PERFORMANCE CHARACTERISTICS

1. SARS-CoV-2 Antigen

Analytical Sensitivity

The limit of detection (LoD) for the Rapid SARS-CoV-2 Antigen Test was established in an analytical sensitivity study performed with one virus strain and one recombinant nucleocapsid protein. The LoD was confirmed in the following table.

No.	Item	Limit of Detection
1	SARS-CoV-2, Virus	1.3 x10^2 $TCID_{50}$/mL
2	SARS-CoV-2, Recombinant nucleocapsid protein	1 ng/mL

Cross Reactivity

The cross reactivity of the Rapid SARS-CoV-2 Antigen Test Card was evaluated with a total of 27 microorganisms. None of the microorganisms tested in the following table gave a positive result.

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus 229E	2.0 x 10^6 $TCID_{50}$/mL	MERS-coronavirus	1.0 x 10^6 $TCID_{50}$/mL
Human coronavirus OC43	2.0 x 10^6 $TCID_{50}$/mL	Chlamydia pneumoniae	2.0 x 10^6 IFU/mL
Human coronavirus NL63	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus pneumoniae	2.0 x 10^6 CFU/mL
Parainfluenza virus 1	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus pyogenes	2.0 x 10^6 CFU/mL
Parainfluenza virus 2	2.0 x 10^6 $TCID_{50}$/mL	Bordetella pertussis	2.0 x 10^6 CFU/mL
Parainfluenza virus 3	2.0 x 10^6 $TCID_{50}$/mL	Mycobacterium tuberculosis	2.0 x 10^6 CFU/mL
Enterovirus EV71	2.0 x 10^6 $TCID_{50}$/mL	Legionella pneumophila	2.0 x 10^6 CFU/mL
Respiratory syncytial virus	2.0 x 10^6 $TCID_{50}$/mL	Mycoplasma pneumoniae	2.0 x 10^6 U/mL
Rhinovirus	2.0 x 10^6 $TCID_{50}$/mL	Haemophilus influenzae	2.0 x 10^6 CFU/mL
Influenza A virus (H1N1)	2.0 x 10^6 $TCID_{50}$/mL	Candida albicans	2.0 x 10^6 CFU/mL
Influenza A virus (H3N2)	2.0 x 10^6 $TCID_{50}$/mL	Staphylococcus aureus	2.0 x 10^6 CFU/mL
Influenza B virus (Yamagata)	2.0 x 10^6 $TCID_{50}$/mL	Pseudomonas aeruginosa	2.0 x 10^6 CFU/mL
Influenza B virus (Victoria)	2.0 x 10^6 $TCID_{50}$/mL	Escherichia coli	2.0 x 10^6 CFU/mL
Adeno virus	2.0 x 10^6 $TCID_{50}$/mL		

Interference

I. Microorganism

Rapid SARS-CoV-2 Antigen Test Card has tested samples with common microorganism. The results showed that these microorganism had no effect on the specificity of the assay up to the listed concentration.

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Influenza B virus (Yamagata)	2.0 x 10^6 $TCID_{50}$/mL	Pseudomonas aeruginosa	2.0 x 10^6 CFU/mL
Influenza B virus (Victoria)	2.0 x 10^6 $TCID_{50}$/mL	Escherichia coli	2.0 x 10^6 CFU/mL
Adeno virus	2.0 x 10^6 $TCID_{50}$/mL		

II. Endogenous Substances

Rapid SARS-CoV-2 Antigen Test Card has tested samples with common endogenous substances. The results showed that these substances had no effect on the specificity of the assay up to the listed concentration.

Substances	Concentrations	Substances	Concentrations
Whole Blood	1% v/v	Homeopathic (Alkalol)	10% v/v
Mucin	2% w/v	CVS Nasal Drops (Phenylephrine)	15% v/v
Tobramycin	0.0004% w/v	Afrin (Oxymetazoline)	15% v/v
Ricola (Menthol)	0.15% w/v	CVS Nasal Spray (Cromolyn)	15% v/v
Chloraseptic (Benzocaine)	0.15% w/v	Fluticasone Propionate	5% v/v
Mupirocin	0.25% w/v	Zicam	5% w/v
Tamiflu (Oseltamivir Phosphate)	0.5% w/v		

Accuracy

The accuracy of Rapid SARS-CoV-2 Antigen Test was established with 566 nasopharyngeal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The following table summarizes the accuracy of the Rapid SARS-CoV-2 Antigen Test compared to RT-PCR.

