=93.41%

2.2 COVID-19 IgG

COVID-19 IgG		Number of patients during the convalescence period	Total
Hangzhou Clungene Biotech	Positive	75	75
	Negative	2	2
Total		77	77

Clinical Sensitivity（%）= 75/（75+2）*100%=97.40%

3. Conclusion

The clinical research is a qualitative test comparison to evaluate the clinical use validity and group professional test applicability of the "COVID-19 IgG/IgM Rapid Test" developed by Hangzhou Clongene Biotech Co., Ltd.

For COVID-19 IgM, when compared to RT-PCR, A statistical comparison was made between the results yielding a sensitivity of 87.01%, a specificity of 98.89% and an accuracy of 93.41%. For COVID-19 IgG, counted the positive rate during the convalescence period, the results yielding a sensitivity of 97.40%.

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杭州隆 HANGZHOU

CE46PT0502

Hangzhou Clongene Biotech Co., Ltd.

COVID-19 IgG/IgM Rapid Test

Sensitivity Study Report

Author: Guoqin Chen

Final report date: 2020.02.12

Management of the study: Hangzhou Clongene Biotech Co., Ltd.
R& D Department
Quality Management department

Place of study: Hangzhou

Sponsor: Hangzhou Clongene Biotech Co., Ltd.

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基生物
LONGENE

Study Director Signature and Verification Dates

Study Director: Guoqin Chen

Company: Hangzhou Clongene Biotech Co., Ltd

Position: Director of R&D Department

Signature: _____ Date: 2020.02.12

Study Handlers: Qingqing Chen

Signature: _____ Date: 2020.02.12

Verifier: Zhiqiang Yin

Signature: _____ Date: 2020.02.12

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技术
BIOTE

The study dates were as follows:

Protocol Effective Date: 2020-02-09
Test Starting Date: 2020-02-11
Test Duration Date: 2020-02-11 ~ 2020-02-11
Final Report Date: 2020-02-12

Study Summary

We tested three batches of the COVID-19 IgG/IgM Rapid Test by clinical specimen. Test results is that all borderline positive serum specimens had positive results, It indicates that the sensitivity of the COVID-19 IgG/IgM Rapid Test is consistent with the standards.

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1. Purpose

This test was to validate that the sensitivity of the COVID-19 IgG/IgM Rapid Test.

2. Reference

The study was conducted according to Technical Specification of COVID-19 IgG/IgM Rapid Test.

3. Materials

3.1 Three sequential batches of the COVID-19 IgG/IgM Rapid Test (Lot#: 2020010078, 2020010079, 20200100803).

3.2 Test samples: 5 borderline COVID-19 IgG positive serum control and 5 borderline COVID-19 IgM positive serum control.

4. Method

Each batch of the COVID-19 IgG/IgM Rapid Test should be tested by each test sample above for five times for each sample.

5. Evaluation Criteria

All the samples shall yield positive results.

6. Result

Carrying out tests in accordance with standard operating procedures for use of the COVID-19 IgG/IgM Rapid Test Cassette. The results as follows ("+"=Positive, "-"= Negative):

Lot#: 2020010078

Specimens	n	Visual Result	
		IgM (+/+)	IgG (+/+)
L 1(borderline COVID-19 IgG positive)	5	0/5	5/5
L 2(borderline COVID-19 IgG positive)	5	0/5	5/5
L 3(borderline COVID-19 IgG positive)	5	0/5	5/5
L 4(borderline COVID-19 IgG positive)	5	0/5	5/5
L 5(borderline COVID-19 IgG positive)	5	0/5	5/5
L 6(borderline COVID-19 IgM positive)	5	5/5	0/5
L 7(borderline COVID-19 IgM positive)	5	5/5	0/5
L 8(borderline COVID-19 IgM positive)	5	5/5	0/5
L 9(borderline COVID-19 IgM positive)	5	5/5	0/5
L10(borderline COVID-19 IgM positive)	5	5/5	0/5

Lot#: 2020010079

Specimens	n	Visual Result	
		IgM (+/+)	IgG (+/+)
L 1(borderline COVID-19 IgG positive)	5	0/5	5/5
L 2(borderline COVID-19 IgG positive)	5	0/5	5/5

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L 3(borderline COVID-19 IgG positive)	5	0/5	5/5
L 4(borderline COVID-19 IgG positive)	5	0/5	5/5
L 5(borderline COVID-19 IgG positive)	5	0/5	5/5
L 6(borderline COVID-19 IgM positive)	5	5/5	0/5
L 7(borderline COVID-19 IgM positive)	5	5/5	0/5
L 8(borderline COVID-19 IgM positive)	5	5/5	0/5
L 9(borderline COVID-19 IgM positive)	5	5/5	0/5
L10(borderline COVID-19 IgM positive)	5	5/5	0/5

