SARS-CoV-2 Antigen Test Kit (colloidal gold method)

Stability study

Manufacturer: BIOTEKE CORPORATION (WUXI) CO., LTD

Catalogue

一、Overview

1. Purposes

Study the validity period of kits and samples under different storage conditions.

2. Product name and specification

Novel coronavirus (2019-nCoV) antigen detection kit (colloidal gold method), referred to as "this kit". Specification：20test/box

3. Reference product composition and product performance indicators

3.1 Reference product composition

Table 1 Reference product composition

Types	No.	Microorganism category
Negative reference	QT01	*Staphylococcus aureus*
	QT02	*Streptococcus pneumoniae*
	QT03	*Measles virus*
	QT04	*Mumps virus*
	QT05	*Adenovirus type 3*
	QT06	*Mycoplasma pneumoniae*
	QT07	*Parainfluenza type 2*
	QT08	*Metapneumovirus*
	QT09	*Coronavirus OC43*
	QT10	*Coronavirus 229E*
	QT11	*Bacillus parapertussis*
	QT12	*Influenza B virus (Victoria line)*
	QT13	*Influenza B virus (Yamagata series)*
	QT14	*H1N1 (2009) influenza virus*
	QT15	*Influenza A H3N2 virus*
	QT16	*Epstein-Barr virus*
	QT17	*Enterovirus CA16*
	QT18	*Rhinovirus*
Positive reference	QY01	SARS-CoV-2
	QY02	SARS-CoV-2
	QY03	SARS-CoV-2
	QY04	SARS-CoV-2
	QY05	SARS-CoV-2
Repetitive reference	CV01	SARS-CoV-2（Moderately Positive）
	CV02	SARS-CoV-2（Weakly positive）
Lowest detection limit reference	S01	SARS-CoV-2

3.2 Performance

Samples to be tested:

Number of samples (Number of repeats): 18 negative enterprise reference samples (external negative controls), 5 positive enterprise reference samples (external positive controls), 2 repeatability enterprise reference samples (external positive controls) and 4 LoD enterprise reference samples (external positive controls). A known positive clinical sample diluted to 3x LoD by negative nasopharyngeal swab specimen,a known positive clinical sample diluted to 5x LoD by negative nasopharyngeal swab specimen, a known negative clinical sample.

Source: from clinically diagnosis SARS-CoV-2 cases and non SARS-CoV-2 cases.

Storage: store at -70℃.

Number of replicates: 1 replicate per negative enterprise reference sample, positive enterprise reference sample and LoD enterprise reference sample. 10 replicates per repeatability enterprise reference sample. 5 replicates per 3x LoD clinical sample, 5x LoD clinical sample and negative clinical sample.

Acceptance criteria:

3.2.1 Appearance

Use visual inspection with normal vision or corrected vision under natural light: the components of the kit should be complete, and the outer packaging should be clean and free of contamination.The test card is sealed and stored without damage and pollution. The sample diluent is colorless, clear and homogeneous, without visible impurities or precipitates.

3.2.2 The width of membrane strip

Take one film strip randomly from the kit and measure with vernier caliper. The width of film strip shall not be less than 2.5mm.

3.2.3 Liquid migration speed

Select three test cards randomly and place them horizontally. Measure the distance L (mm) between the center of the sampling hole and the distal end of the observation window. Use the sample diluent as the sample to be tested and record the time t (s) required for the liquid to move to the far end of the observation window with a stopwatch. Calculate L / T (mm / min), which is the migration speed. The migration speed of liquid should not be less than 10 mm / min.

3.2.**4** Coincidence rate of positive reference

The positive enterprise reference samples should be tested once, and the results should be positive.

3.2.5 Coincidence rate of negative reference

The negative enterprise reference samples should be tested once, and the results should be negative.

3.2.6 Limit of detection (LoD)

Dilute the LoD enterprise reference sample into S1, S2, S3 and S4 by 2 times, 4 times, 8 times and 16 times, respectively. Test each sample once, S1 and S2 results should be positive, and S3 and S4 results can be negative or positive.

