

COVID-19 Saliva Ag Test

Analytical Specificity Test Report

File No.	CORE-CE-COVID S-Ag-07
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1. Test purpose

Detecting potentially interfering substances to determine the analytical specificity of "COVID-19 Saliva Ag Test" produced by Core Technology Co., Ltd.

2. Reagents and materials:

2.1 Test

Product name: COVID-19 Saliva Ag Test

Manufacturer: Core Technology Co., Ltd.

Specification: 1test/pouch

Storage conditions: 2-30°C

According to "Golloid Gold Product Manufacturing Operation Regulations-COVID-19 Saliva Ag", three batches for two rapid test types of strip and cassette were produced to test the analytical specificity .

The product information is shown in the following :

Strip Batch No.: 20200528, 20200529, 20200530;

Cassette Batch No.: 20200528, 20200529, 20200530;

2.2 Specimen to be tested

Specific reference substance group A and B: The names and concentrations of the interfering substances are shown in the following table:

Table 1-1 Specific reference group A

Potential Cross-Reactant		Test Concentration
Virus	Adenovirus	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human metapneumovirus (hMPV)	1.0 x 10 ⁵ TCID ₅₀ /mL
	Rhinovirus	1.0 x 10 ⁵ PFU/mL
	Enterovirus/Coxsackievirus B4	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
	Human coronavirus NL63	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 1	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 2	1.0 x 10 ⁵ TCID ₅₀ /mL

	Human parainfluenza virus 3	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 4	1.0 x 10 ⁵ TCID ₅₀ /mL
	Influenza A	1.0 x 10 ⁵ TCID ₅₀ /mL
	Influenza B	1.0 x 10 ⁵ TCID ₅₀ /mL
	MERS-CoV	1.0 x 10 ⁵ TCID ₅₀ /mL
	Respiratory Syncytial Virus A	1.0 x 10 ⁵ PFU/mL
Bacteria	Bordetella pertussis	1.0 x 10 ⁶ cells/mL
	Chlamydia pneumoniae	1.0 x 10 ⁶ IFU/mL
	Haemophilus influenzae	1.0 x 10 ⁶ cells/mL
	Legionella pneumophila	1.0 x 10 ⁶ cells/mL
	Mycoplasma pneumoniae	1.0 x 10 ⁶ U/mL
	Streptococcus pneumoniae	1.0 x 10 ⁶ cells/mL
	Streptococcus pyogenes (group A)	1.0 x 10 ⁶ cells/mL
	Mycobacterium tuberculosis	1.0 x 10 ⁶ cells/mL
	Staphylococcus aureus	1.0 x 10 ⁶ org/mL
	Staphylococcus epidermidis	1.0 x 10 ⁶ org/mL
	Pooled human nasal wash	N/A
Yeast	Candida albicans	1.0 x 10 ⁶ cells/mL

Table 1-2 Specific reference group B

Substance	Active Ingredient	Concentration
Endogenous	Mucin	2% w/v
	Whole Blood	1% v/v
OTC Nasal Drops	Phenylephrine	15% v/v
OTC Nasal Gel	Sodium Chloride (i.e. NeilMed)	5% v/v
OTC Nasal Spray 1	Cromolyn	15% v/v
OTC Nasal Spray 2	Oxymetazoline	15% v/v
OTC Nasal Spray 3	Fluconazole	5% w/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
OTC Homeopathic Nasal Spray 1	Galphimia glauca, Sabadilla,	20% v/v
OTC Homeopathic Nasal Spray 2	Zincum gluconium (i.e., Zicam)	5% w/v
OTC Homeopathic Nasal Spray 3	Alkalol	10% v/v
OTC Homeopathic Nasal Spray 4	Fluticasone Propionate	5% v/v

Sore Throat Phenol Spray	Phenol	15% v/v
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	0.5% w/v
Antibiotic, Nasal Ointment	Mupirocin1	0.25% w/v
Antibacterial, Systemic	Tobramycin	0.0004% w/v

2.3 Testing equipment: straw, stopwatch, buffer.

3. Test method

3.1 Test method

A sufficient number of products were randomly selected from three batches of each type (strip and cassette) for COVID-19 Saliva Ag Test developed by Core Technology Co., Ltd. Group A and Group B of specific reference were tested separately by 5 tests of each batch and model. Observe and record the test results. For specific testing operation methods, please refer to the product manual.

3.2 Test requirement

The test results of specific reference group A should all be negative;

The test results of specific reference group B should all be negative.

3.3 Interpretation of results

Positive: Two pink-colored lines appear, one in the control region (C) and one in the test region(T).

