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		Version: V1.0
		Page : Total 10 Page 1

Project Name:

SARS-CoV-2 Antigen Test Kit (Colloidal Gold)

Document Name:

Performance Characteristics

Drafted by: 5.1.2e	Checked by: 5.1.2e	Approved by: 5.1.2e
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Summarized review comments:(another page could be attached if not enough)

Revision records

Version	Summarized Revidions	Revisor	Revised Date
V1.0	Initialization Version	5.1.2e	2021.03.15

Performance Characteristics

1. Limit of Detectable (LoD)

1) Test kit: SARS-CoV-2 Antigen Test Kit

Lot No.	Date of Manufacture
2020042101	20200421
2020042301	20200423
2020042501	20200425

2) Test Materials

2.1 The stock viral culture lysate was provided by local CDC and the viral titers was measured by $TCID_{50}$ assay. The original viral concentration was $1.5x10^6$ $TCID_{50}$/mL.

2.2 Using the recombinant Nucleocapsid protein (rNp) , original concentration is 10.0 ug/mL, to evaluate the kit's LoD, to setting the quality control standard.

3) Test method

(1) With the viral lysate stock, made a dilution to each preparation with kit's AE solution to specified concentration listed at following table 1.

(2) With the rNp stock, made a dilution to each preparation with kit's AE solution to specified concentration listed at following table 2.

(3) All diluted samples were tested according to kit's instructions for use.

(4) Repeat testing the LoD candidate concentration of W+ or the last + T line, the confirmed LoD of test kit should be positive at least 19 out of 20 replicates.

Table 1. Diluted preparation of viral titers

Samples No.	Dilution Ratio	Virus Concentration ($TCID_{50}$/mL)
0	Original	$1.5 X 10^6$
1	1:15	$1.0 X 10^5$
2	1:50	$3.0 X 10^4$
3	1:500	$3.0 X 10^3$

4	1:1,000	1.5 X 10^3
5	1:2,000	7.5 X 10^2
6	1:4,000	3.75 X 10^2
7	1:8,000	1.88 X 10^2
8	1:10,000	1.5 X 10^2
9	1:15,000	1.0 X 10^2
10	1:30,000	5.0 X 10^1
11	/	AE solution

Table 2. Diluted preparation of rNp

Samples No.	Dilution Ratio	rNp Concentration (pg/mL)
0	Original	1.0 X 10^7
1	1:100	1.0 X 10^5
2	1:5,000	2.0 X 10^3
3	1:50,000	2.0 X 10^2
4	1:500,000	2.0 X 10^1
5	1:1,000,000	1.0 X 10^1
6	1:2,000,000	0.5 X 10^1
7	/	AE solution

4) Results : as following Table 3-5.

* Intensity of the overall intensity of the test lines are scored as follows :

- Positive Intensity : +
- Very Weak Positive Intensity : W+
- Trace Intensity : +/- No test lines Intensity : -.

Table 3 Test result for LoD - Viral concentration

Samples No.	Dilution	Virus Concentration ($TCID_{50}$/ swab (mL))	Test Result

	Ratio		2020042101	2020042301	2020042501
0	Original	1.5×10^6	/	/	/
1	1:15	1.0×10^5	+	+	+
2	1:50	3.0×10^4	+	+	+
3	1:500	3.0×10^3	+	+	+
4	1:1,000	1.5×10^3	+	+	+
5	1:2,000	7.5×10^2	+	+	+
6	1:4,000	3.75×10^2	+	+	+
7	1:8,000	1.88×10^2	+	+	+
8	1:10,000	1.5×10^2	W+	W+	W+
9	1:15,000	1.0×10^2	+/-	+/-	+/-
10	1:30,000	5.0×10^1	-	-	-
11	/	AE solution	-	-	-

Table 4 Test result for LoD - rNp concentration

Samples No.	Dilution Ratio	rNp Concentration (pg/mL)	Test Result		
			2020042101	2020042301	2020042501
0	Original	1.0×10^7	/	/	/
1	1:100	1.0×10^5	+	+	+
2	1:5,000	2.0×10^3	+	+	+
3	1:50,000	2.0×10^2	+	+	+
4	1:500,000	2.0×10^1	+	+	+
5	1:1,000,000	1.0×10^1	+	+	+
6	1:2,000,000	0.5×10^1	-	-	-
7	/	AE solution	-	-	-

Table 5 Test result for LoD- Repeat Testing

Concentration	Lot No.	Number Positive/Total	Detected Percenta ge (%)
1.5×10^2 $TCID_{50}$ /Swab (mL)	2020042101	20/20	100%
	2020042301	20/20	100%
	2020042501	20/20	100%
rNp 10 pg/mL	2020042101	19/20	95%
	2020042301	19/20	95%
	2020042501	19/20	95%

5) Conclusion

This study shows the SARS-CoV-2 Antigen Test Kit could detect 10000-fold diluted origin viral culture lysate and a 10.0 ug/mL rNp protein stock. The LoD of the test kit is about 1.5 X 10^2 $TCID_{50}$/mL (swab) for viral lysate and 10pg/mL for rNp.