3.2.7 Repeatability

The results of 10 tests on each repeatability enterprise reference sample should be positive and uniform in color.

3.2.8 Accuracy of clinical sample test

Test two clinical positive samples and one clinical negative sample, and the test results should be consistent with the known results.

二、Stability study

2.1Shipping Stability (Unopened kit)

- ***Claims:*** *40℃ for less than 30 days.*
- ***Number of test points:*** *testing at 0,10,20,30,35 days.*
- ***Baseline:*** *0 day from bottling*
- ***Product Lots to be tested:*** *20200801, 20200802, 20200803*
- ***Experimental protocol:*** *Test the kits before transportation. Then the test kits are placed in a shaker that can maintain a constant temperature of 40℃ for transportation simulation, which is shaken at a certain frequency to simulate transportation conditions. The kits are tested at 0,10,20,30,35 days.*
- ***Results:*** *Test results are as follows.*

Lot number	*Performance Time*		*Day 0*	*Day 10*	*Day 20*	*Day 30*	*Day 35*
20200801	*Appearance*		*Qualified*	*Qualified*	*Qualified*	*Qualified*	*Qualified*
	The width of the membrane strip (mm)		*4.03*	*4.10*	*4.04*	*4.06*	*4.08*
	Liquid migration speed (mm/min)		*26.7, 26.71, 26.35*	*26.45, 26.74, 26.62*	*26.32, 26.51, 26.49*	*25.89, 25.78, 26.11*	*26.32, 26.28, 26.42*
	Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*	*5/5（+）*	*5/5（+）*
	Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*	*18/18（-）*	*18/18（-）*
	Repeatability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*
		CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*
	LoD	*S1*	+	+	+	+	+
		S2	+	+	+	+	+
		S3	+	+	+	+	+
		S4	-	+	+	-	+
	Accuracy of clinical sample test	*3*LoD*	+	+	+	+	+
		*5*LoD*	+	+	+	+	+
		Negative	-	-	-	-	-
20200802	*Appearance*		*Qualified*	*Qualified*	*Qualified*	*Qualified*	*Qualified*
	The width of the membrane strip (mm)		*4.05*	*4.07*	*4.03*	*4.02*	*4.06*
	Liquid migration speed (mm/min)		*25.74，25.94，26.7*	*25.86, 25.59, 25.65*	*26.12, 26.11, 26.21*	*26.31, 26.33, 26.41*	*26.45, 26.51, 26.84*
	Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*	*5/5（+）*	*5/5（+）*
	Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*	*18/18（-）*	*18/18（-）*
	Repeatability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*
		CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*

	LoD	*S1*	+	+	+	+	+
		S2	+	+	+	+	+
		S3	+	+	+	+	+
		S4	+	+	+	-	+
	Accuracy of clinical sample test	*3*LoD*	+	+	+	+	+
		*5*LoD*	+	+	+	+	+
		Negative	-	-	-	-	-
20200803	*Appearance*		*Qualified*	*Qualified*	*Qualified*	*Qualified*	*Qualified*
	The width of the membrane strip (mm)		*3.92*	*3.89*	*3.94*	*3.97*	*3.91*
	Liquid migration speed (mm/min)		*26.05，25.83，25.94*	*26.21, 26.45, 25.98*	*26.06, 25.86, 25.81*	*26.11, 26.2, 26.13*	*25.97, 25.92, 26.02*
	Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*	*5/5（+）*	*5/5（+）*
	Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*	*18/18（-）*	*18/18（-）*
	Repeatability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*
		CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*	*10/10（+）*
	LoD	*S1*	+	+	+	+	+
		S2	+	+	+	+	+
		S3	-	+	+	+	+
		S4	-	-	+	+	-
	Accuracy of clinical sample test	*3*LoD*	+	+	+	+	+
		*5*LoD*	+	+	+	+	+
		Negative	-	-	-	-	-

- ***Conclusions:*** *The results show that the test kit stored for 35 days under simulated transportation environment performs normally. Under the principle of ensuring the validity of the test kit, we recommend that the transportation condition of the test kit be stored at 40 ℃, less than 30 days.*