Negative: Only one pink-colored line appears in the control region (C).

Invalid: Control line fails to appear.

4. Test result

Table 2-1 Analyze specific test results

Model	Lot	Adenovirus		Human metapneumovirus (hMPV)		Rhinovirus		Enterovirus/Coxsackievirus B4	
		1.0 x 10 ⁵ TCID ₅₀ /mL		1.0 x 10 ⁵ TCID ₅₀ /mL		1.0 x 10 ⁵ PFU/mL		1.0 x 10 ⁵ TCID ₅₀ /mL	
		-	+	-	+	-	+	-	+
Strip	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0

	20200530	5	0	5	0	5	0	5	0
Cassette	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0

Table 2-2 Analyze specific test results

Model	Lot	Human coronavirus OC43		Human coronavirus 229E		Human coronavirus NL63		Human parainfluenza virus 1	
		1.0 x 10 ⁵ TCID ₅₀ /mL		1.0 x 10 ⁵ TCID ₅₀ /mL		1.0 x 10 ⁵ TCID ₅₀ /mL		1.0 x 10 ⁵ TCID ₅₀ /mL	
		-	+	-	+	-	+	-	+
Strip	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0
Cassette	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0

Table 2-3 Analyze specific test results

Model	Lot	Human parainfluenza virus 2		Human parainfluenza virus 3		Human parainfluenza virus 4		Influenza A	
		1.0 x 10 ⁵ TCID ₅₀ /mL		1.0 x 10 ⁵ TCID ₅₀ /mL		1.0 x 10 ⁵ TCID ₅₀ /mL		1.0 x 10 ⁵ TCID ₅₀ /mL	
		-	+	-	+	-	+	-	+
Strip	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0
Cassette	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0

Table 2-4 Analyze specific test results

Model	Lot	Influenza B		Respiratory Syncytial Virus A		<i>Bordetella pertussis</i>		<i>Chlamydia pneumoniae</i>		<i>MERS-coronavirus</i>	
		1.0 x 10 ⁵ TCID ₅₀ /mL		1.0 x 10 ⁵ PFU/mL		1.0 x 10 ⁶ cells/mL		1.0 x 10 ⁶ IFU/mL		1.0 x 10 ⁵ TCID ₅₀ /mL	
		-	+	-	+	-	+	-	+	-	+
Strip	20200528	5	0	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0	5	0
Cassette	20200528	5	0	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0	5	0

Table 2-5 Analyze specific test results

Model	Lot	<i>Haemophilus influenzae</i>		<i>Legionella pneumophila</i>		<i>Mycoplasma pneumoniae</i>		<i>Streptococcus pneumoniae</i>	
		1.0 x 10 ⁶ cells/mL		1.0 x 10 ⁶ cells/mL		1.0 x 10 ⁶ U/mL		1.0 x 10 ⁶ cells/mL	
		-	+	-	+	-	+	-	+
Strip	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0
Cassette	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0

Table 2-6 Analyze specific test results

Model	Lot	<i>Streptococcus pyogenes</i> (group A)		<i>Mycobacterium tuberculosis</i>		<i>Staphylococcus aureus</i>		<i>Staphylococcus epidermidis</i>	
		1.0 x 10 ⁶ cells/mL		1.0 x 10 ⁶ cells/mL		1.0 x 10 ⁶ org/mL		1.0 x 10 ⁶ org/mL	
		-	+	-	+	-	+	-	+

Strip	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0
Cassette	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0

Table 2-7 Analyze specific test results

Model	Lot	Pooled human nasal wash		<i>Candida albicans</i>	
		N/A		1.0 x 10 ⁶ cells/mL	
		-	+	-	+
Strip	20200528	5	0	5	0
	20200529	5	0	5	0
	20200530	5	0	5	0
Cassette	20200528	5	0	5	0
	20200529	5	0	5	0
	20200530	5	0	5	0

Table 2-8 Analyze specific test results

Model	Lot	Endogenous		Endogenous		OTC Nasal Drops		OTC Nasal Gel	
		Mucin		Whole Blood		Phenylephrine		Sodium Chloride (i.e. NeilMed)	
		2% w/v		1% v/v		15% v/v		5% v/v	
		-	+	-	+	-	+	-	+
Strip	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0
Cassette	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0

	20200530	5	0	5	0	5	0	5	0
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Table 2-9 Analyze specific test results

Model	Lot	OTC Nasal Spray 1		OTC Nasal Spray 2		OTC Nasal Spray 3		Throat Lozenge	
		Cromolyn		Oxymetazoline		Fluconazole		Benzocaine, Menthol	
		15% v/v		15% v/v		5% w/v		0.15% w/v	
		-	+	-	+	-	+	-	+
Strip	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0
Cassette	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0