2. High Dose Hook Effect

Base on the data from LoD analysis study, no high dose hook effect was observed when tested with up to a concentration of 1.0×10^5 $TCID_{50}$/mL (swab) of inactivated SARS-CoV-2 virus with the test kit.

3. Cross Reactivity Study

1) Test kit: SARS-CoV-2 Antigen Test Kit

Lot No.	Date of Manufacture
2020042101	20200421
2020042301	20200423
2020042501	20200425

2) Test Materials

Cross reactivity of SARS-CoV-2 Antigen Test Kit was evaluated by testing normal respiratory track pathogenic microorganisms (bacteria, viruses, yeast) and a pooled human nasal wash that may be present in the nasal cavity.

Potential Cross-Reactant		Test Concentration
Virus	*Respiratory Syncytial Virus A*	1.0×10^5 PFU/mL
	Measles Virus	1.0×10^5 $TCID_{50}$/mL
	HCoV-NL63	1.0×10^4 $TCID_{50}$/mL
	MERS	4.0×10^5 $TCID_{50}$/mL
	Mumps Virus	1.0×10^5 $TCID_{50}$/mL
	Adenovirus Type 3	1.0×10^5 $TCID_{50}$/mL
	Parainfluenza Type 2	1.0×10^5 $TCID_{50}$/mL
	Partial Pulmonary Virus	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL
	Influenza B (Victoria Strain)	1.0×10^5 $TCID_{50}$/mL
	Influenza B (Y Strain)	1.0×10^5 $TCID_{50}$/mL
	Influenza A (H1N1,2009)	1.0×10^5 $TCID_{50}$/mL
	Influenza A (H3N2)	1.0×10^5 $TCID_{50}$/mL
	Avian Influenza Virus H7N9	1.0×10^5 $TCID_{50}$/mL
	Avian Influenza Virus H5N1	1.0×10^5 $TCID_{50}$/mL
	Epstein Barr Virus	1.0×10^5 $TCID_{50}$/mL

	Chlamydia pneumoniae	1.0 x 10^6 IFU/mL
	Pooled human nasal wash	N/A
Yeast	*Candida albicans*	1.0 x 10^6 cells/mL
	Enterovirus CA16	1.0 x 10^5 $TCID_{50}$/mL
	Rhinovirus	1.0 x 10^5 PFU/mL
Bacteria	*Staphylococcus aureus*	1.0 x 10^6 CFU/mL
	Streptococcus pneumoniae	1.0 x 10^6 CFU/mL
	Mycoplasma pneumoniae	1.0 x 10^6 IFU/mL
	Parapertussis	1.0 x 10^6 cells/mL

3) Test Method

(1) Each of the bacteria, viruses, and yeast listed above were tested in duplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (1.5 x 10^2 $TCID_{50}$/swab).

(2) All samples were tested according to kit's instructions for use.

4) Results: as following table 6-8.

Table 6 Lot No. 2020042101

Potential Cross-Reactant		Test Co ıcentration	Test Result			
			With inactive virus		Without inactive virus	
			#1	#2	#1	#2
Virus	*Respiratory Syncytial Virus A*	1.0 x 10^5 PFU/mL	+	+	-	-
	Measles Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Mumps Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	HCoV-NL63	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	MERS	4.0 x 10^4 $TCID_{50}$/mL	+	+	-	-

	Adenovirus Type 3	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Parainfluenza Type 2	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Partial Pulmonary Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza B (Victoria Strain)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza B (Y Strain)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza A (H1N1,2009)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza A (H3N2)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Avian Influenza Virus H7 N9	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Avian Influenza Virus H5 N1	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Epstein Barr Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Enterovirus CA16	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Rhinovirus	1.0 x 10^5 PFU/mL	+	+	-	-
Bacteria	*Staphylococcus aureus*	1.0 x 10^6 CFU/mL	+	+	-	-
	Streptococcus pneumonia e	1.0 x 10^6 CFU/mL	+	+	-	-
	Mycoplasma pneumoniae	1.0 x 10^6 IFU/mL	+	+	-	-
	Parapertussis	1.0 x 10^6 cells/mL	+	+	-	-
	Chlamydia pneumoniae	1.0 x 10^6 IFU/mL	+	+	-	-
	Pooled human nasal was h	N/A	+	+	-	-
Yeast	*Candida albicans*	1.0 x 10^6 cells/mL	+	+	-	-

