

Manufacturer Statement

The following study was done to confirm that the substances do not interfere with the performance of The Novel Coronavirus Ag Rapid Test Device in certain concentration.

The study was conducted according to Technical Specification of The Novel Coronavirus Ag Rapid Test Device. Interferences of common exogenous and endogenous potential interfering substances and cross-reactivity of some kinds of positive samples were tested. It showed that no cross-reactivity and interference was found in these tests.

Effect of other Human CornaVirus Disease:

Analytes	Concertration	Cross-Reactivity	Interference
SARS-CoV S1	50 ug/mL	No	No
MERS- CoV S1	50 ug/mL	No	No
HCoV-NL63 S1	50 ug/mL	No	No
HCoV-HKU1 S1	50 ug/mL	No	No
HCoV-229E S1	50 ug/mL	No	No
HCoV-OC43 S1	50 ug/mL	No	No
Influenza A H1N1 Protein	50 ug/mL	No	No
Influenza B Protein	50 ug/mL	No	No
Human RSV(B1) G Protein	50 ug/mL	No	No

Effect of other common causative agents of Infectious Disease:

Analytes	Concertration	Cross-Reactivity	Interference
HIV	7.34COI	No	No
HAV	5.27COI	No	No
HBsAg	10.0 IU/ml	No	No
HCV	6.77COI	No	No
Syphilis	8.09COI	No	No
Human T-cell Leukemia Virus	1.16g/ml	No	No

Cytomegalovirus	28.1 IU/ml	No	No
Rrubella virus	25.2 IU/ml	No	No
Mycoplasma pneumoniae virus	16.2 IU/ml	No	No
Chlamydia pneumoniae virus	12.3 IU/ml	No	No
Human parainfluenza viruse	6.78 IU/ml	No	No

Effect of the potentially cross-reactive Endogenous Substances:

Analytes	Concertration	Cross-Reactivity	Interference
Albumin	20 mg/mL	No	No
Bilirubin	20 ug/mL	No	No
Hemoglobin	15 mg/mL	No	No
Glucose	20 mg/mL	No	No
Uric Acid	200 ug/mL	No	No
Lipids	20 mg/mL	No	No

Effect of some other common Biological Analytes:

Analytes	Concertration	Cross-Reactivity	Interference
Acetaminophen	200 ug/mL	No	No
Acetoacetic Acid	200 ug/mL	No	No
Acetylsalicylic Acid	200 ug/mL	No	No
Benzoylecgonine	100 ug/mL	No	No
Caffeine	200 ug/mL	No	No
EDTA	800 ug/mL	No	No
Ethanol	1.0%	No	No
Gentisic Acid	200 ug/mL	No	No
P- Hydroxybutyrate	200,000 ug/mL	No	No
Methanol	10.0%	No	No

Zhejiang Quark Biotechnology Co., Ltd.

Add.: No.1 Jiangdong Road, Zhejiang Xinchang High-tech Industrial Park, Xinchang District, Zhejiang, China

Tel:+86 575 86312625 Fax: + 86 575 86766303

Website: www.zjkuake.com



In-vitro Diagnostic Test

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Phenothiazine	200 ug/mL	No	No
Phenylpropanolamine	200 ug/mL	No	No
Salicylic Acid	200 ug/mL	No	No



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Yiwen Shang

Managing Director

Zhejiang Quark Biotechnology Co., Ltd

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浙江夸克生物科技有限公司
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