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Technical information of Artron COVID-19 Antigen Home Test

1. **Product Name:** COVID-19 Antigen Home Test
2. **Catalog Number:** A03-50-422S
3. **Reference Document:** A03-50-422S(V10) IFU
4. **Technical Information**

4.1 Clinical Performance

To investigate the layman usability of Artron COVID-19 Antigen Home Test (Nasal Swab) in the home test use, 105 participants who had never previously used similar home test reagents, including 45 participants for prescription testing and another 60 participants randomly from healthy volunteers were recruited in the study.

The 45 prescription testing participants in the study included 22 SARS-CoV-2 RT-PCR confirmed positives and 23 SARS-CoV-2 RT-PCR confirmed negatives, while all the other 60 healthy participants were confirmed negative with SARS-CoV-2 RT-PCR.

All the antigen test results from the 22 positive cases were interpreted as positive by the operators themselves when testing with Artron COVID-19 Antigen Home Test; the number of cases interpreted as a positive result was 100% consistent with the expected result. The other 84 antigen testing results from the 84 negative cases were all interpreted as negative by the operators; the number of cases interpreted as negative is 100% consistent with the expected result. All the results were consistent with the expected test results (100%). No invalid test results appeared.

Summary of the layman study performance against the comparator method

Artron COVID-19 Antigen Home Test	Participants from prescription (RT-PCR confirmed)		Participants from OCT (RT-PCR confirmed)		Total
	Positive	Negative	Positive	Negative	
Positive	22	0	0	0	22
Negative	0	23	0	60	83

Subtotal	22	23	0	60	105
Performance with 95%CI	Sensitivity		Specificity		Overall Agreement
	100% (84.56-100.00)		100% (95.65-100.00)		100% (96.55- 100.00)

Summary of positive agreement related to Ct value

Original Ct value for N gene	Artron COVID-19 Antigen Home Test: Positivity Agreement with 95%CI
<30	22/22(100%) (84.56-100.00)
≥30	0/0

Due to the relatively small sample size for the home use ongoing laymen clinical study, at the time of the interim analysis, the Artron COVID-19 Antigen Home Test positive agreement established in this is estimated to be between 84.56% and 100% as reflected in the 95% Confidence Interval with Ct value <30. This is consistent with the performance established in a separate multi-site clinical study, where the Artron COVID-19 Antigen Home Test was performed. In that study, Artron COVID-19 Antigen Home Test positive agreement was 96.67% (95%CI: 90.57-99.31) with Ct value below 30. The positive agreement in patients with symptoms within 7 days is 95.24%(95%CI:86.71-99.01). Therefore, negative results in patients with symptom onset greater than seven days should be interpreted with caution, as the sensitivity of the assay decreases over time. Please refer to Artron COVID-19 Antigen Home Test performance in a separate multi-site clinical study established with 330 nasal swabs collected from individual who were suspected of COVID-19 as below:

Summary of Artron COVID-19 Antigen Home Test performance against comparator method

Ct value	RT-PCR Test Results		Antigen Test Results		Artron COVID-19 Antigen Home Test Positive Percent Agreement with 95%CI
			POS	NEG	
<30	POS	90	87	3	87/90(96.67%) (90.57-99.31)
40	NEG	227	1	226	Negative Percent Agreement with 95%CI
					226/227(99.56%) (97.57-99.99)

Summary of positive agreement related to Ct Value

Days post onset of symptoms	Number of cases	Artron COVID-19 Antigen Home Test Positivity Agreement with 95%CI
Asymptomatic	34	31/34(91.18%) (76.32-98.14)
≤7	63	60/63(95.24%) (86.71-99.01)
>7	6	3/6(50%) (11.81-88.19)

4.2 Limit of Detection (LoD)-Analytical Sensitivity

The limit of detection (LoD) of Artron COVID-19 Antigen Home Test is 3.75×10^2 TCID50 /mL for live SARS-CoV-2 strain nCoV-SH01 P6, 1×10^3 TCID50 /mL for the heat inactivated SARS-CoV-2 strains nCoV-SH01 P6 and USA-WA1/2020.

4.3 Cross Reactivity

None of the below mentioned related pathogens cross-reacted with Artron COVID-19 Antigen Home Test when the virus content>10^5PFU/mL and the bacterial content>10^6CFU/mL, nor did they interfere with the test results. The negative matrix prepared from pooled human nasal wash- representative of normal respiratory microbial flora and 20 negative nasal swab specimens from healthy volunteers were detected negative, indicating Artron COVID-19 Antigen home Test has good analytical specificity.

