Pinnacle BioLabs
315 Deaderick Street
15th Floor #1550
Nashville, TN 37238

Product Specifications Master Sheet
for
Pinnacle BioLabs COVID-19 Coronavirus Dual IgG/IgM Rapid Test

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1. Purpose for Submission

Emergency Use Authorization (EUA) is being requested by Pinnacle Biolabs located at 315 Deaderick Street, 15th Floor, #1550, Nashville, TN 37238, for the distribution and use of the SARS-CoV-2 IgG/IgM Rapid Test for the in vitro qualitative detection of IgG and IgM antibodies to the SARS-CoV-2 virus in the human whole blood specimens from patients with suspicion of or symptoms of infection with this virus. Additional testing and confirmation procedures should be performed in consultation with public health and/or other authorities to whom reporting is required. Positive results should also be reported in accordance with local, state, and federal regulations. Performance is unknown in asymptomatic patients.

2. Measurement

Specific IgG and IgM antibodies of the SARS-CoV-2.

3. Applicant

Official Name: Pinnacle Biolabs
Official Address: 315 Deaderick St #1550, Nashville, TN 37238
Official Website: www.PBLabs.com

Represented by: Brij Strategic Consultations, LLC
Address: 20271 Goldenrod Lane, Suite 2020
Germantown, MD 20876

4. Proprietary and Established Names

Proprietary Name - SARS-CoV-2 IgG/IgM Rapid Test

Established Name - Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test

5. Regulatory Information

5.1. Approval/Clearance Status

The SARS-CoV-2 IgG/IgM Rapid Test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption.

5.2. Product Code:

QKO

6. Proposed Intended Use

6.1. Intended Use

The SARS-CoV-2 IgG/IgM Rapid Test is a colloid-gold immunoassay test intended for a lateral flow immunoassay for the qualitative detection and differentiation of IgG and IgM of Novel Coronavirus (SARS-CoV-2) in human blood specimens.

The test identifies anti-Sar-Cov-2 IgG and IgM antibodies in human blood within days of being exposed to the infection. The IgG and IgM antibodies are generally detectable in human whole blood specimens early on during the infection and appearance of early symptoms of COVID-19. It is intended as a rapid screening test with provides results within minutes. Positive results are indicative of active infection. The test is indicated as a screening test. The positive test must be confirmed by other methods, and combined with clinical observations, patient history, and epidemiological information.

The SARS-CoV-2 IgG/IgM Rapid Test comes with instructions to be used rapidly with minimal training. The test uses process that is expected to be very familiar for medically trained professionals and consumers alike. The "COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test" is indicated only for use under the Food and Drug Administration's Emergency Use Authorization at this time.

6.2. Special Conditions for Use Statements:

For prescription use only
For in vitro diagnostic use only

6.3. Special Instrument Requirements:

The "SARS-CoV-2 IgG/IgM Rapid Test" kit contains all the necessary components needed to conduct the test. The results can be visually read and interpreted, and do not require any additional equipment.

7. Device Description and Test Principle

7.1. Product Overview/Test Principle

The “SARS-CoV-2 IgG/IgM Rapid Test” is a colloid-gold immunoassay test intended for a lateral flow immunoassay for the qualitative detection of antibodies to Sars-Cov-2 virus in human whole blood specimens. The test is intended to be used on individuals with signs and symptoms of suspected COVID-19. It is a rapid screening test that provides results within minutes.

The SARS-CoV-2 IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant SARS-CoV-2 antigen conjugated with colloid gold (SARS-CoV-2 conjugated) and quality control antibody gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (IgG and IgM bands) and a control band (C band). The IgG band is pre-coated with monoclonal anti-human IgG for the detection of IgG anti-SARS-CoV-2, IgM band is pre-coated with reagents for the detection of IgM anti-SARS-CoV-2 and the C band is pre-coated with quality control antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette.

SARS-CoV-2 IgM antibodies if present in the specimen will bind to the SARS-CoV-2conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored IgM band, indicating SARS-CoV-2 IgM positive test result.

SARS-CoV-2 IgG antibodies if present in the specimen will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored IgG band, indicating a SARS-CoV-2 IgG positive test result.

7.2. Description of Test Steps

The steps for using the SARS-CoV-2 IgG/IgM Rapid test are described below:

Step 1: Storage and Stability

The kit should be stored at 2~30°C in cool and dry place, protected from light.

Step 2: Open the Test Kit and Prepare for the Test

After opening the aluminum foil pouch, the test card will become invalid due to moisture absorption. Therefore, it is important that the test is performed and resulted within one hour of opening the individually wrapped foil cassette. Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse test.

Step 3: Disinfect

Wash the hand with soap and water; alcohol wipe can also be used to disinfect the hands before sample collection. Choose the non-dominant hand and face it palm side up and gently massage the finger to be pricked as shown in as shown in Figure 71.