Lot#: 2020010080

Specimens	n	Visual Result	
		IgM (+/+)	IgG (+/+)
L 1(borderline COVID-19 IgG positive)	5	0/5	5/5
L 2(borderline COVID-19 IgG positive)	5	0/5	5/5
L 3(borderline COVID-19 IgG positive)	5	0/5	5/5
L 4(borderline COVID-19 IgG positive)	5	0/5	5/5
L 5(borderline COVID-19 IgG positive)	5	0/5	5/5
L 6(borderline COVID-19 IgM positive)	5	5/5	0/5
L 7(borderline COVID-19 IgM positive)	5	5/5	0/5
L 8(borderline COVID-19 IgM positive)	5	5/5	0/5
L 9(borderline COVID-19 IgM positive)	5	5/5	0/5
L10(borderline COVID-19 IgM positive)	5	5/5	0/5

7. Conclusion

All borderline COVID-19 IgG positive serum specimens IgG test region had positive results while IgM test region had negative result, All borderline COVID-19 IgM positive serum specimens IgM test region had positive results while IgG test region had negative result It indicates that the sensitivity of the COVID-19 IgG/IgM Rapid Test is consistent with the standards.

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CE46PT0503

Hangzhou Clongene Biotech Co., Ltd.

COVID-19 IgG/IgM Rapid Test

Specificity Study Report

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杭州隆基生物
HANGZHOU CLONGENE

Author: Guoqin Chen

Final report date: 2020.02.12

Management of the study: Hangzhou Clongene Biotech Co., Ltd.
R& D Department
Quality Management department

Place of study: Hangzhou

Sponsor: Hangzhou Clongene Biotech Co., Ltd.

Study Director Signature and Verification Dates

Study Director: Guoqin Chen

Company: Hangzhou Clongene Biotech Co., Ltd

Position: Director of R&D Department

Signature: _____ Date: 2020.02.12

Study Handlers: Qingqing Chen

Signature: _____ Date: 2020.02.12

Verifier: Zhiqiang Yin

Signature: _____ Date: 2020.02.12

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The study dates were as follows:

Protocol Effective Date: 2020-02-09
Test Starting Date: 2020-02-11
Test Duration Date: 2020-02-11~2020-02-11
Final Report Date: 2020-02-12

Study Summary

We tested three batches of the COVID-19 IgG/IgM Rapid Test.The test results is that all negative controls were tested negative. It indicates that the analytical specificity of the COVID-19 IgG/IgM Rapid Test is consistent with the national standards.

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1. Purpose

The following study was done to validate that the analytical specificity of the COVID-19 IgG/IgM Rapid Test.

2. Reference

The study was conducted according to Technical Specification of COVID-19 IgG/IgM Rapid Test.

3. Materials

3.1 Three sequential batches of the COVID-19 IgG/IgM Rapid Test (Lot#: 2020010078, 2020010079, 2020010080).

3.2 Test samples: 20 COVID-19 IgG/IgM negative controls.

4. Method

Each batch of the COVID-19 IgG/IgM Rapid Test should be tested by each test sample above for once for each sample.

5. Evalutation Criteria

All of the 20 COVID-19 IgG/IgM negative controls should be tested negative

6. Result

Carrying out tests in accordance with standard operating procedures for use of the COVID-19 IgG/IgM Rapid Test.

The results as follows ("+"=Positive , "-"= Negative):

Lot No.	Test Result (-/-)
2020010078	20/20
2020010079	20/20
2020010080	20/20

7. Conclusion

All of the 20 negative controls were tested negative. It indicates that the analytical specificity of the COVID-19 IgG/IgM Rapid Test is good.

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CE46PT0507

Hangzhou Clongene Biotech Co., Ltd.

COVID-19 IgG/IgM Rapid Test

Interference Study Report

Author: Guoqin Chen

Final report date: 2020.02.12

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杭州隆基生
HANGZHOU CLONGE

Management of the study: Hangzhou Clongene Biotech Co., Ltd.
R& D Department
Quality Management department

Place of study: Hangzhou

Sponsor: Hangzhou Clongene Biotech Co., Ltd.

Study Director Signature and Verification Dates

Study Director: Guoqin Chen

Company: Hangzhou Clongene Biotech Co., Ltd

Position: Director of R&D Department

Signature: _____ Date: 2020.02.12

Study Handlers: Qingqing Chen

Signature: _____ Date: 2020.02.12

Verifier: Zhiqiang Yin

Signature: _____ Date: 2020.02.12

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The study dates were as follows:

Protocol Effective Date: 2020-02-09
Test Starting Date: 2020-02-11
Test Duration Date: 2020-02-11 ~ 2020-02-11
Final Report Date: 2020-02-12

Study Summary

Some potentially interfering substances were added to either COVID-19 IgG/IgM negative serum specimens or positive serum specimens, none of the substances at the certain concentration tested interfered in the assay.

