

Endogenous Interference Studies

1 Experimental Purpose

The aim of this study is to evaluate when coronavirus (SARS-CoV-2) is combined with some drugs and whole blood, if there is any effect on the result of the V-CHEK 2019-nCoV Ag Saliva Rapid Test Card(Immunochromatography).

2 Experimental materials

2.1 The following three batches of V-CHEK 2019-nCoV Ag Saliva Rapid Test Card(Immunochromatography) were used.

LOT No.: 05820010C,

LOT No.: 05820011C,

LOT No.: 05820012C.

2.2 Interfering substances and concentrations are as follows:

No.	Substance	Concentration
1	Whole Blood(human)	4%
2	Ibuprofen	1mg/mL
3	Tetracycline	3µg/mL
4	Chloramphenicol	3µg/mL
5	Erythromycin	3µg/mL
6	Mucin	0.50%
7	Ricola (Menthol)	1.5mg/mL
8	Sucrets (Dyclonin/Menthol)	1.5mg/mL
9	Chloraseptic (Menthol/Benzocaine)	1.5mg/mL
10	CVS Nasal Drops (Phenylephrine)	15% v/v
11	Afrin (Oxymetazoline)	15% v/v
12	Nasal Gel (Oxymetazoline)	10% v/v
13	Zicam	5% v/v
14	Sore Throat Phenol Spray	15% v/v
15	Tobramycin	4ug/mL
16	Mupirocin	10mg/mL
17	Fluticasone Propionate	5% v/v
18	Tamiflu (Oseltamivir Phosphate)	5mg/mL
19	CVS Nasal Spray (Cromolyn)	15% v/v
20	Homeopathic (Alkalol)	1 : 10

2.3 SARS-CoV-2 virus culture is from BEI Resource, catalog NR-52286. NR-52286 is a preparation of severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), isolate USA-WA1/2020 that has been inactivated by heating to 65°C for 30 minutes. The material was supplied frozen at a concentration 1.6×10^5 TCID₅₀/ml, of Pre-Inactivation Titer by TCID₅₀ Assay in Vero E6 Cells (7 days at 37°C and 5% CO₂) according to BEI Resource.

3 Experimental method

3.1 The substances in section 2.2 were mixed with pH 7.0 PBS buffer, shown in Table 1 below.

3.2 Add the concentrated coronavirus culture to the solutions from section 3.1 to prepare the mixture with the virus culture concentration three times of the minimum detection limit (300 TCID₅₀ / mL), and use the prepared mixture for test according to the instructions, each tests were repeated 3 times, with results recorded and data analyzed. The sample numbers are shown in Table 1 below.

Table 1 Endogenous Interference Substances table

Sample No.	Substance	Concentration	Final Virus cultures Concentration
1	Whole Blood(human)	4%	0×10 ² TCID ₅₀ / mL
2	Ibuprofen	1mg/mL	
3	Tetracycline	3µg/mL	
4	Chloramphenicol	3µg/mL	
5	Erythromycin	3µg/mL	
6	Mucin	0.50%	
7	Ricola (Menthol)	1.5mg/mL	
8	Sucrets (Dyclonin/Menthol)	1.5mg/mL	
9	Chloraseptic (Menthol/Benzocaine)	1.5mg/mL	
10	CVS Nasal Drops (Phenylephrine)	15% v/v	
11	Afrin (Oxymetazoline)	15% v/v	
12	Nasal Gel (Oxymetazoline)	10% v/v	
13	Zicam	5% v/v	
14	Sore Throat Phenol Spray	15% v/v	
15	Tobramycin	4ug/mL	
16	Mupirocin	10mg/mL	
17	Fluticasone Propionate	5% v/v	
18	Tamiflu (Oseltamivir Phosphate)	5mg/mL	
19	CVS Nasal Spray (Cromolyn)	15% v/v	
20	Homeopathic (Alkalol)	1: 10	
21	Whole Blood(human)	4%	3×10 ² TCID ₅₀ / mL
22	Ibuprofen	1mg/mL	
23	Tetracycline	3µg/mL	
24	Chloramphenicol	3µg/mL	
25	Erythromycin	3µg/mL	
26	Mucin	0.50%	
27	Ricola (Menthol)	1.5mg/mL	
28	Sucrets (Dyclonin/Menthol)	1.5mg/mL	
29	Chloraseptic (Menthol/Benzocaine)	1.5mg/mL	
30	CVS Nasal Drops (Phenylephrine)	15% v/v	
31	Afrin (Oxymetazoline)	15% v/v	
32	Nasal Gel (Oxymetazoline)	10% v/v	
33	Zicam	5% v/v	



34	Sore Throat Phenol Spray	15% v/v	
35	Tobramycin	4ug/mL	
36	Mupirocin	10mg/mL	
37	Fluticasone Propionate	5% v/v	
38	Tamiflu (Oseltamivir Phosphate)	5mg/mL	
39	CVS Nasal Spray (Cromolyn)	15% v/v	
40	Homeopathic (Alkalol)	1: 10	

4 Experimental Results

The detailed data are shown in Linde data file, Endogenous interference section. Samples number 1 to 20 all show negative results, while samples number 21 to 40 all show positive results.

5 Experimental conclusions

Three batches of antigen detection kits were used in the endogenous interference studies. Based on the results, when the V-CHEK 2019-nCoV Ag Saliva Rapid Test Card(Immunochromatography) was used to detect the high concentration of whole blood and other nasal and throat medicines, in the absence or presence of the coronavirus (SARS- CoV-2), there are no false negatives or false positives. Therefore, the above interference substances will not interfere with the antigen test results.


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