



Hangzhou Testsea Biotechnology Co.,Ltd

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# Clinical Study Report of COVID-19 IgG/IgM Rapid Test

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Applicant: HangZhou Testsea Biotechnology Co.,Ltd

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## Clinical Study Report of COVID-19 IgG/IgM Rapid Test

### 1. Purpose of the test

Through test on certain quantity of representative clinical specimens, and scientific and rational statistic analysis on the test result, evaluate the consistency of the result of SARS-CoV-2 IgG/IgM Rapid Test produced by HangZhou Testsea Biotechnology and compare with RT-PCR product, and evaluate its clinical application capacity.

### 2. Overall design of the test

The test of parallel contrast is adopted, and RT-PCR similar product which has been launched is taken as comparison device. The COVID-19 IgG/IgM Rapid Test produced by our company and the comparison device will parallel test on the same specimens, and the result will be recorded respectively.

### 3. Study method

Perform the clinical study by SARS-CoV-2 IgG/IgM Rapid Test, and compare with RT-PCR similar product.

### 3.1 Specimens size and its confirmation basis

To investigate the function of product, a side-by-side comparison was conducted using The COVID-19 IgG/IgM Rapid Test and a commercially available COVID-19 RT-PCR. Testing was performed on 100 clinical specimens previously collected from subjects present for COVID-19 IgG/IgM Testing. Allow the test, Blood specimen to reach room temperature (15-30°C) prior to testing.

### 3.2 Selection of specimen

The samples were selected from medical institution .To protect the privacy of the specimen suppliers, the providers' name shouldn't appear in the test record.

### 3.3 The selection of comparison device and confirmation method

RT-PCR product is selected as the comparison method, and the infection time information will be a supplementary explanation.

## 4. Clinical test result

### 4.1. Positive result of COVID-19 IgG

NO.	PCR	IgG
Positive1#	+	+
Positive2#	+	+
Positive3#	+	+
Positive4#	+	+
Positive5#	+	+
Positive6#	+	+
Positive7#	+	+
Positive8#	+	+
Positive9#	+	+
Positive10#	+	+/-
Positive11#	+	-
Positive12#	+	+
Positive13#	+	+
Positive14#	+	+/-
Positive15#	+	+
Positive16#	+	+
Positive17#	+	+
Positive18#	+	+
Positive19#	+	+
Positive20#	+	+
Positive21#	+	+



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Positive22#	+	+
Positive23#	+	+
Positive24#	+	+
Positive25#	+	+
Positive26#	+	+
Positive27#	+	-
Positive28#	+	+
Positive29#	+	+
Positive30#	+	+
Positive31#	+	+
Positive32#	+	+
Positive33#	+	+
Positive34#	+	+
Positive35#	+	+
Positive36#	+	+
Positive37#	+	+
Positive38#	+	+
Positive39#	+	+
Positive40#	+	+
Positive41#	+	+
Positive42#	+	+
Positive43#	+	+
Positive44#	+	+
Positive45#	+	+
Positive46#	+	+
Positive47#	+	+

Positive48#	+	+
Positive49#	+	+
Positive50#	+	+

#### 4.2. Negative result of COVID-19 IgG

NO.	PCR	IgG
Negative# 1	-	-
Negative# 2	-	-
Negative# 3	-	-
Negative# 4	-	-
Negative# 5	-	-
Negative# 6	-	-
Negative# 7	-	-
Negative# 8	-	-
Negative# 9	-	-
Negative# 10	-	-
Negative# 11	-	-
Negative# 12	-	-
Negative# 13	-	-
Negative# 14	-	-
Negative# 15	-	-
Negative# 16	-	-
Negative# 17	-	-
Negative# 18	-	-
Negative# 19	-	-
Negative# 20	-	-
Negative# 21	-	-



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Negative# 22	-	-
Negative# 23	-	-
Negative# 24	-	-
Negative# 25	-	-
Negative# 26	-	-
Negative# 27	-	-
Negative# 28	-	-
Negative# 29	-	-
Negative# 30	-	-
Negative# 31	-	-
Negative# 32	-	-
Negative# 33	-	-
Negative# 34	-	-
Negative# 35	-	-
Negative# 36	-	-
Negative# 37	-	-
Negative# 38	-	-
Negative# 39	-	-
Negative# 40	-	-
Negative# 41	-	-
Negative# 42	-	-
Negative# 43	-	-
Negative# 44	-	-
Negative# 45	-	-
Negative# 46	-	-
Negative# 47	-	-

Negative# 48	-	-
Negative# 49	-	-
Negative# 50	-	-

### 4.3. Positive result of COVID-19 IgM

NO.	PCR	IgM
Positive1#	+	+
Positive2#	+	+
Positive3#	+	+
Positive4#	+	+
Positive5#	+	+
Positive6#	+	+/-
Positive7#	+	+
Positive8#	+	+/-
Positive9#	+	+
Positive10#	+	+
Positive11#	+	-
Positive12#	+	+
Positive13#	+	+
Positive14#	+	+
Positive15#	+	+
Positive16#	+	-
Positive17#	+	+
Positive18#	+	+
Positive19#	+	+
Positive20#	+	+
Positive21#	+	+





