

*Stability testing of in vitro diagnostic
reagents*

according to EN 13640:2002

Device: SARS-CoV-2 IgG/IgM Rapid Test

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According to EN ISO 23640:2015, Study the shelf life stability, transportation stability and unsealing stability of SARS-CoV-2 IgG/IgM Rapid Test .

1. Unsealing Stability study

1.1 Design scheme of shelf life stability study

Before starting the unsealing stability study, the design scheme of shelf life stability study of SARS-CoV-2 IgG/IgM Rapid Test need to be followed the requirements of EN13640:2002. The specific design scheme is shown in the table below:

Table 1 Unsealing stability study plan

Protocol	stability of the IVD reagent in use after the first opening of the primary container
responsibilities	R & D department is responsible for the implementation of the plan
clear IVD reagent identification	
presumed storage condition	-4 °C, 2 °C, 30 °C, 40 °C -20-16 °C, -4-0 °C, 2-8 °C, 20-30 °C, 36-40 °C (humidity are all below 30%) and humidity 10-30%, 40-60%, 70-90% (The temperature is in the range of 20 °C)
objective and purpose of testing	Study the stability of unsealed product
information about the samples	20200203, 20200205, 20200208 three lots ;
storage conditions recommended for the samples	Store at 2-8 °C
simulation of transport as appropriate	Unsealing stability does not consider the transportation process.
intervals between examination	Every 30 minutes, select 5 cassette d to restore the room temperature.
examinations to be	Collect serum, plasma and whole blood from positive Novel

performed at the end of each interval	Coronavirus infection patient
stability criteria to be met	Collect serum, plasma and whole blood from negative Novel Coronavirus infection patient
interpretation of data	Statistical analysis of the data

3.2 Stability study result of unsealing

Analyze the results of the unsealing stability study of the three lots. The result is shown in the table below:

Table2 Stability study results of unsealing

Result Time	Condition	Temperature as below Humidity <30%				Temperature 20°C Humidity as below		
		-4°C	2°C	30°C	40°C	10-30 %	40-60 %	70-90 %
Onset		+●	+●	+●	+●	+●	+●	+●
0.5 hour		+●	+●	+●	+●	+●	+●	+●
1 hour		+●	+●	+●	+●	+●	+●	+●
1.5 hour		+●	+●	+●	+●	+●	+●	+●
2.0 hour		+●	+●	+●	+●	+●	+●	-●
2.5 hour		+●	+●	+●	+●	+●	-●	-○
3.0 hour		+●	+●	+●	+●	+●	-○	-○
3.5 hour		+●	+●	+●	+●	+●	-○	-○
4.0 hour		+●	+●	+●	+●	+●	-○	-○
4.5 hour		+●	+●	+●	+●	+●	-○	-○
5.0 hour		+●	+●	+●	+●	+●	-○	-○
5.5 hour		+●	+●	+●	-●	+●	-○	-○
6.0 hour		-●	+●	+●	-●	+●	-○	-○
6.5 hour		-●	+●	+●	-○	+●	-○	-○
7.0 hour		-○	+●	+●	-○	+●	-○	-○
7.5 hour		-○	-●	-●	-○	-●	-○	-○
8.0 hour		-○	-○	-○	-○	-○	-○	-○

Note: "+" indicates the sensitivity test is qualified, and "-" indicates the sensitivity test is unqualified.

"●" indicates the negative test is qualified, and "○" indicates the negative test is unqualified.

According to the analysis of the test results, the unsealed test cassette is very sensitive to humidity and slightly less sensitive to temperature. The best storage

temperature of the unsealed test cassette is 2-30 °C, and the environmental humidity is preferably not more than 40%, the best is less than 30%. Under this condition, the unsealed test cassette can be stored for at least 7 hour. Excessive humidity and high or low temperature will make the test cassette lost efficacy quickly. In actual use, the test cassette should be used as soon as possible after sealing to prevent failure.

3.3 Extraction buffer stability of unsealing

The extraction buffer in this kit is mainly composed of Phosphate buffered saline and preservative, which is not sensitive to temperature and humidity condition. In the actual use process, the extraction solution shall be used as soon as possible after unsealing.

2. Accelerate Stability Study

2.1 Design scheme of accelerate stability study

Before starting the stability study, the design scheme of accelerate stability study of SARS-CoV-2 IgG/IgM Rapid Test need to be followed the requirements of EN ISO 23640: 2015. The specific design scheme is shown in the table below:

Table3 Shelf life stability study plan

Protocol	IVD reagent shelf-life including transport stability
responsibilities	R & D department is responsible for the implementation of the plan
clear IVD reagent identification	
presumed storage conditions	30°C, 34°C, 37°C, 40°C, 45°C
Accelerating contrast reagent	HP antibody detection kit Registration certificate : 国械注准20163402241
objective and purpose of testing	Study of Shelf life and stability during transportation
information about the samples	20200203, 20200205, 20200208 three lots ;
storage conditions recommended for the samples	Stored at 2-8°C

19	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖
20	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖
21	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖
22	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖
23	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖
24	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖
25	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖
26	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖
27	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖
28	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	+⊖	-⊖
29	+⊖	+⊖	+⊖	+⊖	-⊖	+⊖	+⊖	+⊖	+⊖	-⊖
30	+⊖	+⊖	+⊖	+⊖	-⊖	+⊖	+⊖	+⊖	+⊖	-⊖

Note: "+" indicates the sensitivity test is qualified, and "-" indicates the sensitivity test is unqualified.