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Technical data shall not be used for commercial propaganda

1. Purpose

The following study was done to confirm that the substances do not interfere with the performance of the COVID-19 IgG/IgM Rapid Test in certain concentration.

2. Reference

The study was conducted according to Technical Specification of COVID-19 IgG/IgM Rapid Test.

3. Materials

Three sequential batches of COVID-19 IgG/IgM Rapid Test (Lot#: 2020010078, 2020010079, 2020010080)

4. Method

4.1 Effect of other common causative agents of infectious disease

Some positive specimens of other common infectious diseases were spiked into the Novel coronavirus positive and negative specimens and tested separately by each batch of the COVID-19 IgG/IgM Rapid Test.

4.2 Effect of the potentially cross-reactive endogenous substances

Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the Novel coronavirus positive and negative specimens and tested separately by each batch of the COVID-19 IgG/IgM Rapid Test.

4.3 Effect of some other common biological analytes

Some other common biological analytes, such as acetaminophen, caffeine, ethanol, were spiked into the Novel coronavirus positive and negative specimens and tested separately by each batch of the COVID-19 IgG/IgM Rapid Test.

5. Result

Carrying out tests in accordance with standard operating procedures for use of the COVID-19 IgG/IgM Rapid Test Cassette. The results as follows ("+"=Positive, "-"= Negative):

5.1 Effect of other common causative agents of infectious disease

Lot#: 2020010078

Analytes	Specimens		
	Negative	IgG Positive	IgM Positive
HIV positive specimen	-(10/10)	+(10/10)	+(10/10)

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HTLV positive specimen	-(10/10)	+(10/10)	+(10/10)
CMV positive specimen	-(10/10)	+(10/10)	+(10/10)
FLUA positive specimen	-(10/10)	+(10/10)	+(10/10)
FLUB positive specimen	-(10/10)	+(10/10)	+(10/10)
RSV positive specimen	-(10/10)	+(10/10)	+(10/10)
MP positive specimen	-(10/10)	+(10/10)	+(10/10)
CP positive specimen	-(10/10)	+(10/10)	+(10/10)
HPIVs positive specimen	-(10/10)	+(10/10)	+(10/10)

5.2 Effect of the potentially cross-reactive endogenous substances

Lot#: 2020010078

Analytes	Conc.	Specimens		
		Negative	IgG Positive	IgM Positive
Albumin	20mg/ml	-(10/10)	+(10/10)	+(10/10)
Bilirubin	20μg/ml	-(10/10)	+(10/10)	+(10/10)
Hemoglobin	15mg/ml	-(10/10)	+(10/10)	+(10/10)
Glucose	20mg/ml	-(10/10)	+(10/10)	+(10/10)
Uric Acid	200μg/ml	-(10/10)	+(10/10)	+(10/10)
Lipids	20mg/ml	-(10/10)	+(10/10)	+(10/10)

Lot#: 2020010079

Analytes	Conc.	Specimens		
		Negative	IgG Positive	IgM Positive
Albumin	20mg/ml	-(10/10)	+(10/10)	+(10/10)
Bilirubin	20μg/ml	-(10/10)	+(10/10)	+(10/10)
Hemoglobin	15mg/ml	-(10/10)	+(10/10)	+(10/10)
Glucose	20mg/ml	-(10/10)	+(10/10)	+(10/10)
Uric Acid	200μg/ml	-(10/10)	+(10/10)	+(10/10)
Lipids	20mg/ml	-(10/10)	+(10/10)	+(10/10)

Lot#: 2020010080

Analytes	Conc.	Specimens		
		Negative	IgG Positive	IgM Positive
Albumin	20mg/ml	-(10/10)	+(10/10)	+(10/10)
Bilirubin	20μg/ml	-(10/10)	+(10/10)	+(10/10)
Hemoglobin	15mg/ml	-(10/10)	+(10/10)	+(10/10)
Glucose	20mg/ml	-(10/10)	+(10/10)	+(10/10)

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Uric Acid	200μg/ml	-(10/10)	+(10/10)	+(10/10)
Lipids	20mg/ml	-(10/10)	+(10/10)	+(10/10)

5.3 Effect of some other common biological analytes

Lot#: 2020010078

Analytes	Conc. (μg/ml)	Specimens		
		Negative	IgG Positive	IgM Positive
Acetaminophen	200	-(10/10)	+(10/10)	+(10/10)
Acetoacetic Acid	200	-(10/10)	+(10/10)	+(10/10)
Acetylsalicylic Acid	200	-(10/10)	+(10/10)	+(10/10)
Benzoylecgonine	100	-(10/10)	+(10/10)	+(10/10)
Caffeine	200	-(10/10)	+(10/10)	+(10/10)
EDTA	800	-(10/10)	+(10/10)	+(10/10)
Ethanol	1.0%	-(10/10)	+(10/10)	+(10/10)
Gentisic Acid	200	-(10/10)	+(10/10)	+(10/10)
β - Hydroxybutyrate	20,000	-(10/10)	+(10/10)	+(10/10)
Methanol	10.0%	-(10/10)	+(10/10)	+(10/10)
Phenothiazine	200	-(10/10)	+(10/10)	+(10/10)
Phenylpropanolamine	200	-(10/10)	+(10/10)	+(10/10)
Salicylic Acid	200	-(10/10)	+(10/10)	+(10/10)