Table 7 Lot No. 2020042301

Potential Cross-Reactant		Test Co ıcentration	Test Result			
			With inactive virus		Without inactive virus	
			#1	#2	#1	#2
Virus	*Respiratory Syncytial Virus A*	1.0 x 10^5 PFU/mL	+	+	-	-
	Measles Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	HCoV-NL63	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	MERS	4.0 x 10^4 $TCID_{50}$/mL	+	+	-	-
	Mumps Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Adenovirus Type 3	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Parainfluenza Type 2	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Partial Pulmonary Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza B (Victoria Strain)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza B (Y Strain)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza A (H1N1,2009)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza A (H3N2)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Avian Influenza Virus H7 N9	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Avian Influenza Virus H5 N1	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Epstein Barr Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Enterovirus CA16	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-

	Rhinovirus	1.0 x 10^5 PFU/mL	+	+	-	-
Bacteria	*Staphylococcus aureus*	1.0 x 10^6 CFU/mL	+	+	-	-
	Streptococcus pneumonia e	1.0 x 10^6 CFU/mL	+	+	-	-
	Mycoplasma pneumoniae	1.0 x 10^6 IFU/mL	+	+	-	-
	Parapertussis	1.0 x 10^6 cells/mL	+	+	-	-
	Chlamydia pneumoniae	1.0 x 10^6 IFU/mL	+	+	-	-
	Pooled human nasal was h	N/A	+	+	-	-
Yeast	*Candida albicans*	1.0 x 10^6 cells/mL	+	+	-	-

Table 8 Lot No. 2020042501

Potential Cross-Reactant		Test Co ıcentration	Test Result			
			With inactive virus		Without inactive virus	
			#1	#2	#1	#2
Virus	*Respiratory Syncytial Virus A*	1.0 x 10^5 PFU/mL	+	+	-	-
	Measles Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Mumps Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	HCoV-NL63	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	MERS	4.0 x 10^4 $TCID_{50}$/mL	+	+	-	-
	Adenovirus Type 3	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Parainfluenza Type 2	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Partial Pulmonary Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza B (Victoria Strain)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-

	Influenza B (Y Strain)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza A (H1N1,2009)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Influenza A (H3N2)	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Avian Influenza Virus H7 N9	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Avian Influenza Virus H5 N1	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Epstein Barr Virus	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Enterovirus CA16	1.0 x 10^5 $TCID_{50}$/mL	+	+	-	-
	Rhinovirus	1.0 x 10^5 PFU/mL	+	+	-	-
Bacteria	*Staphylococcus aureus*	1.0 x 10^6 CFU/mL	+	+	-	-
	Streptococcus pneumonia e	1.0 x 10^6 CFU/mL	+	+	-	-
	Mycoplasma pneumoniae	1.0 x 10^6 IFU/mL	+	+	-	-
	Parapertussis	1.0 x 10^6 cells/mL	+	+	-	-
	Chlamydia pneumoniae	1.0 x 10^6 IFU/mL	+	+	-	-
	Pooled human nasal was h	N/A	+	+	-	-
Yeast	*Candida albicans*	1.0 x 10^6 cells/mL	+	+	-	-

5) Conclusion

No cross-reactivity or interference came out of these tests when tested at the concentration listed above.

4. Endogenous Interfering Substances Study

1) Test kit: SARS-CoV-2 Antigen Test Kit

Lot No.	Date of Manufacture

Substance	Active Ingredient	Concentration
Endogenous	Whole Blood	1.2 % v/v
	Mucin	2.0 % w/v
Nasal Drops	Sodium Chloride	5% v/v

2020042101	20200421
2020042301	20200423
2020042501	20200425

2) Test Materials

The following interfering substances, that may be introduced into the nas al cavity or nasopharynx, were evaluated with the SARS-CoV-2 Antigen

Test Kit at the concentrations listed below.

Nasal Spray	Fluticasone Propionate	0.3 ng/mL
	Gluconic Acid Zinc	5 % w/v
	Fluconazole	5 % w/v
	Oxymetazoline	12 % v/v
	Cromolyn	15 % v/v
Sore Throat Phenol Spray	Phenol	15 % v/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
Anti-viral Drug	Tamiflu (Oseltamivir Phospha	1.3 mg/mL
	Ribavirin	12.9 mg/mL
Antibacterial, Systemic	Tobramycin	4.0 ug/mL

3) Test Method

(1) Each of the Endogenous Interfering Substances listed above were tested in duplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (1.5 x 10^2 $TCID_{50}$/swab).

(2) All samples were tested according to kit's instructions for use.

4) Results: as following table 9-11.