2.2. Real-time stability study (Unopened kit)

- ***Claims:*** *Store at 2 ℃~30 ℃, valid for 18 months.*
- ***Number of test points:*** *testing at 0,1,2,3,6,12,18,20 months*
- ***Baseline:*** *0 day from bottling*
- ***Product Lots to be tested:*** *20200801, 20200802, 20200803*
- ***Experimental protocol:*** *Test the kits as soon as they are bottled. After the kits were qualified, each batch of kits were divided into two parts, one was stored at 2 ~ 8 ℃ and the other was stored at 30 ℃ for real-time stability study. The kits were stored for 1,2,3,6,12,18,20 months and then taken out for testing. Real time stability is still in progress.*
- ***Results:*** *Test results are as follows.*

Baseline Result

Performance / *Lot number*		*20200801*	*20200802*	*20200803*
Appearance		*Qualified*	*Qualified*	*Qualified*
The width of the membrane strip (mm)		*4.04*	*4.06*	*4.07*
Liquid migration speed (mm/min)		*26.24, 26.51, 25.77*	*25.98, 25.94, 25.88*	*26.01, 26.11, 26.08*
Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*
Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*
Repeatability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*
	CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*
LoD	*S1*	+	+	+
	S2	+	+	+
	S3	+	+	+
	S4	-	+	-
Accuracy of clinical sample test	*3*LoD*	+	+	+
	*5*LoD*	+	+	+
	Negative	-	-	-

Results of kits stored at 2~8℃

Lot number	*Time* / *Performance*		*1 month*	*2 months*	*3 months*	*6 months*	*12 months*	*18 months*	*20 months*
20200801	*Appearance*		*Qualified*	*Qualified*	*Qualified*	*On-going*			
	The width of the membrane strip (mm)		*3.91*	*4.05*	*4.01*				
	Liquid migration speed (mm/min)		*26.19，26.13，25.94*	*25.74，26.05，24.95*	*26.53，25.6，26.13*				
	Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*				
	Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*				
	Repeatability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*				
		CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*				
	LoD	*S1*	+	+	+				

		S2	+	+	+				
		S3	+	-	-				
		S4	-	-	+				
	Accuracy of clinical sample test	*3*LoD*	+	+	+				
		*5*LoD*	+	+	+				
		Negative	-	-	-				
20200802	*Appearance*		*Qualified*	*Qualified*	*Qualified*	*On-going*			
	The width of the membrane strip (mm)		*4.02*	*3.99*	*4.01*				
	Liquid migration speed (mm/min)		*26.13，26.35，25.83*	*26.35，25.94，24.95*	*26.05，24.95，25.94*				
	Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*				
	Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*				
	Repeatability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*				
		CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*				
	LoD	*S1*	+	+	+				
		S2	+	+	+				
		S3	-	+	-				
		S4	-	-	+				
	Accuracy of clinical sample test	*3*LoD*	+	+	+				
		*5*LoD*	+	+	+				
		Negative	-	-	-				
20200803	*Appearance*		*Qualified*	*Qualified*	*Qualified*	*On-going*			
	The width of the membrane strip (mm)		*4.03*	*4.02*	*4.01*				
	Liquid migration speed (mm/min)		*26.05，25.94，26.21*	*26.05，25.83，24.95*	*26.13，24.95，25.94*				
	Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*				
	Coincidence rate of negative		*18/18（-）*	*18/18（-）*	*18/18（-）*				

	reference								
	Repeatability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*				
		CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*				
	LoD	*S1*	+	+	+				
		S2	+	+	+				
		S3	-	-	+				
		S4	+	-	-				
	Accuracy of clinical sample test	*3*LoD*	+	+	+				
		*5*LoD*	+	+	+				
		Negative	-	-	-				