Lot#: 2020010079

Analytes	Conc. (μg/ml)	Specimens		
		Negative	IgG Positive	IgM Positive
Acetaminophen	200	-(10/10)	+(10/10)	+(10/10)
Acetoacetic Acid	200	-(10/10)	+(10/10)	+(10/10)
Acetylsalicylic Acid	200	-(10/10)	+(10/10)	+(10/10)
Benzoylecgonine	100	-(10/10)	+(10/10)	+(10/10)
Caffeine	200	-(10/10)	+(10/10)	+(10/10)
EDTA	800	-(10/10)	+(10/10)	+(10/10)
Ethanol	1.0%	-(10/10)	+(10/10)	+(10/10)
Gentisic Acid	200	-(10/10)	+(10/10)	+(10/10)
β - Hydroxybutyrate	20,000	-(10/10)	+(10/10)	+(10/10)
Methanol	10.0%	-(10/10)	+(10/10)	+(10/10)
Phenothiazine	200	-(10/10)	+(10/10)	+(10/10)
Phenylpropanolamine	200	-(10/10)	+(10/10)	+(10/10)
Salicylic Acid	200	-(10/10)	+(10/10)	+(10/10)

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Lot#: 2020010080

Analytes	Conc. (μg/ml)	Specimens		
		Negative	IgG Positive	IgM Positive
Acetaminophen	200	-(10/10)	+(10/10)	+(10/10)
Acetoacetic Acid	200	-(10/10)	+(10/10)	+(10/10)
Acetylsalicylic Acid	200	-(10/10)	+(10/10)	+(10/10)
Benzoylecgonine	100	-(10/10)	+(10/10)	+(10/10)
Caffeine	200	-(10/10)	+(10/10)	+(10/10)
EDTA	800	-(10/10)	+(10/10)	+(10/10)
Ethanol	1.0%	-(10/10)	+(10/10)	+(10/10)
Gentisic Acid	200	-(10/10)	+(10/10)	+(10/10)
β - Hydroxybutyrate	20,000	-(10/10)	+(10/10)	+(10/10)
Methanol	10.0%	-(10/10)	+(10/10)	+(10/10)
Phenothiazine	200	-(10/10)	+(10/10)	+(10/10)
Phenylpropanolamine	200	-(10/10)	+(10/10)	+(10/10)
Salicylic Acid	200	-(10/10)	+(10/10)	+(10/10)

6. Conclusion

Interferences of common exogenous and endogenous potential interfering substances and cross-reactivity of some kinds of positive samples were tested. It showed that no interference was found in these tests.

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CE46PT0501

Hangzhou Clongene Biotech Co., Ltd.

COVID-19 IgG/IgM Rapid Test

Stability Study Report

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杭州隆基生物
HANGZHOU CLONGENE B

Author: Guoqin Chen

Final report date: 2020.03.02

Management of the study: Hangzhou Clongene Biotech Co., Ltd.
R & D Department
Quality Management Department

Place of study: Hangzhou

Sponsor: Hangzhou Clongene Biotech Co., Ltd.

Study Director Signature and Verification Dates

Study Director: Guoqin Chen

Company: Hangzhou Clongene Biotech Co., Ltd

Position: Director of R&D Department

Signature: _____ Date: 2020.03.02

Study Handlers: Qingqing Chen

Signature: _____ Date: 2020.03.01

Verifier: Zhiqiang Yin

Signature: _____ Date: 2020.03.02

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The study dates were as follows:

Protocol Effective Date: 2020-02-02
Test starting Date: 2020-02-03
Test duration date: 2020-02-03 ~ 2020-03-02
Final Report Date: 2020-03-02

Study Summary

The COVID-19 IgG/IgM Rapid Test, from batch 2020010078, 2020010079, 2020010080, taken for accelerated stability study, whose sensitivity , specificity meet the requirements, indicate that the product possesses the ideal stability under transport and storage condition of 4℃~30℃, and the expiry date under the above condition is 24 months. However, we recommend that users should use cassette as soon as possible but within 1 hour after removal from pouch specially if the room temperature is more than 30℃ and in high humidity environment.

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1. Purpose

The objective and purpose of this stability studies is to make sure the product's shelf-life, transport and storage conditions, and stability of the reagent in-use after the first opening of the primary container.