Table 9 Lot No. 2020042101

Substance	Active Ingredient	Concentration	Test Result			
			With inactive virus		Without inactive virus	
			#1	#2	#1	#2
Endogenous	Whole Blood	1.2 % v/v	+	+	-	-
	Mucin	2.0 % w/v	+	+	-	-

Nasal Drops	Sodium Chloride	5% v/v	+	+	-	-
Nasal Spray	Fluticasone Propionat e	0.3 ng/mL	+	+	-	-
	Gluconic Acid Zinc	5 % w/v	+	+	-	-
	Fluconazole	5 % w/v	+	+	-	-
	Oxymetazoline	12 % v/v	+	+	-	-
	Cromolyn	15 % v/v	+	+	-	-
Sore Throat Phenol Spray	Phenol	15 % v/v	+	+	-	-
Throat Lozenge	Benzocaine, Menthol	0.15% w/v	+	+	-	-
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	1.3 mg/mL	+	+	-	-
	Ribavirin	12.9 mg/mL	+	+	-	-
Antibacterial, Sy stemic	Tobramycin	4.0 ug/mL	+	+	-	-

Table 10 Lot No. 2020042301

Substance	Active Ingredient	Concentratio n	Test Result			
			With inactive virus		Without inactive virus	
			#1	#2	#1	#2
Endogenous	Whole Blood	1.2 % v/v	+	+	-	-
	Mucin	2.0 % w/v	+	+	-	-
Nasal Drops	Sodium Chloride	5% v/v	+	+	-	-
Nasal Spray	Fluticasone Propionat e	0.3 ng/mL	+	+	-	-
	Gluconic Acid Zinc	5 % w/v	+	+	-	-
	Fluconazole	5 % w/v	+	+	-	-
	Oxymetazoline	12 % v/v	+	+	-	-

	Cromolyn	15 % v/v	+	+	-	-
Sore Throat Phenol Spray	Phenol	15 % v/v	+	+	-	-
Throat Lozenge	Benzocaine, Menthol	0.15% w/v	+	+	-	-
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	1.3 mg/mL	+	+	-	-
	Ribavirin	12.9 mg/mL	+	+	-	-
Antibacterial, Sy stemic	Tobramycin	4.0 ug/mL	+	+	-	-

Table 11 Lot No. 2020042501

Substance	Active Ingredient	Concentration	Test Result			
			With inactive virus		Without inactive virus	
			#1	#2	#1	#2
Endogenous	Whole Blood	1.2 % v/v	+	+	-	-
	Mucin	2.0 % w/v	+	+	-	-
Nasal Drops	Sodium Chloride	5% v/v	+	+	-	-
Nasal Spray	Fluticasone Propionat e	0.3 ng/mL	+	+	-	-
	Gluconic Acid Zinc	5 % w/v	+	+	-	-
	Fluconazole	5 % w/v	+	+	-	-
	Oxymetazoline	12 % v/v	+	+	-	-
	Cromolyn	15 % v/v	+	+	-	-
Sore Throat Phenol Spray	Phenol	15 % v/v	+	+	-	-
Throat Lozenge	Benzocaine, Menthol	0.15% w/v	+	+	-	-
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	1.3 mg/mL	+	+	-	-

	Ribavirin	12.9 mg/mL	+	+	-	-
Antibacterial, Sy stemic	Tobramycin	4.0 ug/mL	+	+	-	-

5) Conclusion

The Endogenous Interfering Substances listed above were tested in duplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (1.5 x 102TCID50/swab) and were no affect to the performance of the test kit.

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Stability Study

This document was

Prepared by 5.1.2e

Reviewed by 5.1.2e

Approved by 5.1.2e

Accelerated Temperature Study

1. General Information

The stability of the SARS-CoV-2 Antigen Test Kit was evaluated using closed original kit at accelerated temperature (37 ± 1°C).

The accelerated temperature study was performed in closed original box to evaluate the stability in higher temperature however may easily occur during transportation. Stability study was performed with 3 batches of production kit.

2. Materials

2.1 test kit:

The SARS-CoV-2 Antigen Test Kit used in this study was approved by QA Dept. of the company. The lot numbers and the estimated expiry dates are listed as below :

Lot No.	Date of Manufacture	Estimated Expiry Dates
2020022101	20200221	20210621
2020022401	20200224	20210628
2020022601	20200226	20210704

2.2 In house references

References No.	Acceptance Criteria	References No.	Acceptance Criteria
S1	+	N14	-
S2	+ / -	N15	-
S3	-	N16	-
N1	-	N17	-
N2	-	N18	-
N3	-	N19	-
N4	-	N20	-
N5	-	P1	3+
N6	-	P2	2+
N7	-	P3	1+

N8	-	P4	3+
N9	-	P5	2+
N10	-	P6	1+
N11	-	P7	2+
N12	-	P8	1+
N13	-		

3. Procedure

3.1 Three lots of test kits were used to perform as per instructions for use.

3.2 All kit components are stored in the closed original condition at accelerated temperature (37 ± 1°C).

3.3 Evaluations of kits were performed on day 0, 10 and 21 from the date of manufacture.

3.4 For each test, the whole test kit reagents were used.

3.5 Intensity of the test line for in-house references are scored as follows :

- Strong Positive Intensity : 3+
- Medium Positive Intensity : 2+
- Weak Positive Intensity : 1+
- Negative (No test line) Intensity : —

4. Results

4.1 The stability data of Lot No. 2020022101,2020022401 and 2020022601 kit at accelerated temperature (37 ± 1°C) are summarized as Table1.