Figure 71. Massage fingertip

Step 4: Puncture Skin

Remove the cap from the finger-stick device and use the disposable finger-stick device to stick the ring finger as shown in Figure 72.

Figure 72. Finger Stick Device

Step 5: Remove Excess Blood

It is recommended to wipe off the first droplet of blood with the provided gauze pad shown in Figure 73.

Figure 73. First droplet of blood removal with gauze pad

Step 6: Pipette Blood

Fill the pipette dropper with the blood specimen as shown in Figure 74.

Figure 74. Pipetting of blood

Step 7: Add Blood Drops to the Test Strip

Holding the dropper vertically, dispense 1 drop (about 10 µL) of whole blood into the sample well, making sure that there are no air bubbles as shown in Figure 75.

Figure 75. Blood drops added to test strip

Step 8: Add Diluent

Add 2 drops (about 70-100 µL) of Sample Diluent immediately as shown in Figure 76.

Figure 76. Diluent added to test strip

Step 9: Read Results

Set up timer for 15 minutes. Read and record results at the 14-1minute mark. It is important not to read results after 15 minutes as described in Section 8.

7.3. Control Material(s) to be used with COVID-19 (Sars-Cov-2) IgM/IgG Rapid test:

The quality control is embedded in the test strip. The test card contains a quality control band C. Regardless of the presence or absence of a detection band, the red quality control band C should appear. The quality control band is a color band of the quality control antibody immune complex. If the quality control band C does not appear, the test result is invalid, and the sample needs to be tested again with another test card.

8. Interpretation of Results

8.1. Examination and Interpretation of Patient Specimen Results:

The results for the “SARS-CoV-2 IgG/IgM Rapid Test” can be read as follows:

Figure 81. IgM/IgG positive

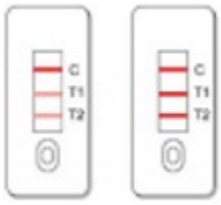


Figure 82. IgG positive/ IgM negative

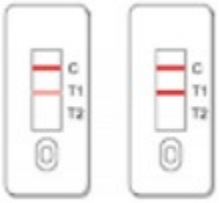


Figure 83. IgM positive, IgG Negative

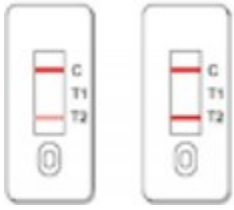
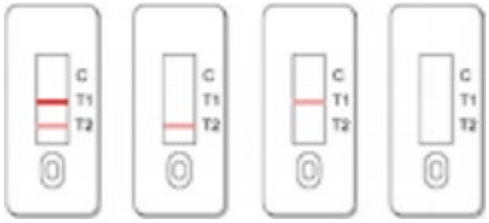


Figure 84. Negative

Figure 85. Invalid Cases



9. Product Manufacturing

The SARS-CoV-2 IgG/IgM Rapid Test has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA.

9.1 Overview of Manufacturing and Distribution

The SARS-CoV-2 IgG/IgM Rapid Test was designed and manufactured with personnel and machinery consistent with practices for the production of immunoassay devices based on ISO 13485-2016 medical device quality management system**.**

Each test kit box is supplied with sufficient components for 25 tests. Up to 25 different samples can be tested using one text box, or fewer samples can be tested more than 1 times. The product will be distributed by Pinnacle BioLabs.

9.2 Components Included with the Test

Components supplied with the test kit box include:

- 25 Individually wrapped test cassette device(s)
- Disposable pipettes (25)
- 5 mL buffer
- Instructions for Use
- Results Interpretation Quick Guide.

9.3 Components Required but Not Included with the Test

Components required but not included with the test: Timer

9.4 Testing Capabilities

Total time of 15-20 minutes is required to complete each test.

9.5 Reagent Stability

Stability testing of in vitro diagnostic reagents are described in detail in Appendix 13.2

10. Performance Evaluation

The clinical trial test implementation and result statistics are detailed in Appendix 13.1.

11. Package Label:

The label for the package is provided in Figure 111.

Figure 111. Package Label

12. **Record Keeping** and Reporting Information to FDA:

Pinnacle BioLabs will track adverse events and report to FDA under 21 CFR Part 803. A website will be available to report on adverse events, and this website will be referenced in the Fact Sheet for Health Care providers as well as through the "COVID-19 (Sars-Cov-2) IgM/IgG test" Product Support website: https://pblabs.com/. Each report of an adverse event will be processed according to Pinnacle BioLabs Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, Pinnacle BioLabs will also maintain records of device usage/purchase. Pinnacle BioLabs will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which Pinnacle BioLabs becomes aware. Pinnacle BioLabs will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Records will be made available to FDA for inspection upon request.