2. References

The study was conducted according to Technical Specification of COVID-19 IgG/IgM Rapid Test.

3. Materials and Equipment

3.1 Reagents: three batches of the COVID-19 IgG/IgM Rapid Test kits (Lot#: 2020010078, 2020010079, 2020010080).

3.2 Micrometer, Timer, Specimen collection container

4. Method

In this test, the stability was evaluated under the following four conditions:

4.1 Accelerated stability test

Formula to decide the shelf -life (according to Arrhenius's equation):

$AAF = Q_{10}^{(T_{AA} - T_{RT})/10}$

AAF =Accelerated aging factor

Q_{10}= An aging factor for 10°C increase or decrease in temperature(Using the Arrhenius equation with Q_{10} equal to 3 is a means of calculating an aging factor.)

T_{AA} = Accelerated aging temperature (55°C);

T_{RT} = Ambient temperature (25°C): Select a temperature that represents the actual product storage and use conditions (NOTE 1—This temperature is typically between 20 to 25°C. A temperature of 25°C is considered a conservative approach).

Where Q_{10} = 3; ambient temperature = 25°C; accelerated aging temperature = 55°C;

$AAF = 3.0^{(55-25)/10}$;

$AAF = 3.0^{3.0} = 27$;

AAT = 365*2 days/27; and

AAT = 28 days at accelerated aging conditions for a shelf-life test of 24 months (real-time equivalent).

Method: Take enough COVID-19 IgG/IgM Rapid Test from the three sequential batches of the COVID-19 IgG/IgM Rapid Test (Lot#: 2020010078, 2020010079, 2020010080) and store them under 55℃ for 28 days. The relative humidity is normal. Observe and record down the result of stability research.

Test frequency: Carry out a test after 10,15,20,25,26,27,28 days from the beginning of this study.

Test duration date: 2020-02-03 ~ 2020-03-02

The amount of each test: 33 copies.

Test item:

Test Item	Test Sample	Test Content
Physical property	PBS	Testing each sample three times
Specificity	20 COVID-19 IgG and IgM negative controls	Testing each sample once
Sensitivity	1 borderline COVID-19 IgG positive serum control and 1 borderline COVID-19 IgM positive serum control	Testing each sample five times

4.2 In-use stability

Method: Take enough COVID-19 IgG/IgM Rapid Test (first removing from foil pouch) from the three

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sequential batches of the COVID-19 IgG/IgM Rapid Test (Lot#: 2020010078, 2020010079, 2020010080) to store under the normal conditions (the temperature range is within 4℃~30℃, and the relative humidity is normal) and the abnormal conditions (the temperature range is within 30℃~50℃, and the relative humidity is higher than 80%) respectively for 3 hours. Observe and record down the result of stability research.

Test duration date: 2020-02-10 ~ 2020-02-10

Test frequency: once a hour.

The amount of each test: 33 copies.

Test item:

Test Item	Test Sample	Test Content
Physical property	PBS	Testing each sample three times
Specificity	20 COVID-19 IgG and IgM negative controls	Testing each sample once
Sensitivity	1 borderline COVID-19 IgG positive serum control and 1 borderline COVID-19 IgM positive serum control	Testing each sample five times

4.3 Transport simulation

Method: Take enough COVID-19 IgG/IgM Rapid Test (Lot#: 2020010078, 2020010079, 2020010080) to be sent to Wondfo Biotech. Co. Ltd located in Guangzhou by Express, and then delegate the company to refund the kits intact by Express. Test the performance of the test kits and record down the result of stability research.

Test duration date: 2020-02-10 ~ 2020-02-20

The amount of test: 33 copies.

Test item:

Test Item	Test Sample	Test Content
Physical property	PBS	Testing each sample three times
Specificity	20 COVID-19 IgG and IgM negative controls	Testing each sample once
Sensitivity	1 borderline COVID-19 IgG positive serum control and 1 borderline COVID-19 IgM positive serum control	Testing each sample five times

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5. Evaluation Criteria

5.1 Physical property: The surface of reagent is flat and clean, no damage, all the materials are assembled well, and no missing component.The width of the membrane shall be wider than 2.5mm.If the liquid migration rate is not be lower than 10mm/min, then the test for qualified.

5.2 Specificity: All of the negative serum controls should be tested negative.

5.3 Sensitivity: The COVID-19 IgG borderline positive serum pecimens should be tested IgG positive. The COVID-19 IgM borderline positive serum pecimens should be tested IgM positive.