Results of kits stored at 30 ℃

Lot number	*Performance* \ *Time*		*1 month*	*2 months*	*3 months*	*6 months*	*12 months*	*18 months*	*20 months*
20200801	*Appearance*		*Qualified*	*Qualified*	*Qualified*	*On-going*			
	The width of the membrane strip (mm)		*4.05*	*4.04*	*4.03*				
	Liquid migration speed (mm/min)		*25.74，26.21，26.35*	*25.42，25.74，24.83*	*26.0，24.83，26.53*				
	Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*				
	Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*				
	Repeatability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*				
		CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*				
	LoD	*S1*	+	+	+				
		S2	+	+	+				
		S3	+	-	+				
		S4	-	+	-				
	Accuracy of clinical sample test	*3*LoD*	+	+	+				
		*5*LoD*	+	+	+				
		Negative	-	-	-				
2020	*Appearance*		*Qualifi*	*Qualified*	*Qualified*	*On-going*			

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	The width of the membrane strip (mm)		*3.97*	*3.94*	*3.95*				
	Liquid migration speed (mm/min)		*26.71，26.05，25.6*	*25.94，26.19，24.95*	*26.35，25.74，25.27*				
	Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*				
	Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*				
	Repeat ability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*				
		CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*				
	LoD	*S1*	+	+	+				
		S2	+	+	+				
		S3	-	+	-				
		S4	-	-	+				
	Accuracy of clinical sample test	*3*LoD*	+	+	+				
		*5*LoD*	+	+	+				
		Negative	-	-	-				
2020 0803	*Appearance*		*Qualified*	*Qualified*	*Qualified*	*On-going*			
	The width of the membrane strip (mm)		*4.04*	*4.02*	*4.03*				
	Liquid migration speed (mm/min)		*25.74，25.83，25.42*	*24.95，25.94，26.05*	*25.6，26.0，24.95*				
	Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*				
	Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*				
	Repeat ability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*				
		CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*				
	LoD	*S1*	+	+	+				
		S2	+	+	+				
		S3	-	-	+				
		S4	+	-	-				

	Accuracy of clinical sample test	*3*LoD*	+	+	+				
		*5*LoD*	+	+	+				
		Negative	-	-	-				

2.3. In-use/Opened Kit Stability - Sample diluent

- ***Claims:*** *Store at 2 ℃~30 ℃, valid for 18 months.*
- ***Number of test points:*** *testing at 1,2,3,6,12,18,20 months*
- ***Baseline:*** *Opening the bottle for the first time, 0 day from bottling.*
- ***Product Lots to be tested:*** *20200801*
- ***Experimental protocol:*** *Take out a number of test kits and use them for the first time (all bottles of sample diluent are opened to test the physical properties of the kit, the coincidence rate of positive reference, the coincidence rate of negative reference, repeatability, limit of detection and accuracy of clinical sample test). After opening the bottle, the sample diluent is immediately capped and divided into two parts: Part A is kept at 2 ~ 8 ℃ and part B is kept at 30 ℃ The remaining test cards were stored at room temperature (30 ℃). In the bottle opening test after 1, 2, 3, 6, 12, 18 and 20 months of storage, 10 drops of sample diluent were vertically extruded and discarded according to the operation in the manual. The appearance of the sample treatment solution was observed (whether it was colorless, clear and homogeneous liquid, without visible impurities or precipitates). Besides the appearance, the positive reference coincidence rate, negative reference coincidence rate, repeatability, limit of detection and accuracy of clinical sample test were also tested. The test is still in progress.*
- ***Results:*** *Test results are as follows.*

Baseline Result

Appearance	*The width of the membrane strip (mm)*	*Liquid migration speed (mm/min)*	*Coincidence rate of positive reference*	*Coincidence rate of negative reference*	*Repeatability*		*LoD*				*Accuracy of clinical sample test*		
					CV01	*CV02*	*S1*	*S2*	*S3*	*S4*	*3*LoD*	*5*LoD*	*Negative*
Qualified	*4.05*	*26.53，26.13，25.94*	*5/5（+）*	*18/18（-）*	*10/10（+）*	*10/10（+）*	+	+	-	-	+	+	-

Appearance Results of Sample diluent

Temp ℃	*2~8 ℃*						
Time	*1 month*	*2 months*	*3 months*	*6 months*	*12 months*	*18 months*	*20 months*
Appearance	*Qualified*	*Qualified*	*Qualified*	*On-going*			
Temp ℃	*30 ℃*						
Appearance	*1 month*	*2 months*	*3 months*	*6 months*	*12 months*	*18 months*	*20 months*
Appearance	*Qualified*	*Qualified*	*Qualified*	*On-going*			