13. APPENDIX

13.1. Test Implementation and Result Statistics

13.1.1. Statistics of test results

Collected 81 cases clinical specimen from Novel Coronavirus infected patients, include 49 cases blood specimen from confirmed Positive Novel Coronavirus infected patients and 32 cases from confirmed negative Novel Coronavirus infected patients.

13.1.2. Statistics of Positive Specimen

Since IgM is released first followed by IgG a few days later in the course of an infection, the detection of IgM and IgG can indicate the stage of infection in an individual.

The positive diagnosis based on sampling time were classified as Table 131 shows.

Table 131. Positive Diagnosis Based on Sampling Time

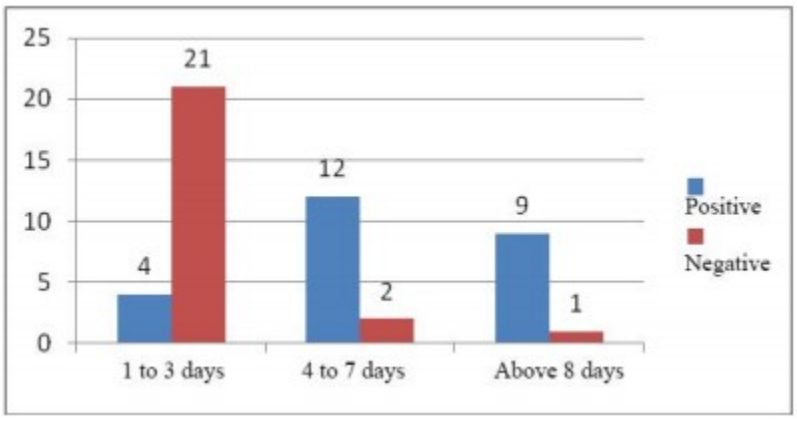
		IgM		IgG	
Specimen Positive Time	**Number of Specimens**	**Positive**	**Negative**	**Positive**	**Negative**
1 Day	15	2	13	2	13
2 Days	9	2	7	2	7
3 Days	1	0	1	0	1
4 Days	5	4	1	5	0
5 Days	3	3	0	3	0
6 Days	4	3	1	3	1
7 Days	2	2	0	2	0
8 Days	3	2	1	2	1
9 Days	2	2	0	2	0
10 Days	3	3	0	3	0
12 Days	2	2	0	2	0

The 49 positive specimens were further classified according to the time when the specimens were taken. Samples were divided into samples taken 1-3 days after the positive diagnosis, samples taken 4-7 days after the positive diagnosis, and samples taken more than 8 days after the positive diagnosis (Table 132; Figure 131).

Table 132. Classification and statistical results of positive specimens

		IgM		**IgG**	
Specimen Positive Time	**Number of Specimens**	**Positive**	**Negative**	**Positive**	**Negative**
1-3 Days	25	4	21	4	21
4-7 Days	14	12	2	13	1
Above 8 Days	10	9	1	9	1

Figure 131. Classification Statistics of Positive Test Results



13.1.3. Classification and analysis of positive specimen from clinical positive confirmed to sampling date

A total of 24 specimens were tested from 1 to 3 days, the IgM positive rate was 16% and the IgG positive rate was 16%. A total of 14 specimens were tested from 4 to 7 days, the IgM positive rate was 85.7% and the IgG positive rate was 92.8%. A total of 10 specimens were tested in the range of more than 8 days, the IgM positive rate was 90% and the IgG positive rate was 90%.

13.1.4. Statistical analysis of confirmed negative specimens

32 cases of confirmed negative specimens were tested and the negative coincidence rate was 100%. Statistics are shown in Table 133.

Table 133. Confirmed Negative Cases

	IgM		IgG	
Number of Specimens	**Positive**	**Negative**	**Positive**	**Negative**
32	0	32	0	32

13.2. Stability testing of in vitro diagnostic reagents

13.2.1. Unsealing Stability study

Before starting the unsealing stability study, the design scheme of shelf life stability study of SARS-CoV-2 IgG/IgM Rapid Test needed to be followed according to the requirements of EN13640:2002. The specific design scheme is shown in Table 134:

Table 134. Unsealing stability study plan

Responsibilities	R & D department is responsible for the implementation of the plan
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 performed at the end of each interval	Collect serum,plasma and whole blood from positive Novel Coronavirus infection patient
Stability criteria to be met	Collect serum,plasma and whole blood from negative Novel Coronavirus infection patien
Interpretation of data	Statistical analysis of the data

The results of the unsealing stability study are shown in Table 135.