6. Result

6.1 Accelerated stability study

Lot#: 2020010078

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
5th day	Qualified	-(20/20)	+(5/5)	+(5/5)
10th day	Qualified	-(20/20)	+(5/5)	+(5/5)

15th day	Qualified	-(20/20)	+(5/5)	+(5/5)
20th day	Qualified	-(20/20)	+(5/5)	+(5/5)
25th day	Qualified	-(20/20)	+(5/5)	+(5/5)
26th day	Qualified	-(20/20)	+(5/5)	+(5/5)
27th day	Qualified	-(20/20)	+(5/5)	+(5/5)
28th day	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

Lot#: 2020010079

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
5th day	Qualified	-(20/20)	+(5/5)	+(5/5)
10th day	Qualified	-(20/20)	+(5/5)	+(5/5)
15th day	Qualified	-(20/20)	+(5/5)	+(5/5)
20th day	Qualified	-(20/20)	+(5/5)	+(5/5)
25th day	Qualified	-(20/20)	+(5/5)	+(5/5)
26th day	Qualified	-(20/20)	+(5/5)	+(5/5)
27th day	Qualified	-(20/20)	+(5/5)	+(5/5)
28th day	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

Lot#: 2020010080

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
5th day	Qualified	-(20/20)	+(5/5)	+(5/5)
10th day	Qualified	-(20/20)	+(5/5)	+(5/5)
15th day	Qualified	-(20/20)	+(5/5)	+(5/5)
20th day	Qualified	-(20/20)	+(5/5)	+(5/5)
25th day	Qualified	-(20/20)	+(5/5)	+(5/5)
26th day	Qualified	-(20/20)	+(5/5)	+(5/5)
27th day	Qualified	-(20/20)	+(5/5)	+(5/5)
28th day	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

6.2 In-use stability

6.3.1 The normal conditions (the temperature range is with in 4℃~30℃, and the relative humidity is normal)

Lot#: 2020010078

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
1st hour	Qualified	-(20/20)	+(5/5)	+(5/5)
2nd hour	Qualified	-(20/20)	+(5/5)	+(5/5)

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3rd hour	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

Lot#: 2020010079

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
1st hour	Qualified	-(20/20)	+(5/5)	+(5/5)
2nd hour	Qualified	-(20/20)	+(5/5)	+(5/5)
3rd hour	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

Lot#: 2020010080

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
1st hour	Qualified	-(20/20)	+(5/5)	+(5/5)
2nd hour	Qualified	-(20/20)	+(5/5)	+(5/5)
3rd hour	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

6.3.2 The abnormal conditions (the temperature range is within 30℃~50℃, and the relative humidity is higher than 80%)

Lot#: 2020010078

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
1st hour	Qualified	-(20/20)	+(5/5)	+(5/5)
2nd hour	Qualified	-(20/20)	+(5/5)	+(5/5)
3rd hour	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

Lot#: 2020010079

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
1st hour	Qualified	-(20/20)	+(5/5)	+(5/5)
2nd hour	Qualified	-(20/20)	+(5/5)	+(5/5)
3rd hour	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

Lot#: 2020010080

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)

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1st hour	Qualified	-(20/20)	+(5/5)	+(5/5)
2nd hour	Qualified	-(20/20)	+(5/5)	+(5/5)
3rd hour	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

Notes: The positive results of the test cassettes are not obvious relatively (The shade of color in the test region (T) becomes shallow.) when have taken for 3 hours in the abnormal conditions.

6.3 Transport simulation

Lot#: 2020010078

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
11st day	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

Lot#: 2020010079

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
11st day	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

Lot#: 2020010080

Results / Time	Physical property	Specificity	Sensitivity	
			L1(borderline COVID-19 IgG positive)	L2(borderline COVID-19 IgM positive)
11st day	Qualified	-(20/20)	+(5/5)	+(5/5)

Result specification: "+"=Positive "-"= Negative

7. Conclusion

The COVID-19 IgG/IgM Rapid Test, from batch 2020010078, 2020010079, 2020010080, whether stored under 55℃ for 28 days, they may still meet the related test criterion. The stability of the reagent (from batch 2020010078, 2020010079, 2020010080) in-use after the first opening of the primary container for 3 hours is ideal. And the reagent keep good performance after transport test for 10 days .Based on the above result, it should be reliable to define the condition for transporting and storing the test kit as follows: the temperature range is 4℃~30℃, the relative humidity is normal, and the expiry date under the above condition is 24 months. However, we recommend that users should use cassettes as soon as possible but within 1 hour after removal from pouch specially if the room temperature is more than 30℃ and in high humidity environment.

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CE46PT0504

Hangzhou Clongene Biotech Co., Ltd.

COVID-19 IgG/IgM Rapid Test

Repeatability Study Report

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Author: Guoqin Chen

Final report date: 2020.02.12

Management of the study: Hangzhou Clongene Biotech Co., Ltd.
R& D Department
Quality Management department

Place of study: Hangzhou

Sponsor: Hangzhou Clongene Biotech Co., Ltd.