Potential cross-reactive pathogen	**Concentration of the pathogen**	**SARS-CoV-2 virus (USA-WA1/2020) $TCID_{50}$/mL**	
		0	**3×10^3**
Negative Matrix (Pooled human nasal wash)		(-)	N/A
Coronavirus OC43 (ATCC: VR-1558™)	1.6×10^5 $TCID_{50}$/mL	(-)	(+)
Coronavirus NL63	1.41×10^5 $TCID_{50}$/mL	(-)	(+)
Coronavirus 229E	1.41×10^5 $TCID_{50}$/mL	(-)	(+)
SARS Coronavirus (2003-00592 strain)	$>10^5$ $TCID_{50}$/mL	(-)	(+)
MERS Coronavirus (Florida/USA-2_Saudi Arabia_2014)	3.55×10^5 $TCID_{50}$/mL	(-)	(+)
H1N1 influenza virus (2009) (Canada/629/09 strain)	1.26×10^6 $TCID_{50}$/mL	(-)	(+)
H1N1 influenza virus (ATCC: VR-98™)	$1\times10^{7.5}$ $TCID_{50}$/mL	(-)	(+)
Seasonal H3N2 influenza virus (Brisbane/10/07 strain)	5.01×10^5 $TCID_{50}$/mL	(-)	(+)
Influenza B (Yamagata/16/88 strain)	$1\times10^{5.39}$ $TCID_{50}$/mL	(-)	(+)
Influenza B (Victoria/2/87 strain)	1.86×10^5 $TCID_{50}$/mL	(-)	(+)
Parainfluenza virus type 1 (ATCC: VR-94™)	1.6×10^7 $TCID_{50}$/mL	(-)	(+)
Parainfluenza virus type 2 (ATCC: VR-92™)	1.6×10^8 $TCID_{50}$/mL	(-)	(+)
Parainfluenza virus type 3 (ATCC: VR-93™)	1.6×10^6 $TCID_{50}$/mL	(-)	(+)

Parainfluenza virus type 4b (ATCC: VR-1377)	1.6×10^5 $TCID_{50}$/mL	(-)	(+)
Respiratory syncytial virus (ATCC: VR-1580™)	7.0×10^5 PFU/mL	(-)	(+)
Rhinovirus A (73) (ATCC: VR-1183™)	$5 \times 10^{5.5}$ $TCID_{50}$/mL	(-)	(+)
Rhinovirus B (B42)	1.05×10^6 $TCID_{50}$/mL	(-)	(+)
Adenovirus type 1 (C)	2.57×10^8 $TCID_{50}$/mL	(-)	(+)
Adenovirus type 2 (C)	1.15×10^7 $TCID_{50}$/mL	(-)	(+)
Adenovirus type 3 (B)	3.8×106 $TCID_{50}$/mL	(-)	(+)
Adenovirus type 4	$1 \times 10^{6.34}$ $TCID_{50}$/mL	(-)	(+)
Adenovirus type 5	$1 \times 10^{7.53}$ $TCID_{50}$/mL	(-)	(+)
Adenovirus type 7 (7A)	$1 \times 10^{5.15}$ $TCID_{50}$/mL	(-)	(+)
Enterovirus Group A (71)(2003)	$1 \times 10^{5.86}$ $TCID_{50}$/mL	(-)	(+)
Enterovirus group D (68)	1.6×10^6 $TCID_{50}$/mL	(-)	(+)
Epstein-Barr virus (B95-8)	2.70×10^8 cp/mL	(-)	(+)
Measles virus	$1 \times 10^{7.77}$ $TCID_{50}$/mL	(-)	(+)
Human cytomegalovirus	$1 \times 10^{5.62}$ $TCID_{50}$/mL	(-)	(+)
Rotavirus, WA strain	$1 \times 10^{7.06}$ $TCID_{50}$/mL	(-)	(+)
Mumps virus 1	$1 \times 10^{6.10}$ $TCID_{50}$/mL	(-)	(+)
Varicella-zoster virus (strain 82)	4.28×10^8 cp/mL	(-)	(+)
Metapneumovirus (Peru6-2003)	$>1 \times 10^6$ cp/mL	(-)	(+)
Mycoplasma pneumoniae (M129)	3.16×10^8 CCU/mL	(-)	(+)
Chlamydia pneumoniae (ATCC: VR-1435™)	1.44×10^8 IFU/mL	(-)	(+)
Haemophilus influenzae (ATCC: 49144™)	1×10^7 CFU/mL	(-)	(+)
Legionella (ATCC: 33152™)	1×10^7 CFU/mL	(-)	(+)
Mycobacterium tuberculosis (ATCC: 25177™)	1×10^7 CFU/mL	(-)	(+)
Streptococcus pyogenes (ATCC: 19615™)	1×10^7 CFU/mL	(-)	(+)
Streptococcus pneumoniae (ATCC:49619™)	1×10^7 CFU/mL	(-)	(+)
Staphylococcus epidermidis (PCI 1200, ATCC: 12228™)	1×10^7 CFU/mL	(-)	(+)
Staphylococcus aureus (ATCC: 12600™)	1×10^7 CFU/mL	(-)	(+)
Bordetella pertussis type 5 (ATCC: 9340-FZ™)	1×10^7 CFU/mL	(-)	(+)
Pneumocystis (W303-Pji strain)	5.12×10^8 CFU/mL	(-)	(+)
Candida albicans (ATCC: 44373)	1×10^7 CFU/mL	(-)	(+)
20 negative nasal swab	N/A	(-)	N/A