Table 135. Unsealing stability study results

	Temperature as below Humility ＜30%				Temperature 20℃ Humility as below		
Time (hrs)	**-4℃**	**2℃**	**30℃**	**40℃**	**10-30%**	**40-60%**	**70-90%**
Onset	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●
0.5	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●
1	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●
1.5	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●
2.0	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●	- ●
2.5	+ ●	+ ●	+ ●	+ ●	+ ●	- ●	- ○
3.0	+ ●	+ ●	+ ●	+ ●	+ ●	- ○	- ○
3.5	+ ●	+ ●	+ ●	+ ●	+ ●	- ○	- ○
4.0	+ ●	+ ●	+ ●	+ ●	+ ●	- ○	- ○
4.5	+ ●	+ ●	+ ●	+ ●	+ ●	- ○	- ○
5.0	+ ●	+ ●	+ ●	+ ●	+ ●	- ○	- ○
5.5	+ ●	+ ●	+ ●	- ●	+ ●	- ○	- ○
6.0	- ●	+ ●	+ ●	- ●	+ ●	- ○	- ○
6.5	- ●	+ ●	+ ●	- ○	+ ●	- ○	- ○
7.0	- ○	+ ●	+ ●	- ○	+ ●	- ○	- ○
7.5	- ○	- ●	- ●	- ○	- ●	- ○	- ○
8.0	- ○	- ○	- ○	- ○	- ○	- ○	- ○

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 was very sensitive to humidity and slightly less sensitive to temperature. The best storage temperature for the unsealed test cassette was 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 hours. Excessive humidity and high or low temperature will make the test cassette lose efficacy rapidly. In actual use, the test cassette should be used as soon as possible after sealing to prevent failure.

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

13.2.2. Accelerated Stability Study

Before starting the stability study, the design scheme of the accelerated stability study of SARS-CoV-2 IgG/IgM Rapid Test needed to be followed according to the requirements of EN ISO 23640: 2015. The specific design scheme is shown in Table 136.

Table 136. Accelerated Stability Study Plan

Responsibilities	R & D department is responsible for the implementation of the plan
Presumed storage conditions	30°C，34°C，37°C，40°C，45°C
Accelerating contrast reagent	HP antibody detection kit Registration certificate: 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
Simulation of transport as appropriate	Analyze the stability of the product during transportation according to the transportation conditions
Intervals between examinations	Take out the kits from storage for testing each day

Examinations to be performed at the end of each interval	Collect serum,plasma and whole blood from positive Novel 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

The results of the accelerated stability study are detailed in table

Table 137. Accelerated Stability Study Results

	Coronavirus (COVID-19) IgG/ IgM Rapid Test					**HP antibody detection kit**				
Time (Days)	**Temperature °C**									
	30	**34**	**37**	**40**	**45**	**30**	**34**	**37**	**40**	**45**
Start	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
1	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
2	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
3	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
4	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
5	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
6	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
7	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
8	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
9	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
10	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
11	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
12	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
13	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○

14	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
15	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
16	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
17	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
18	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
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.

A comparison of the accelerated stability results of SARS-CoV-2 IgG/IgM Rapid Test and HP antibody detection kit shows that the 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.

13.2.3. Transportation Stability Analysis

13.2.3.1. Method of Transportation

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

13.2.3.2. Lighting Effect

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

13.2.3.3. Humidity Effect

Each component in the kit is sealed and 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.

13.2.4. HP Antibody Detection Kit Stability Experimental Data

The stability results for the HP antibody detection kit are described in table.

Table 138. HP antibody detection kit stability results

Time (weeks)	Temperature (°C)			
	-4	**2**	**30**	**40**
Start	+○	+○	+○	+○
1	+○	+○	+○	+○
2	+○	+○	+○	+○
3	+○	+○	+○	+○
4	+○	+○	+○	+○
8	+○	+○	+○	+○
12	+○	+○	+○	+○
16	+○	+○	+○	+○

Time (weeks)	Temperature (°C)			
	-4	**2**	**30**	**40**
20	+○	+○	+○	+○
24	+○	+○	+○	+○
28	+○	+○	+○	+○
32	+○	+○	+○	+○
36	−○	+○	+○	+○
40	−○	+○	+○	−○
44	−○	+○	+○	−○
48	−○	+○	+○	−○
52	−○	+○	+○	−○
56	−○	+○	+○	−○
60	−○	+○	+○	−○
64	−○	+○	+○	−○
68	−○	+○	+○	−○
72	−○	+○	+○	−○
76	−○	+○	+○	−○
80	−○	+○	+○	−○
84	−○	+○	+○	−○
88	−○	+○	+○	−○
92	−○	+○	+○	−○
96	−○	+○	+○	−○
100	−○	+○	+○	−○
104	−○	+○	+○	−○
108	−○	+○	+○	−○

Time (weeks)	Temperature (°C)			
	-4	**2**	**30**	**40**
114	−○	+○	+○	- ○

Note: "+" indicates the sensitivity test is qualified, and "-" indicates the sensitivity test is unqualified.
“○” indicates the specificity test is qualified.

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