Results of Coincidence rate of positive reference, Coincidence rate of negative reference, Repeatability, LoD, Accuracy of clinical sample test

2~8℃								
Performance Time		*1 month*	*2 months*	*3 months*	*6 months*	*12 months*	*18 months*	*20 months*
Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*				
Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*				
Repeatability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*				
	CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*				
LoD	*S1*	+	+	+				
	S2	+	+	+				
	S3	-	+	-				
	S4	+	-	-				
Accuracy of clinical sample test	*3*LoD*	+	+	+				
	*5*LoD*	+	+	+				
	Negative	-	-	-				
30℃								
Performance Time		*1 month*	*2 months*	*3 months*	*6 months*	*12 months*	*18 months*	*20 months*
Coincidence rate of positive reference		*5/5（+）*	*5/5（+）*	*5/5（+）*				
Coincidence rate of negative reference		*18/18（-）*	*18/18（-）*	*18/18（-）*				
Repeatability	*CV01*	*10/10（+）*	*10/10（+）*	*10/10（+）*				
	CV02	*10/10（+）*	*10/10（+）*	*10/10（+）*				
LoD	*S1*	+	+	+				
	S2	+	+	+				
	S3	+	-	-				
	S4	-	-	+				
Accuracy of clinical sample test	*3*LoD*	+	+	+				
	*5*LoD*	+	+	+				
	Negative	-	-	-				

2.4. In-use/Opened Kit Stability - Test card

- ***Claims:*** *Store at 30℃, stable for 1 hour*
- ***Number of test points:*** *testing at 0,20,40,60,80 minutes*
- ***Baseline:*** *Tearing off the foil pouch for the first time, 0 day from foil pouch sealing*
- ***Product Lots to be tested:*** *20200801*

- ***Experimental protocol:*** *Take out a number of test kits, take out the test card from the kit, and use it for the first time (tear the aluminum foil pouch, test the physical properties of the kit, the coincidence rate of positive reference and negative reference, repeatability, limit of detection, and accuracy of clinical sample test), and place the unsealed test card at room temperature (30 ℃), and store the sample diluent at 2 ~ 8 ℃. After opening, the test cards were placed for 20 minutes, 40 minutes, 60 minutes and 80 minutes respectively for physical properties, positive reference coincidence rate, negative reference coincidence rate, limit of detection, repeatability and accuracy of clinical sample test.*
- ***Results:*** *Test results are as follows.*

Performance \ Time		0 minute	20 minutes	40 minutes	60 minutes	80 minutes
Appearance		Qualified	Qualified	Qualified	Qualified	Qualified
The width of the membrane strip (mm)		4.06	4.05	4.03	4.04	4.03
Liquid migration speed (mm/min)		25.68, 25.76, 25.94	25.74, 26.71, 26.0	26.71, 26.35, 27.29	26.35, 26.21, 26.53	26.04, 26.08, 26.11
Coincidence rate of positive reference		5/5（+）	5/5（+）	5/5（+）	5/5（+）	5/5（+）
Coincidence rate of negative reference		18/18（-）	18/18（-）	18/18（-）	18/18（-）	18/18（-）
Repeatability	CV01	10/10（+）	10/10（+）	10/10（+）	10/10（+）	10/10（+）
	CV02	10/10（+）	10/10（+）	10/10（+）	10/10（+）	10/10（+）
LoD	S1	+	+	+	+	+
	S2	+	+	+	+	+
	S3	+	-	-	+	+
	S4	+	+	-	-	+
Accuracy of clinical sample test	3*LoD	+	+	+	+	+
	5*LoD	+	+	+	+	+
	Negative	-	-	-	-	-

- ***Conclusions:*** *The results showed that the performance of test card remained stable for 80 minutes after foil pouch being teared off. Under the principle of ensuring the validity of the test kit, we recommend that test cards should be used as soon as possible within 1 hour after opening the foil pouch.*