		RT-PCR		
		Positive	**Negative**	**Total**
Rapid SARS-CoV-2 Antigen Test	**Positive**	98	4	102
	Negative	4	460	464
	Total	102	464	566

The sensitivity was 96.08% (95%CI: 92.31%~99.85%). The specificity was 99.14% (95%CI: 98.30%~99.98%). The accuracy was 98.59% (95%CI: 97.61%~99.56%).

2. Influenza A

Analytical Sensitivity

Item	Limit of Detection
Most of Influenza A strains	1.2 x10^3 $TCID_{50}$/mL

Analytical Reactivity

The influenza A strain listed tested positive in the Rapid Influenza A+B Antigen Test. Although the specific influenza strains causing infection in human can vary, all contain the conserved nucleoproteins targeted by Rapid Influenza A+B Antigen Test.

Strains	Sources	Subtypes	Concentration
Flu A/Hubei/PR8/2001	Human	H1N1	1.8×10^5 $TCID_{50}$/mL
Flu A/New Kaledonia/20/99	Human	H1N1	1.8×10^5 $TCID_{50}$/mL
Flu A/Yamagata/32/89	Human	H1N1	1.8×10^5 $TCID_{50}$/mL
Flu A/Beijing/262/95	Human	H1N1	1.8×10^5 $TCID_{50}$/mL
Flu A/Singapore/1/57	Human	H2N2	3.0×10^5 $TCID_{50}$/mL
Flu A/Hubei/3/2005	Human	H3N2	3.0×10^5 $TCID_{50}$/mL
Flu A/Akita/1/94	Human	H3N2	3.0×10^5 $TCID_{50}$/mL
Flu A/Kita Kyusyu/159/93	Human	H3N2	3.0×10^5 $TCID_{50}$/mL
Flu A/Iowa/15/30	Swine	H1N1	3.0×10^5 $TCID_{50}$/mL
Flu A/Hongkong/168/93	Swine	H1N1	3.0×10^5 $TCID_{50}$/mL
Flu A/Anhui/24/2004	Swine	H5N1	6.0×10^6 $TCID_{50}$/mL
Flu A/Hubei/134/2000	Swine	H9N2	6.0×10^6 $TCID_{50}$/mL
Flu A/Hubei/251/2001	Swine	H9N2	6.0×10^6 $TCID_{50}$/mL
Flu A/Yuyao/1/2006	Chicken	H5N1	6.0×10^5 $TCID_{50}$/mL
Flu A/Yuyao/2/2006	Chicken	H5N1	6.0×10^5 $TCID_{50}$/mL
Flu A/Jiangsu/2/2004	Chicken	H5N1	6.0×10^5 $TCID_{50}$/mL
Flu A/Hubei/216/83	Duck	H7N8	3.0×10^6 $TCID_{50}$/mL
Flu A/Hubei/118/2003	Duck	H9N2	1.5×10^6 $TCID_{50}$/mL
Flu A/Hubei/155/2003	Duck	H9N2	6.0×10^6 $TCID_{50}$/mL
Flu A/Hubei/137/1982	Duck	H10N4	3.0×10^6 $TCID_{50}$/mL
Flu A/Singapore/3/97	Duck	H5N3	6.0×10^5 $TCID_{50}$/mL
Flu A/Henan/1/2004	Tree sparrow	H5N1	6.0×10^6 $TCID_{50}$/mL
Flu A/Henan/2/2004	Tree sparrow	H5N1	3.0×10^6 $TCID_{50}$/mL
Flu A/Henan/4/2004	Tree sparrow	H5N1	6.0×10^5 $TCID_{50}$/mL
Flu A/Wisconsin/66	Turkey	H9N2	6.0×10^5 $TCID_{50}$/mL
Flu A/England/1/63	Turkey	H7N3	6.0×10^5 $TCID_{50}$/mL
Flu A/Singapore/1/57	Bird	H5N1	6.0×10^5 $TCID_{50}$/mL
Flu A/Hunan/71/2004	Bird	H5N1	6.0×10^5 $TCID_{50}$/mL
Flu A/Shanxi/50/2006	Bird	H5N1	6.0×10^5 $TCID_{50}$/mL
Flu A/Shanxi/42/2006	Bird	H5N1	6.0×10^5 $TCID_{50}$/mL
Flu A/Fujian/320/2004	Bird	H5N1	3.0×10^6 $TCID_{50}$/mL

Accuracy

The following table summarizes the accuracy of the Rapid Influenza A+B Antigen Test compared to Cell Culture for Detection of Flu A.

		Cell Culture		
		Positive	Negative	Total
Rapid Influenza A+B Antigen Test	Positive	42	3	45
	Negative	8	117	125
	Total	50	120	170

The sensitivity was 84.00% (95%CI: 73.84%~94.16%). The specificity was 98.04% (95%CI: 94.71%~99.99%). The accuracy was 93.53% (95%CI: 89.83%~97.23%).