4.2 The three batches of closed original kit stored at accelerated temperature (37 ± 1°C) were stable with no lessening of intensities of the test lines (T) for in-house references till 21 days, when the studies were completed.

Table1. Summary of intensity score of Lot No. 2020022101-2020022601 for References

Ref. No.	Acceptance Criteria	Test Intervals (Day)								
		Lot No. 2020022101			Lot No. 2020022401			Lot No. 2020022601		
		0	10	21	0	10	21	0	10	21
S1	+	+	+	+	+	+	+	+	+	+

S2	+/-	+	+	+	+	+	+	+	+	+
S3	-	-	-	-	-	-	-	-	-	-
N1	-	-	-	-	-	-	-	-	-	-
N2	-	-	-	-	-	-	-	-	-	-
N3	-	-	-	-	-	-	-	-	-	-
N4	-	-	-	-	-	-	-	-	-	-
N5	-	-	-	-	-	-	-	-	-	-
N6	-	-	-	-	-	-	-	-	-	-
N7	-	-	-	-	-	-	-	-	-	-
N8	-	-	-	-	-	-	-	-	-	-
N9	-	-	-	-	-	-	-	-	-	-
N10	-	-	-	-	-	-	-	-	-	-
N11	-	-	-	-	-	-	-	-	-	-
N12	-	-	-	-	-	-	-	-	-	-
N13	-	-	-	-	-	-	-	-	-	-
N14	-	-	-	-	-	-	-	-	-	-
N15	-	-	-	-	-	-	-	-	-	-
N16	-	-	-	-	-	-	-	-	-	-
N17	-	-	-	-	-	-	-	-	-	-
N18	-	-	-	-	-	-	-	-	-	-
N19	-	-	-	-	-	-	-	-	-	-
N20	-	-	-	-	-	-	-	-	-	-
P1	3+	3+	3+	3+	3+	3+	3+	3+	3+	3+
P2	2+	2+	2+	2+	2+	2+	2+	2+	2+	2+
P3	1+	1+	1+	1+	1+	1+	1+	1+	1+	1+
P4	3+	3+	3+	3+	3+	3+	3+	3+	3+	3+
P5	2+	2+	2+	2+	2+	2+	2+	2+	2+	2+
P6	1+	1+	1+	1+	1+	1+	1+	1+	1+	1+
P7	2+	2+	2+	2+	2+	2+	2+	2+	2+	2+
P8	1+	1+	1+	1+	1+	1+	1+	1+	1+	1+

5. Conclusion

Stability studies of the SARS-CoV-2 Antigen Test Kit at accelerated temperature (37 ± 1°C) indicated that the kits are stable for at least 21 days when stored unopened, in accelerated temperature condition.

Real time stability Study

1. General information

The stability of the SARS-CoV-2 Antigen Test Kit was evaluated using closed or iginal kit, at room temperature (2~30°C, at the three different temperature, as is 5±3°C, 20±1°C and 29±1°C).

Stability studies were performed on 3 batches of production kits.

2. Materials

2.1 test kit:

The SARS-CoV-2 Antigen Test Kit used in this study was approved by QA Dept. of the company. The lot numbers and the estimated expiry dates are listed as below :

Lot No.	Date of Manufacture	Estimated Expiry Dates
2020022101	20200221	20210621
2020022401	20200224	20210628
2020022601	20200226	20210704

2.2 In house references

References No.	Acceptance Criteria	References No.	Acceptance Criteria
S1	+	N14	-
S2	+ / -	N15	-
S3	-	N16	-
N1	-	N17	-
N2	-	N18	-
N3	-	N19	-
N4	-	N20	-
N5	-	P1	3+
N6	-	P2	2+
N7	-	P3	1+
N8	-	P4	3+
N9	-	P5	2+

N10	-	P6	1+
N11	-	P7	2+
N12	-	P8	1+
N13	-		

3. Procedure

3.1 Three batches of the SARS-CoV-2 Antigen Test Kit were used, one each from Batch 2020022101, 2020022401 and 2020022601. Assay was performed as per instructions for use.

3.2 All kit components are stored in the closed original condition at room temperature (2~30°C, at the three different temperature, as is 5±3°C, 20±1°C and 29±1°C).