“⊖” indicates the specificity test is qualified, and “⊕” indicates the specificity test is unqualified.

Comparison the accelerated stability results of SARS-CoV-2 IgG/IgM Rapid Test and HP antibody detection kit, SARS-CoV-2 IgG/IgM Rapid Test product stability reached the level of HP antibody detection kit stability.

HP antibody detection kit has a shelf life of up to 24 months from the shelf life stability Test, so a shelf life of 24 months for SARS-CoV-2 IgG/IgM Rapid Test is appropriate.

3 Transportation stability analysis

3.1 method of transportation

Products are transported by cars and trains for short distance, transported by sea and air for long distance.

3.2 Lighting effect

The product is sealed and packaged during transportation. The inner material is aluminum foil pouch; the light will not affect the product.

3.3 Humidity effect

Each component in the kit is sealed, it is not sensitive to humidity during transportation, that is, the humidity will not affect the validity of the kit during transportation.

Based on the above analysis, the main factors such as light, humidity, and temperature which will affect product performance during the entire transportation process, are under control and will not affect the product performance.

4 HP antibody detection kit Stability experimental data

The analytical specificity and sensitivity are tested according to the operating methods and requirements, the test results are shown in Table 2.

Table5 Shelf life stability study results

Time	Temperature range			
	-4℃	2℃	30℃	40℃
Start	+⊖	+⊖	+⊖	+⊖
1 week	+⊖	+⊖	+⊖	+⊖
2 weeks	+⊖	+⊖	+⊖	+⊖
3 weeks	+⊖	+⊖	+⊖	+⊖
4 weeks	+⊖	+⊖	+⊖	+⊖
8 weeks	+⊖	+⊖	+⊖	+⊖
12 weeks	+⊖	+⊖	+⊖	+⊖
16 weeks	+⊖	+⊖	+⊖	+⊖
20 weeks	+⊖	+⊖	+⊖	+⊖
24 weeks	+⊖	+⊖	+⊖	+⊖
28 weeks	+⊖	+⊖	+⊖	+⊖
32 weeks	+⊖	+⊖	+⊖	+⊖
36 weeks	-⊖	+⊖	+⊖	+⊖
40 weeks	-⊖	+⊖	+⊖	-⊖
44 weeks	-⊖	+⊖	+⊖	-⊖
48 weeks	-⊖	+⊖	+⊖	-⊖
52 weeks	-⊖	+⊖	+⊖	-⊖
56 weeks	-⊖	+⊖	+⊖	-⊖
60 weeks	-⊖	+⊖	+⊖	-⊖
64 weeks	-⊖	+⊖	+⊖	-⊖
68 weeks	-⊖	+⊖	+⊖	-⊖
72 weeks	-⊖	+⊖	+⊖	-⊖
76 weeks	-⊖	+⊖	+⊖	-⊖
80 weeks	-⊖	+⊖	+⊖	-⊖
84 weeks	-⊖	+⊖	+⊖	-⊖
88 weeks	-⊖	+⊖	+⊖	-⊖
92 weeks	-⊖	+⊖	+⊖	-⊖

96 weeks	-⊖	+⊖	+⊖	-⊖
100 weeks	-⊖	+⊖	+⊖	-⊖
104 weeks	-⊖	+⊖	+⊖	-⊖
108 weeks	-⊖	+⊖	+⊖	-⊖
114 weeks	-⊖	+⊖	+⊖	-⊖

Note: "+" indicates the sensitivity test is qualified, and "-" indicates the sensitivity test is unqualified.

“⊖”Indicates the specificity test is qualified, and “⊕”indicates the specificity test is unqualified.

According to the analysis of the test results, under the freezing condition, the effectiveness of the kit decreases rapidly, and the high temperature will also have a certain impact on the effectiveness of the kit. The best storage temperature is 2-30 °C, and the validity of the kit can be set as 24 months.

Compared the storage condition in 2-30 °C, when Store at temperature of -4 °C will accelerate product aging time is 82 weeks, When store at temperature of 40° C will accelerate product aging time is 78 weeks .The temperature has a great effect on the aging of the product. Store at the condition of 2-30 °C, the quality of the product is stable for 24months.