3. Influenza B

Analytical Sensitivity

Item	Limit of Detection
Most of Influenza B strains	1.0 x$10^4$$TCID_{50}$/mL

Analytical Reactivity

Rapid Influenza A+B Antigen Test detects all nine influenza B strains.

Accuracy

The following table summarizes the accuracy of the Rapid Influenza A+B Antigen Test compared to Cell Culture for Detection of Flu B.

		Cell Culture		
		Positive	**Negative**	**Total**
Rapid Influenza A+B Antigen Test	**Positive**	31	1	32
	Negative	5	119	124
	Total	36	120	156

The sensitivity was 86.11% (95%CI: 74.81%~97.41%). The specificity was 99.17% (95%CI: 97.54%~99.99%). The accuracy was 96.15% (95%CI: 93.14%~99.17%).

Cross Reactivity

The cross reactivity of the Rapid Influenza A+B Antigen Test was evaluated with a total of 28 bacteria, 11 viruses and 4 Mycoplasma. None of the microorganisms tested in the following table gave a positive result.

Bacteria panel	
Acinetobacter baumannii	*Bacteroides fragilis*
Bordetella pertussis	*Candida albicans*
Candida glabrata	*Cardiobacterium hominis*
EikeneUa corrodens	*Enterococcus gallinarum*
Escherichia coil	*Haemophilus phrophlus*
aemophilus influenzae	*Haemophilus parainfluenzae*
Haemophilus paraphrophilus	*Kingella kingae*
Klebsiella pneumoniae	*Listeria monocytogenes*
Moraxella catarrhalis	*Neisseria gonorrhoeae Proteus mirabilis*
Proteus vulgaris	*Pseudomonas aeruginosa*
Serratia marcescens	*Staphylococcus aureus*
Staphylococcus epidermidis	*Streptococcus pneumoniae*
Streptococcus, pyogenes	*Streptococcus agalactiae*
Streptococcus sp. group C, G, F	*Streptococcus mutans*

Virus other than influenza panel	
Adenovirus Type 1 ~ 8,11,19,37	Coxsackie virus Type A16 · B1 ~ 5
Cytomegalovirus	Echovirus Type 3,6,9,11,14,18,30
Enterovirus Type 71	HSV-1
Mumps virus	Parainfluenza virus Type 1 ~ 3

Poliovirus Type 1 ~ 3	Respiratory syncytial virus
Rhinovirus Type 1A,13,14	

Mycoplasma panel	
Chlamydia pneumoniae	*Chlamydia psittaci*
Chlamydia trachomatis	*Mycoplasma pneumoniae*

LIMITATIONS

1. The test is limited to the qualitative detection of SARS-CoV-2 viral antigen and influenza type A and type B viral antigens in nasopharyngeal swab specimens. The exact concentration of SARS-CoV-2 viral antigen and influenza type A and type B viral antigens cannot be determined by this assay.
2. Proper specimen collection is critical, and failure to follow the procedure may give inaccurate results. Improper specimen collection, storage or repeated freezing and thawing of specimens can lead to inaccurate results.
3. A negative test result may occur if the level of antigen in a specimen is below the limit of detection of the test.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
5. Negative test results do not rule out other potential non-SARS-CoV-2 viral infections and non-influenza viral infections. Negative results should be confirmed by other methods, such as molecular diagnosis or cell culture.
6. Positive test results do not rule out co-infections with other pathogens.
7. Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
8. The amount of SARS-CoV-2 antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5-7 of illness are more likely to be tested negative compared to a RT-PCR assay.
9. The Rapid SARS-CoV-2 Antigen Test Card can detect both viable and non-viable SARS-CoV-2 material. The Rapid SARS-CoV-2 Antigen Test Card for rapid detection of SARS-CoV-2 performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
10. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
11. The kit was validated with the assorted swabs. Use of alternative swabs may result in false negative results.
12. Specimen stability recommendations are based upon stability data from influenza testing and performance may be different with SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection, and within two hours after specimen collection.
13. The validity of Rapid SARS-CoV-2 Antigen Test Card has not been proven for dentification/confirmation of tissue culture isolates and should not be used in this capacity.

REFERENCES

1. Wu C, Liu Y, Yang Y, Zhang P, Zhong W, Wang Y, et al. (February 2020). "Analysis of therapeutic targets for SARS-CoV-2 and discovery of potential drugs by computational methods". Acta Pharmaceutica Sinica B. doi:10.1016.