3.3 Evaluation of kit's stability was planned to perform at Month 0, 3, 6, 12 and 14 from the date of manufacture.

3.4 For each assay, the whole test kit reagents were used.

3.5 Intensity of the test line for in-house references are scored as follows :

- Strong Positive Intensity : 3+
- Medium Positive Intensity : 2+
- Weak Positive Intensity : 1+
- Negative (No test line) Intensity : —

4. Results

4.1 The stability data of Lot 2020022101 kit at room temperature (2~30°C, at the three different temperature, as is 5±3°C, 20±1°C and 29±1°C) are summarized in Table 2-4.

4.2 The stability data of Lot 2020022401 kit at room temperature (2~30°C, at the three different temperature, as is 5±3°C, 20±1°C and 29±1°C) are summarized in Table 5-7.

4.3 The stability data of Lot 2020022601 kit at room temperature (2~30°C, at the three different temperature, as is 5±3°C, 20±1°C and 29±1°C) are summarized in Table 8-10.

Table 2. Summary of intensity score of Lot 2020022101 for References (Store at 5±3°C) .

Ref. No.	Acceptance Criteria	Test Intervals (Month)				
		0	3	6	12	14
S1	+	+	+	+	/	/
S2	+/-	+	+	+	/	/
S3	-	-	-	-	/	/
N1	-	-	-	-	/	/
N2	-	-	-	-	/	/
N3	-	-	-	-	/	/
N4	-	-	-	-	/	/
N5	-	-	-	-	/	/
N6	-	-	-	-	/	/
N7	-	-	-	-	/	/
N8	-	-	-	-	/	/
N9	-	-	-	-	/	/
N10	-	-	-	-	/	/
N11	-	-	-	-	/	/
N12	-	-	-	-	/	/
N13	-	-	-	-	/	/
N14	-	-	-	-	/	/
N15	-	-	-	-	/	/
N16	-	-	-	-	/	/
N17	-	-	-	-	/	/
N18	-	-	-	-	/	/
N19	-	-	-	-	/	/
N20	-	-	-	-	/	/
P1	3+	3+	3+	3+	/	/
P2	2+	2+	2+	2+	/	/
P3	1+	1+	1+	1+	/	/
P4	3+	3+	3+	3+	/	/
P5	2+	2+	2+	2+	/	/
P6	1+	1+	1+	1+	/	/
P7	2+	2+	2+	2+	/	/
P8	1+	1+	1+	1+	/	/

Table 3. Summary of intensity score of Lot 2020022101 for References (Store

at 20±1°C) .

Ref. No.	Acceptance Criteria	Test Intervals (Month)				
		0	3	6	12	14
S1	+	+	+	+	/	/
S2	+/-	+	+	+	/	/
S3	-	-	-	-	/	/
N1	-	-	-	-	/	/
N2	-	-	-	-	/	/
N3	-	-	-	-	/	/
N4	-	-	-	-	/	/
N5	-	-	-	-	/	/
N6	-	-	-	-	/	/
N7	-	-	-	-	/	/
N8	-	-	-	-	/	/
N9	-	-	-	-	/	/
N10	-	-	-	-	/	/
N11	-	-	-	-	/	/
N12	-	-	-	-	/	/
N13	-	-	-	-	/	/
N14	-	-	-	-	/	/
N15	-	-	-	-	/	/
N16	-	-	-	-	/	/
N17	-	-	-	-	/	/
N18	-	-	-	-	/	/
N19	-	-	-	-	/	/
N20	-	-	-	-	/	/
P1	3+	3+	3+	3+	/	/
P2	2+	2+	2+	2+	/	/
P3	1+	1+	1+	1+	/	/
P4	3+	3+	3+	3+	/	/
P5	2+	2+	2+	2+	/	/
P6	1+	1+	1+	1+	/	/
P7	2+	2+	2+	2+	/	/
P8	1+	1+	1+	1+	/	/

Table 4. Summary of intensity score of Lot 2020022101 for References (Store

at 29±1°C) .

Ref. No.	Acceptance Criteria	Test Intervals (Month)				
		0	3	6	12	14
S1	+	+	+	+	/	/
S2	+/-	+	+	+	/	/
S3	-	-	-	-	/	/
N1	-	-	-	-	/	/
N2	-	-	-	-	/	/
N3	-	-	-	-	/	/
N4	-	-	-	-	/	/
N5	-	-	-	-	/	/
N6	-	-	-	-	/	/
N7	-	-	-	-	/	/
N8	-	-	-	-	/	/
N9	-	-	-	-	/	/
N10	-	-	-	-	/	/
N11	-	-	-	-	/	/
N12	-	-	-	-	/	/
N13	-	-	-	-	/	/
N14	-	-	-	-	/	/
N15	-	-	-	-	/	/
N16	-	-	-	-	/	/
N17	-	-	-	-	/	/
N18	-	-	-	-	/	/
N19	-	-	-	-	/	/
N20	-	-	-	-	/	/
P1	3+	3+	3+	3+	/	/
P2	2+	2+	2+	2+	/	/
P3	1+	1+	1+	1+	/	/
P4	3+	3+	3+	3+	/	/
P5	2+	2+	2+	2+	/	/
P6	1+	1+	1+	1+	/	/
P7	2+	2+	2+	2+	/	/
P8	1+	1+	1+	1+	/	/

Table 5. Summary of intensity score of Lot 2020022401 for References (Store

at 5±3°C) .