Study Director Signature and Verification Dates

Study Director: Guoqin Chen

Company: Hangzhou Clongene Biotech Co., Ltd

Position: Director of R&D Department

Signature: _____ Date: 2020.02.12

Study Handlers: Qingqing Chen

Signature: _____ Date: 2020.02.12

Verifier: Zhiqiang Yin

Signature: _____ Date: 2020.02.12

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Technical data shall not be used for commercial propaganda

The study dates were as follows:

Protocol Effective Date: 2010-02-09
Test Starting Date: 2020-02-11
Test Duration Date: 2020-02-11 ~ 2020-02-11
Final Report Date: 2020-02-12

Study Summary

All reagents from three sequential batches were tested with 1 borderline COVID-19 IgG positive serum control and 1 borderline COVID-19 IgG positive serum control. All of the test results were positive, and the color degree of the test results was uniform. It indicates that the within-batch repeatability and between-run repeatability of the COVID-19 IgG/IgM Rapid Test are both good.

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1. Purpose

This test was to validate that the repeatability of COVID-19 IgG/IgM Rapid Test is good.

2. Reference

The study was conducted according to Technical Specification of COVID-19 IgG/IgM Rapid Test.

3. Materials

3.1 Reagents: three sequential batches of the COVID-19 IgG/IgM Rapid Test (Lot#: 2020010078, 2020010079, 2020010080).

3.2 Test Samples:1 borderline COVID-19 IgG positive serum control and 1 borderline COVID-19 IgG positive serum control.

4. Method

Each batch of the COVID-19 IgG/IgM Rapid Test should be tested by above test samples for 10 times.

4.1 Evaluation Criteria

If the test results of reagents from the same batch are positive, and the color degree of the test results is uniform, it indicates that the within-batch repeatability is good. If the test results of reagents from the different batches are positive, and the color degree of the test results is uniform, it indicates that the between-run repeatability is good.

5. Result

Carrying out tests in accordance with standard operating procedures for use of the COVID-19 IgG/IgM Rapid Test. The results as follows ("+"=Positive, "-"= Negative):

Sample / No.	Borderline COVID-19 IgG positive		
	Lot#: 2020010078	Lot#: 2020010079	Lot#: 2020010080
1	+	+	+
2	+	+	+
3	+	+	+
4	+	+	+
5	+	+	+
6	+	+	+
7	+	+	+
8	+	+	+
9	+	+	+
10	+	+	+

Sample / No.	Borderline COVID-19 IgM positive		
	Lot#: 2020010078	Lot#: 2020010079	Lot#: 2020010080
1	+	+	+
2	+	+	+
3	+	+	+

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Sample / No.	Borderline COVID-19 IgM positive		
	Lot#: 2020010078	Lot#: 2020010079	Lot#: 2020010080
4	+	+	+
5	+	+	+
6	+	+	+
7	+	+	+
8	+	+	+
9	+	+	+
10	+	+	+

6. Conclusion

All of the test results were positive, and the color degree of the test results was uniform. It indicates that the within-batch repeatability and between-run repeatability of the COVID-19 IgG/IgM Rapid Test are both good.

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CE46PT0505

Hangzhou Clongene Biotech Co., Ltd.

COVID-19 IgG/IgM Rapid Test

Reproducibility Study Report

Author: Guoqin Chen

Final report date: 2020.02.14

Management of the study: Hangzhou Clongene Biotech Co., Ltd.
R& D Department
Quality Management department

Place of study: Hangzhou

Sponsor: Hangzhou Clongene Biotech Co., Ltd.

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Technical data shall not be used for commercial propaganda

Study Director Signature and Verification Dates

Study Director: Guoqin Chen

Company: Hangzhou Clongene Biotech Co., Ltd

Position: Director of R&D Department

Signature: _____ Date: 2020.02.14

Study Handlers: Qingqing Chen

Signature: _____ Date: 2020.02.14

Verifier: Zhiqiang Yin

Signature: _____ Date: 2020.02.14

技术资料不得用于商业宣传
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The study dates were as follows:

Protocol Effective Date: 2020-02-09
Test Starting Date: 2020-02-11
Test Duration Date: 2020-02-11~ 2020-02-13
Final Report Date: 2020-02-14

Study Summary

Sixty (60) clinical serum specimens (20 negative, 20 borderline positive and 20 positive) , were used in this study. Each specimen was run in triplicate for three days at each POL. It indicates that the reproducibility of COVID-19 IgG/IgM Rapid Test is very good.

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Technical data shall not be used for commercial propaganda

1. Purpose

This test was to validate that the reproducibility of the COVID-19 IgG/IgM Rapid Test is good.

2. Reference

The study was conducted according to Technical Specification of COVID-19 IgG/IgM Rapid Test .

3. Materials

Three sequential batches of the COVID-19 IgG/IgM Rapid Test (Lot#: 2020010078, 2020010079, 2020010080).

