Interfering Substance Study Report of COVID-19 Antigen Rapid Test

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1. Purpose

Evaluate interfering substance influence for COVID-19 Antigen Rapid Test .

2. Material

ICOV-502 Lot1: COV20060001-T
Lot2: COV20060002-T
Lot3: COV20060003-T

Interfering substances
Negative sample
SARS-COV-2 antigen weak positive sample

3. Test methods

Dilute the interfering substance to the following concentration with negative sample and SARS-COV-2 Antigen weak positive respectively:
Whole Blood 20μl/ml
Mucin 50μg/ml
Budesonide Nasal Spray 200μl/ml
Dexamethasone 0.8mg/ml
Flunisolide 6.8ng/ml
Mupirocin 12mg/ml
Oxymetazoline 0.6mg/ml
Phenylephrine 12mg/ml
Rebetol 4.5μg/ml
Relenza 282ng/ml
Tamiflu 1.1μg/ml
Tobryamycin 2.43mg/ml
Test them according to the package insert in triplicate. Read the result at 15 minutes. Results were present in table below.

4. Acceptance Criteria

Interfering substance have no influence. When a positive sample is tested, the result is positive; When a nagative sample is tested, the result is nagative.

5. Result

Table: Interfering Substances Results

Analytes	Conc.	COV20060001-T					
		Negative			SARS-COV-2 Antigen weak Positive		
Whole Blood	20µl/ml	-	-	-	+	+	+
Mucin	50µg/ml	-	-	-	+	+	+
Budesonide Nasal Spray	200µl/ml	-	-	-	+	+	+
Dexamethasone	0.8mg/ml	-	-	-	+	+	+
Flunisolide	6.8ng/ml	-	-	-	+	+	+
Mupirocin	12mg/ml	-	-	-	+	+	+
Oxymetazoline	0.6mg/ml	-	-	-	+	+	+
Phenylephrine	12mg/ml	-	-	-	+	+	+
Rebetol	4.5µg/ml	-	-	-	+	+	+
Relenza	282ng/ml	-	-	-	+	+	+
Tamiflu	1.1µg/ml	-	-	-	+	+	+
Tobryamycin	2.43mg/ml	-	-	-	+	+	+
Analytes	Conc.	COV20060002-T					
		Negative			SARS-COV-2 Antigen weak Positive		
Whole Blood	20µl/ml	-	-	-	+	+	+
Mucin	50µg/ml	-	-	-	+	+	+
Budesonide Nasal	200µl/ml	-	-	-	+	+	+

Spray							
Dexamethasone	0.8mg/ml	-	-	-	+	+	+
Flunisolide	6.8ng/ml	-	-	-	+	+	+
Mupirocin	12mg/ml	-	-	-	+	+	+
Oxymetazoline	0.6mg/ml	-	-	-	+	+	+
Phenylephrine	12mg/ml	-	-	-	+	+	+
Rebetol	4.5μg/ml	-	-	-	+	+	+
Relenza	282ng/ml	-	-	-	+	+	+
Tamiflu	1.1μg/ml	-	-	-	+	+	+
Tobryamycin	2.43mg/ml	-	-	-	+	+	+
Analytes	Conc.	COV20060003-T					
		Negative			SARS-COV-2 Antigen weak Positive		
Whole Blood	20μl/ml	-	-	-	+	+	+
Mucin	50μg/ml	-	-	-	+	+	+
Budesonide Nasal Spray	200μl/ml	-	-	-	+	+	+
Dexamethasone	0.8mg/ml	-	-	-	+	+	+
Flunisolide	6.8ng/ml	-	-	-	+	+	+
Mupirocin	12mg/ml	-	-	-	+	+	+
Oxymetazoline	0.6mg/ml	-	-	-	+	+	+

Phenylephrine	12mg/ml	-	-	-	+	+	+
Rebetol	4.5μg/ml	-	-	-	+	+	+
Relenza	282ng/ml	-	-	-	+	+	+
Tamiflu	1.1μg/ml	-	-	-	+	+	+
Tobryamycin	2.43mg/ml	-	-	-	+	+	+

Note: "-" means negative result, "+" means positive result

As can be seen from the above table, the results were still negative after different concentrations of interferences were diluted with negative samples. After dilution with the positive sample, the result is still positive, so the addition of the interference has no influence on the test result of the negative positive sample.

6. Conclusion

No substances showed any interference with the test. There were no obvious differences among the 3 lots of products.