Ref. No.	Acceptance Criteria	Test Intervals (Month)				
		0	3	6	12	14
S1	+	+	+	+	/	/
S2	+/-	+	+	+	/	/
S3	-	-	-	-	/	/
N1	-	-	-	-	/	/
N2	-	-	-	-	/	/
N3	-	-	-	-	/	/
N4	-	-	-	-	/	/
N5	-	-	-	-	/	/
N6	-	-	-	-	/	/
N7	-	-	-	-	/	/
N8	-	-	-	-	/	/
N9	-	-	-	-	/	/
N10	-	-	-	-	/	/
N11	-	-	-	-	/	/
N12	-	-	-	-	/	/
N13	-	-	-	-	/	/
N14	-	-	-	-	/	/
N15	-	-	-	-	/	/
N16	-	-	-	-	/	/
N17	-	-	-	-	/	/
N18	-	-	-	-	/	/
N19	-	-	-	-	/	/
N20	-	-	-	-	/	/
P1	3+	3+	3+	3+	/	/
P2	2+	2+	2+	2+	/	/
P3	1+	1+	1+	1+	/	/
P4	3+	3+	3+	3+	/	/
P5	2+	2+	2+	2+	/	/
P6	1+	1+	1+	1+	/	/
P7	2+	2+	2+	2+	/	/
P8	1+	1+	1+	1+	/	/

Table 6. Summary of intensity score of Lot 2020022401 for References (Store

at 20±1°C) .

Ref. No.	Acceptance Criteria	Test Intervals (Month)				
		0	3	6	12	14
S1	+	+	+	+	/	/
S2	+/-	+	+	+	/	/
S3	-	-	-	-	/	/
N1	-	-	-	-	/	/
N2	-	-	-	-	/	/
N3	-	-	-	-	/	/
N4	-	-	-	-	/	/
N5	-	-	-	-	/	/
N6	-	-	-	-	/	/
N7	-	-	-	-	/	/
N8	-	-	-	-	/	/
N9	-	-	-	-	/	/
N10	-	-	-	-	/	/
N11	-	-	-	-	/	/
N12	-	-	-	-	/	/
N13	-	-	-	-	/	/
N14	-	-	-	-	/	/
N15	-	-	-	-	/	/
N16	-	-	-	-	/	/
N17	-	-	-	-	/	/
N18	-	-	-	-	/	/
N19	-	-	-	-	/	/
N20	-	-	-	-	/	/
P1	3+	3+	3+	3+	/	/
P2	2+	2+	2+	2+	/	/
P3	1+	1+	1+	1+	/	/
P4	3+	3+	3+	3+	/	/
P5	2+	2+	2+	2+	/	/
P6	1+	1+	1+	1+	/	/
P7	2+	2+	2+	2+	/	/
P8	1+	1+	1+	1+	/	/

Table 7. Summary of intensity score of Lot 2020022401 for References (Store

at 29±1°C) .

Ref. No.	Acceptance Criteria	Test Intervals (Month)				
		0	3	6	12	14
S1	+	+	+	+	/	/
S2	+/-	+	+	+	/	/
S3	-	-	-	-	/	/
N1	-	-	-	-	/	/
N2	-	-	-	-	/	/
N3	-	-	-	-	/	/
N4	-	-	-	-	/	/
N5	-	-	-	-	/	/
N6	-	-	-	-	/	/
N7	-	-	-	-	/	/
N8	-	-	-	-	/	/
N9	-	-	-	-	/	/
N10	-	-	-	-	/	/
N11	-	-	-	-	/	/
N12	-	-	-	-	/	/
N13	-	-	-	-	/	/
N14	-	-	-	-	/	/
N15	-	-	-	-	/	/
N16	-	-	-	-	/	/
N17	-	-	-	-	/	/
N18	-	-	-	-	/	/
N19	-	-	-	-	/	/
N20	-	-	-	-	/	/
P1	3+	3+	3+	3+	/	/
P2	2+	2+	2+	2+	/	/
P3	1+	1+	1+	1+	/	/
P4	3+	3+	3+	3+	/	/
P5	2+	2+	2+	2+	/	/
P6	1+	1+	1+	1+	/	/
P7	2+	2+	2+	2+	/	/
P8	1+	1+	1+	1+	/	/

Table 8. Summary of intensity score of Lot 2020022601 for References (Store

at 5±3°C) .