4. Methodology

Reproducibility studies were performed for COVID-19 IgG/IgM Rapid Test at three physician office laboratories (POL). Sixty (60) clinical serum specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL.

5. Evaluation Criteria

The intra-assay agreement should not be less than 99% at each site, and the inter-site agreement should not be less than 99% as well.

6. Result

Carrying out tests in accordance with standard operating procedures for use of the COVID-19 IgG/IgM Rapid Test. The results as follows ("+"=Positive, "-"= Negative):

Lot#: COVID20200101

Date	Specimen	Test Result		
		Site A	Site B	Site C
1st day	Negative	-(20/20)	-(20/20)	-(20/20)
	Borderline IgG positive	+(10/10)	+(10/10)	+(10/10)
	Borderline IgM positive	+(10/10)	+(10/10)	+(10/10)
	IgG Positive	+(10/10)	+(10/10)	+(10/10)
	IgM Positive	+(10/10)	+(10/10)	+(10/10)
2nd day	Negative	-(20/20)	-(20/20)	-(20/20)
	Borderline IgG positive	+(10/10)	+(10/10)	+(10/10)
	Borderline IgM positive	+(10/10)	+(10/10)	+(10/10)
	IgG Positive	+(10/10)	+(10/10)	+(10/10)
	IgM Positive	+(10/10)	+(10/10)	+(10/10)
3rd day	Negative	-(20/20)	-(20/20)	-(20/20)
	Borderline IgG positive	+(10/10)	+(10/10)	+(10/10)
	Borderline IgM positive	+(10/10)	+(10/10)	+(10/10)
	IgG Positive	+(10/10)	+(10/10)	+(10/10)

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Date	Specimen	Test Result		
		Site A	Site B	Site C
	IgM Positive	+(10/10)	+(10/10)	+(10/10)
Intra-assay agreement		100%	100%	100%
Inter-site agreement		100%		

Lot#: COVID20200102

Date	Specimen	Test Result		
		Site A	Site B	Site C
1st day	Negative	-(20/20)	-(20/20)	-(20/20)
	Borderline IgG positive	+(10/10)	+(10/10)	+(10/10)
	Borderline IgM positive	+(10/10)	+(10/10)	+(10/10)
	IgG Positive	+(10/10)	+(10/10)	+(10/10)
	IgM Positive	+(10/10)	+(10/10)	+(10/10)
2nd day	Negative	-(20/20)	-(20/20)	-(20/20)
	Borderline IgG positive	+(10/10)	+(10/10)	+(10/10)
	Borderline IgM positive	+(10/10)	+(10/10)	+(10/10)
	IgG Positive	+(10/10)	+(10/10)	+(10/10)
	IgM Positive	+(10/10)	+(10/10)	+(10/10)
3rd day	Negative	-(20/20)	-(20/20)	-(20/20)
	Borderline IgG positive	+(10/10)	+(10/10)	+(10/10)
	Borderline IgM positive	+(10/10)	+(10/10)	+(10/10)
	IgG Positive	+(10/10)	+(10/10)	+(10/10)
	IgM Positive	+(10/10)	+(10/10)	+(10/10)
Intra-assay agreement		100%	100%	100%
Inter-site agreement		100%		

Lot#: COVID20200103

Date	Specimen	Test Result		
		Site A	Site B	Site C
1st day	Negative	-(20/20)	-(20/20)	-(20/20)
	Borderline IgG positive	+(10/10)	+(10/10)	+(10/10)
	Borderline IgM positive	+(10/10)	+(10/10)	+(10/10)
	IgG Positive	+(10/10)	+(10/10)	+(10/10)
	IgM Positive	+(10/10)	+(10/10)	+(10/10)
2nd day	Negative	-(20/20)	-(20/20)	-(20/20)
	Borderline IgG positive	+(10/10)	+(10/10)	+(10/10)
	Borderline IgM positive	+(10/10)	+(10/10)	+(10/10)
	IgG Positive	+(10/10)	+(10/10)	+(10/10)
	IgM Positive	+(10/10)	+(10/10)	+(10/10)
3rd day	Negative	-(20/20)	-(20/20)	-(20/20)

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Date	Specimen	Test Result		
		Site A	Site B	Site C
	Borderline IgG positive	+(10/10)	+(10/10)	+(10/10)
	Borderline IgM positive	+(10/10)	+(10/10)	+(10/10)
	IgG Positive	+(10/10)	+(10/10)	+(10/10)
	IgM Positive	+(10/10)	+(10/10)	+(10/10)
Intra-assay agreement		100%	100%	100%
Inter-site agreement		100%		

7. Conclusion

Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100%. The inter-site agreement was 100 %. All test results of the three sequential batches products were consistent, and met the test criterion. It indicates that the reproducibility of COVID-19 IgG/IgM Rapid Test is good.

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