Table 2-10 Analyze specific test results

Model	Lot	OTC Homeopathic Nasal Spray 1		OTC Homeopathic Nasal Spray 2		OTC Homeopathic Nasal Spray 3		OTC Homeopathic Nasal Spray 4	
		Galphimia glauca, Sabadilla,		Zincum gluconium (i.e., Zicam)		Alkalol		Fluticasone Propionate	
		20% v/v		5% w/v		10% v/v		5% v/v	
		-	+	-	+	-	+	-	+
Strip	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0
Cassette	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0

Table 2-11 Analyze specific test results

Model	Lot	Sore Throat Phenol Spray		Anti-viral Drug		Antibiotic, Nasal Ointment		Antibacterial, Systemic	
		Phenol		Tamiflu (Oseltamivir Phosphate)		Mupirocin ¹		Tobramycin	
		15% v/v		0.5% w/v		0.25% w/v		0.0004% w/v	
		-	+	-	+	-	+	-	+
Strip	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0
Cassette	20200528	5	0	5	0	5	0	5	0
	20200529	5	0	5	0	5	0	5	0
	20200530	5	0	5	0	5	0	5	0

From the above test results, it can be seen that the test results of the same model and batch of products are the same for the same sample; the test results of the same model and three batches of products are the same. The above results show that the specificity of this product is good, and there are no intra-assay and inter-assay differences.

5. Test conclusion:

The above test results can be concluded that the test result is negative for interference substances with concentrations less than or equal to the following concentrations.

It show that the specificity of this product is good, and there are no intra-assay and inter-assay differences.

Potential Cross-Reactant		Test Concentration
Virus	Adenovirus	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human metapneumovirus (hMPV)	1.0 x 10 ⁵ TCID ₅₀ /mL
	Rhinovirus	1.0 x 10 ⁵ PFU/mL
	Enterovirus/Coxsackievirus B4	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
	Human coronavirus NL63	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 1	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 2	1.0 x 10 ⁵ TCID ₅₀ /mL

	Human parainfluenza virus 3	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 4	1.0 x 10 ⁵ TCID ₅₀ /mL
	Influenza A	1.0 x 10 ⁵ TCID ₅₀ /mL
	Influenza B	1.0 x 10 ⁵ TCID ₅₀ /mL
	MERS-CoV	1.0 x 10 ⁵ TCID ₅₀ /mL
	Respiratory Syncytial Virus A	1.0 x 10 ⁵ PFU/mL
Bacteria	Bordetella pertussis	1.0 x 10 ⁶ cells/mL
	Chlamydia pneumoniae	1.0 x 10 ⁶ IFU/mL
	Haemophilus influenzae	1.0 x 10 ⁶ cells/mL
	Legionella pneumophila	1.0 x 10 ⁶ cells/mL
	Mycoplasma pneumoniae	1.0 x 10 ⁶ U/mL
	Streptococcus pneumoniae	1.0 x 10 ⁶ cells/mL
	Streptococcus pyogenes (group A)	1.0 x 10 ⁶ cells/mL
	Mycobacterium tuberculosis	1.0 x 10 ⁶ cells/mL
	Staphylococcus aureus	1.0 x 10 ⁶ org/mL
	Staphylococcus epidermidis	1.0 x 10 ⁶ org/mL
	Pooled human nasal wash	N/A
Yeast	Candida albicans	1.0 x 10 ⁶ cells/mL

Substance	Active Ingredient	Concentration
Endogenous	Mucin	2% w/v
	Whole Blood	1% v/v
OTC Nasal Drops	Phenylephrine	15% v/v
OTC Nasal Gel	Sodium Chloride (i.e. NeilMed)	5% v/v
OTC Nasal Spray 1	Cromolyn	15% v/v
OTC Nasal Spray 2	Oxymetazoline	15% v/v
OTC Nasal Spray 3	Fluconazole	5% w/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
OTC Homeopathic Nasal Spray 1	Galphimia glauca, Sabadilla,	20% v/v
OTC Homeopathic Nasal Spray 2	Zincum gluconium (i.e., Zicam)	5% w/v
OTC Homeopathic Nasal Spray 3	Alkalol	10% v/v
OTC Homeopathic Nasal Spray 4	Fluticasone Propionate	5% v/v
Sore Throat Phenol Spray	Phenol	15% v/v
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	0.5% w/v
Antibiotic, Nasal Ointment	Mupirocin1	0.25% w/v

Antibacterial, Systemic	Tobramycin	0.0004% w/v
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