Ref. No.	Acceptance Criteria	Test Intervals (Month)				
		0	3	6	12	14
S1	+	+	+	+	/	/
S2	+/-	+	+	+	/	/
S3	-	-	-	-	/	/
N1	-	-	-	-	/	/
N2	-	-	-	-	/	/
N3	-	-	-	-	/	/
N4	-	-	-	-	/	/
N5	-	-	-	-	/	/
N6	-	-	-	-	/	/
N7	-	-	-	-	/	/
N8	-	-	-	-	/	/
N9	-	-	-	-	/	/
N10	-	-	-	-	/	/
N11	-	-	-	-	/	/
N12	-	-	-	-	/	/
N13	-	-	-	-	/	/
N14	-	-	-	-	/	/
N15	-	-	-	-	/	/
N16	-	-	-	-	/	/
N17	-	-	-	-	/	/
N18	-	-	-	-	/	/
N19	-	-	-	-	/	/
N20	-	-	-	-	/	/
P1	3+	3+	3+	3+	/	/
P2	2+	2+	2+	2+	/	/
P3	1+	1+	1+	1+	/	/
P4	3+	3+	3+	3+	/	/
P5	2+	2+	2+	2+	/	/
P6	1+	1+	1+	1+	/	/
P7	2+	2+	2+	2+	/	/
P8	1+	1+	1+	1+	/	/

Table 9. Summary of intensity score of Lot 2020022601 for References (Store

at 20±1°C) .

Ref. No.	Acceptance Criteria	Test Intervals (Month)				
		0	3	6	12	14
S1	+	+	+	+	/	/
S2	+/-	+	+	+	/	/
S3	-	-	-	-	/	/
N1	-	-	-	-	/	/
N2	-	-	-	-	/	/
N3	-	-	-	-	/	/
N4	-	-	-	-	/	/
N5	-	-	-	-	/	/
N6	-	-	-	-	/	/
N7	-	-	-	-	/	/
N8	-	-	-	-	/	/
N9	-	-	-	-	/	/
N10	-	-	-	-	/	/
N11	-	-	-	-	/	/
N12	-	-	-	-	/	/
N13	-	-	-	-	/	/
N14	-	-	-	-	/	/
N15	-	-	-	-	/	/
N16	-	-	-	-	/	/
N17	-	-	-	-	/	/
N18	-	-	-	-	/	/
N19	-	-	-	-	/	/
N20	-	-	-	-	/	/
P1	3+	3+	3+	3+	/	/
P2	2+	2+	2+	2+	/	/
P3	1+	1+	1+	1+	/	/
P4	3+	3+	3+	3+	/	/
P5	2+	2+	2+	2+	/	/
P6	1+	1+	1+	1+	/	/
P7	2+	2+	2+	2+	/	/
P8	1+	1+	1+	1+	/	/

Table 10. Summary of intensity score of Lot 2020022601 for References (Store at

29±1°C) .

Ref. No.	Acceptance Criteria	Test Intervals (Month)				
		0	3	6	12	14
S1	+	+	+	+	/	/
S2	+/-	+	+	+	/	/
S3	-	-	-	-	/	/
N1	-	-	-	-	/	/
N2	-	-	-	-	/	/
N3	-	-	-	-	/	/
N4	-	-	-	-	/	/
N5	-	-	-	-	/	/
N6	-	-	-	-	/	/
N7	-	-	-	-	/	/
N8	-	-	-	-	/	/
N9	-	-	-	-	/	/
N10	-	-	-	-	/	/
N11	-	-	-	-	/	/
N12	-	-	-	-	/	/
N13	-	-	-	-	/	/
N14	-	-	-	-	/	/
N15	-	-	-	-	/	/
N16	-	-	-	-	/	/
N17	-	-	-	-	/	/
N18	-	-	-	-	/	/
N19	-	-	-	-	/	/
N20	-	-	-	-	/	/
P1	3+	3+	3+	3+	/	/
P2	2+	2+	2+	2+	/	/
P3	1+	1+	1+	1+	/	/
P4	3+	3+	3+	3+	/	/
P5	2+	2+	2+	2+	/	/
P6	1+	1+	1+	1+	/	/
P7	2+	2+	2+	2+	/	/
P8	1+	1+	1+	1+	/	/

5. Conclusion

5.1 The 3 batches of closed original kits stored at room temperature is stable with no lessening of intensity of the test line for in-house references till 3rd month.

5.2 The subsequent data will be available according to the performance schedule.

5.3 All 3 batches of kits, Lot 2020022101, 2020022401 and 2020022601, showed similar stability till the present studies.

Summary

Stability studies of the SARS-CoV-2 Antigen Test Kit at accelerated temperature (37±1°C) and room temperature (2~30°C, at the three different temperature, as is 5±3°C, 20±1°C and 29±1°C) indicated that the kits are stable for at least 21 days under accelerated temperature (37±1°C) and 3 months at room temperature when stored unopened, in its original conditions.