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Positive22#	+	+
Positive23#	+	+
Positive24#	+	+
Positive25#	+	+
Positive26#	+	+
Positive27#	+	+
Positive28#	+	+
Positive29#	+	-
Positive30#	+	+
Positive31#	+	+
Positive32#	+	+
Positive33#	+	+
Positive34#	+	+
Positive35#	+	-
Positive36#	+	+
Positive37#	+	+
Positive38#	+	-
Positive39#	+	+
Positive40#	+	+
Positive41#	+	+
Positive42#	+	+
Positive43#	+	-
Positive44#	+	+
Positive45#	+	+
Positive46#	+	+
Positive47#	+	+

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Positive48#	+	+
Positive49#	+	+
Positive50#	+	+

#### 4.4. Negative result of COVID-19 IgM

NO.	PCR	IgG
Negative# 1	-	-
Negative# 2	-	-
Negative# 3	-	-
Negative# 4	-	-
Negative# 5	-	-
Negative# 6	-	-
Negative# 7	-	-
Negative# 8	-	-
Negative# 9	-	-
Negative# 10	-	-
Negative# 11	-	-
Negative# 12	-	-
Negative# 13	-	-
Negative# 14	-	-
Negative# 15	-	-
Negative# 16	-	-
Negative# 17	-	-
Negative# 18	-	-
Negative# 19	-	-
Negative# 20	-	-
Negative# 21	-	-



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Negative# 22	-	-
Negative# 23	-	-
Negative# 24	-	-
Negative# 25	-	-
Negative# 26	-	-
Negative# 27	-	-
Negative# 28	-	-
Negative# 29	-	-
Negative# 30	-	-
Negative# 31	-	-
Negative# 32	-	-
Negative# 33	-	-
Negative# 34	-	-
Negative# 35	-	-
Negative# 36	-	-
Negative# 37	-	-
Negative# 38	-	-
Negative# 39	-	-
Negative# 40	-	-
Negative# 41	-	-
Negative# 42	-	-
Negative# 43	-	-
Negative# 44	-	-
Negative# 45	-	-
Negative# 46	-	-
Negative# 47	-	-

Negative# 48	-	-
Negative# 49	-	-
Negative# 50	-	-

#### 4.5.Statistic analysis method of test result

This test will adopt statistic analysis on pair enumeration data, and will record analysis in the form of fourfold table, see below:

Table 1 fourfold table for evaluating diagnostic test

		Comparison		Total
		positive	negative	
Test device	positive	a	b	r1
	negative	c	d	r2
total		C1	C2	N

Positive conformity rate=  $[a/(a+c)] \times 100\%$

Negative conformity rate=  $[d/(b+d)] \times 100\%$

Total conformity rate=  $[(a+d)/(a+b+c+d)] \times 100\%$

We'll do Kappa consistency test on the result, and when the Kappa value is between 0-1, it means better consistency between the test result of the two devices. It is normally considered consistent when the Kappa value bigger than 0.75.

$$\text{Kappa} = \frac{N(a+d) - (\gamma_{1C_1} + \gamma_{2C_2})}{N^2 - (\gamma_{1C_1} + \gamma_{2C_2})}$$

#### 4.6.Discussion and conclusion

**Table 2 fourfold table for COVID IgG result**

		PCR		total
		positive	negative	
COVID-19 Test Cassette	positive	48	0	48
	negative	2	50	52
Total		50	50	100
% Agreement		≥96%	>99.9%	>98%

Positive Agreement= $48/50 \times 100\% = >96\%$  (95%CI\*(86.3%~99.5%))

Negative

Agreement= $50/50 \times 100\% = >99.9\%$  (95%CI\*:94.2%~100%)

Total Agreement=(48+50)

$/(50+50) \times 100\% = >98\%$  (95%CI\*:92.9%~99.7%)

Kappa=0.95

**Table 3 fourfold table for COVID IgM result**

		PCR		total
		positive	negative	
COVID-19 Test Cassette	positive	44	0	44
	negative	6	50	56
Total		50	50	100
% Agreement		≥88%	>99.9%	>94%

Positive Agreement= $44/50 \times 100\% = >88\%$  (95% CI\*: (75.7%~95.5%))

Negative

Agreement= $50/50 \times 100\% = >99.9\%$  (95% CI\*: 94.2%~100%)

Total Agreement=(44+50)

$/(50+50) \times 100\% = >94\%$  (95% CI\*: 87.4%~97.8%)

Kappa=0.88

Clinical study has been conducted on altogether 100 specimens.

Testsea tests were parallel comparison studied with comparison device, the total conformity rate of the test result of Testsea test and of PCR product for comparison is  $\geq 99\%$ .