specimens			

- **Endogenous/Exogenous Interference Study**

There was no interference for potential interfering substances listed below.

Interfering substances	Interfering substances Final concentration	SARS-COV-2 Virus ($TCID_{50}$/mL)	
		0	3×10^3
Endogenous interfering substances			
Mucin	2% W/V	(-)	(+)
Whole blood	4% W/V	(-)	(+)
OCT Nasal skin steroids			
Beclomethasone	0.5mg/ml	(-)	(+)
Dexamethasone	1mg/ml	(-)	(+)
Flunisolide	5mg/ml	(-)	(+)
Triamcinolone acetonide	1mg/ml	(-)	(+)
Budesonide	2mg/ml	(-)	(+)
Mometasone	2mg/ml	(-)	(+)
Fluticasone	1mg/ml	(-)	(+)
Naso GEL (NeiMed)	5%V/V	(-)	(+)
OTC Nasal drops or spray			
Phenylephrine	10% (V/V)	(-)	(+)
Oxymetazoline	10% (V/V)	(-)	(+)
Sodium chloride (with preservatives)	10% (V/V)	(-)	(+)
Menthol	1.5 mg/mL	(-)	(+)
Benzocaine	1.5 mg/mL	(-)	(+)
CVS Nasal Spray (Cromolyn)	15 % V/V	(-)	(+)
Zicam	5%V/V	(-)	(+)
Homeopathic (Alkalol)	1:10	(-)	(+)
Sore Throat Phenol Spray	15%V/V	(-)	(+)
Anti-viral drugs			
alpha interferon	200,000IU/ml	(-)	(+)
Zanamivir	1mg/ml	(-)	(+)
Ribavirin	2mg/ml	(-)	(+)

Oseltamivir	12mg/ml	(-)	(+)
Peramivir	2mg/ml	(-)	(+)
Lopinavir	2mg/ml	(-)	(+)
Ritonavir	2mg/ml	(-)	(+)
Abidor	4mg/ml	(-)	(+)
Antibiotic drugs			
Levofloxacin	5mg/ml	(-)	(+)
Azithromycin	1mg/ml	(-)	(+)
Ceftriaxone	1mg/ml	(-)	(+)
Meropenem	2mg/ml	(-)	(+)
Mupirocin	10mg/ml	(-)	(+)
Systemic antibacterial drugs			
Tobramycin	1mg/ml	(-)	(+)
Allergic symptom relief medication			
Histamine Dihydrochloride	10mg/ml	(-)	(+)
Others			
Biotin	1mg/ml	(-)	(+)

4.4 HOOK Effect

There was no hook effect at 9.55×10^6 TCID50 /mL of SARS-CoV-2 strain USA-WA1/2020.

4.5 Mutants detection

Artron COVID-19 Antigen Home Test could identify recombinant wild-type SARS-CoV-2 nucleocapsid protein and the four-recombinant mutant nucleocapsid proteins from mutants “UK mutant B.1.1.7”, “South Africa mutant B.1.351”, “Brazil mutant P.1” and Omicron (B.1.1.529) respectively.

The results showed Artron COVID-19 Antigen Home Test has similar detection sensitivity with original wild-type N protein when testing these three recombinant mutant N proteins at a concentration of 100pg/mL.