

---

## Interference Substances Study Report

### 1. Purpose

To evaluate potential cross-reactivity and interference of endogenous interference substances that may cause symptoms similar with SARS-CoV-2 infection.

### 2. Scope

The Coronavirus Ag Rapid Saliva Test Device produced by Innovation Biotech (Beijing) Co., Ltd.

### 3. Materials and Equipment

- (1) The Coronavirus Ag Rapid Saliva Test Device (Lot: 20201010).
- (2) The inactivated SARS-CoV-2 virus was acquired from Vero E6 cell culture, which titers is  $6 \times 10^5$ TCID<sub>50</sub>/ml and the strains is BetaCoV/Wuhan/IPBCAMS-WH-01/2019;
- (3) The negative saliva swabs samples were collected from healthy person following the product instruction.
- (4) The negative matrix samples were acquired by mixture of the negative saliva swabs samples, use for dilute the inactivated SARS-CoV-2 virus.
- (5) The endogenous interference substances such as Whole Blood, Mucin, Benzocaine, NeilMed, CVS Nasal Drops (Phenylephrine), Oxymetazoline, CVS Nasal Spray (Cromolyn), Zicam, Sore Throat Phenol Spray, Tobramycin, Mupirocin, Fluticasone Propionate, Tamiflu were used to cross-reactivity study.

The concentration of the endogenous interference substances listed in Table 1.

**Table 1: Concentration of the endogenous interference substances**

Substance	Concentration
Whole Blood	4%
Mucin	0.5%
Benzocaine	1.5 mg/mL
NeilMed	5% v/v
CVS Nasal Drops (Phenylephrine)	15% v/v
Oxymetazoline	15% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 µg/mL
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v
Tamiflu	5 mg/mL

### 4. Procedure/Protocol

#### 4.1 Negative Samples Preparation

The negative matrix samples was acquired by mixture of the negative saliva swabs samples, use for dilute the endogenous interference substances listed in Table 1.

According to Table 1, spike the endogenous interference substances into negative matrix samples to the corresponding concentration.

#### 4.2 Positive Samples Preparation

The positive matrix samples acquired from dilute the SARS-CoV-2 ( $6 \times 10^5$  TCID<sub>50</sub>/ml) into the negative matrix samples in 1:3000 dilution, the final concentration of SARS-CoV-2 in positive matrix samples is  $3 \times \text{LoD}$ , define the  $3 \times \text{LoD}$  samples as the positive matrix samples.

According to Table 1, spike the endogenous interference substances into the  $3 \times \text{LoD}$  samples to the corresponding concentration.

#### 4.3 Test procedure

Use the Coronavirus Ag Rapid Saliva Test Device test the prepared samples. Each sample test 3 times.

#### 5. Acceptance Criteria

The test results of negative samples of the Coronavirus Ag Rapid Saliva Test Device should be negative result, the test results of positive samples of the Coronavirus Ag Rapid Saliva Test Device should be positive result.

#### 6. Results

The Coronavirus Ag Rapid Saliva Test Device test result were summarized in Table 2.

**Table 2: The Test Result for interference substances study**

Substance	Concentration	Result					
		Positive Sample			Negative Sample		
		1	2	3	1	2	3
Whole Blood	4%	4	4	4	-	-	-
Mucin	0.5%	4	4	4	-	-	-
Benzocaine)	1.5 mg/mL	4	4	4	-	-	-
NeilMed	5% v/v	4	4	4	-	-	-
CVS Nasal Drops (Phenylephrine)	15% v/v	4	4	4	-	-	-
Oxymetazoline)	15% v/v	4	4	4	-	-	-
CVS Nasal Spray (Cromolyn)	15% v/v	4	4	4	-	-	-
Zicam	5% v/v	4	4	4	-	-	-
Sore Throat Phenol Spray	15% v/v	4	4	4	-	-	-
Tobramycin	4 µg/mL	4	4	4	-	-	-
Mupirocin	10 mg/mL	4	4	4	-	-	-
Fluticasone Propionate	5% v/v	4	4	4	-	-	-
Tamiflu	5 mg/mL	4	4	4	-	-	-

Note: “-” indicate negative; “Number” indicate positive, the bigger the number, the darker the color.

~~The results show that endogenous interference substances listed in Table 1 has no inference effect on the negative and positive test results, and these substances do not cross-react with Coronavirus Ag Rapid Saliva Test Device.~~

## 7. Conclusion

The substances which listed in the following table have no cross-reaction with the Coronavirus Ag Rapid Saliva Test Device.

<b>Substance</b>	<b>Concentration</b>
Whole Blood	4%
Mucin	0.5%
Benzocaine	1.5 mg/mL
NeilMed	5% v/v
CVS Nasal Drops (Phenylephrine)	15% v/v
Oxymetazoline)	15% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 µg/mL
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v
Tamiflu	5 mg/mL