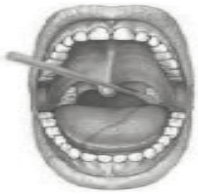
ANBIO / EDELVITAL™ 3in1

SARS-COV-2 ANTIGEN SCHNELLTESTKIT (LUTSCHTEST, NASAL, RACHEN)

I	II	III
		
Vorderer Nasenabstrich	Rachenabstrich	Lutschtest

99,52%* Genauigkeit

3in1 SARS-COV-2
Antigen Schnelltest Kit

Sonderzulassung nach §11 Absatz 1 MPG von Antigen-Tests zur Eigenanwendung durch Laien (Selbsttests) **5640-S-058/21**

- 20x Testkarte
- 20x Extraktionsrohr mit Lösung
- 20x Tupfer
- 1x Packungsbeilage

Vorteile:

- **3 in 1 Probenentnahme mit vorderem Nasen- bzw. Rachenabstrich oder als Lutschtest.**
- **Einfachste Handhabung mit nur 3 Arbeitsschritten und einzeln vorabgefüllten, gebrauchsfertigen Lösungen.**
- **Schneller Nachweis von SARS-COV-2-Nucleocapsid-Antigen in 15 Minuten.**
- **Keine Instrumentierung erforderlich. Kostengünstige Lösung für groß angelegte Tests.**
- **Weiterverarbeitung potentiell positiver Proben mit PCR möglich da Viole wiederverschließbar**

99,52 %* Genauigkeit	
99.18%* Empfindlichkeit	**100 %*** Spezifität
2-30 °C Lagertemperatur	**24 Monate** Haltbarkeit

Der EDELVITAL 3 in 1 Rapid COVID-19-Antigen-Test ist eine kolloidale Gold-Immunochromatographie zum qualitativen Nachweis von Nucleocapsid-Antigenen aus menschlichen Nasen - Rachenabstrichen oder Speichel von Personen, bei denen der Verdacht auf COVID-19 besteht.

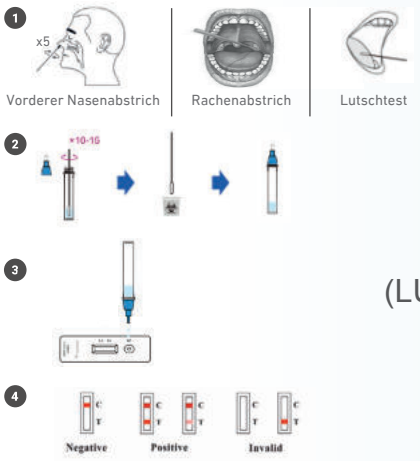
CE

ortotec medizinprodukte

ortotec Medizinprodukte, Dr. Harald Kiss,
Rainerstrasse 9, A-5020 Salzburg, www.ortotec.at

Test Ablauf

Lesen Sie die Gebrauchsanweisung
für den exakten Vorgang.



EDELVITAL™
präsentiert:

3in1

SARS-COV-2 ANTIGEN
SCHNELLTESTKIT
(LUTSCHTEST, NASAL, RACHEN)

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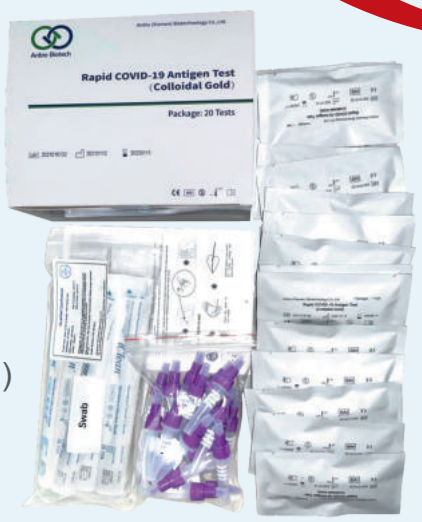
Genauigkeit



ANBIO 3in1 SARS-COV-2 Antigen Schnelltest Kit (Nasal, Rachen, Lutschtest)

99,52 %*
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99,18 %*	**100** %*
Empfindlichkeit	Spezifität
2-30 °C	**24** Monate
Lagertemperatur	Haltbarkeit

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Die klinische Leistung des COVID-19-Antigen-Schnelltests (kolloidales Gold) wurde durch Testen von 1096 positiven und 793 negativen Proben auf SARS-CoV-2-Antigen mit einer Sensitivität von 99,18% (95% CI: 98,45% - 99,62%) und einer Spezifität von 100% (95% CI: 99,54% - 100%) bestimmt. Klinische Proben wurden mit einer RT-PCR-Referenzmethode als positiv oder negativ bestimmt.

Eine Packung beinhaltet:

20x Testkarte
20x Extraktionsrohr mit Lösung
20x Tupfer
1x Packungsbeilage

Der 3in1 Antigen Schnelltest mit noch einfacherer Handhabung

Zertifiziert & zuverlässig

Der ANBIO 3in1 Rapid COVID-19-Antigen-Test ist eine kolloidale Gold-Immunochromatographie zum qualitativen Nachweis von Nucleocapsid-Antigenen aus SARS-CoV-2 in menschlichen Nasentupfern, Rachenabstrichen oder Speichel von Personen, bei denen der Verdacht auf COVID-19 besteht.

Vorteile:

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- Einfachste Handhabung mit nur 3 Arbeitsschritten und einzeln abgefüllten, gebrauchsfertigen Lösungen.
- Hohe Leistung durch klinische Studie nachgewiesen.
- Schneller Nachweis von SARS-COV-2-Nucleocapsid-Antigen in 15 Minuten.
- Keine Instrumentierung erforderlich.
- Kostengünstige Lösung für groß angelegte Tests.

Verpackungseinheiten:
20 Stück per Packung
500 Stück per Karton

Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

SELBSTVERPFLICHTUNG für das Inverkehrbringen von Schnelltests zum Nachweis eines Vorliegens einer Infektion mit SARS-CoV-2 gemäß § 323c Abs. 18 der Bundesabgabenordnung, idgF

An das
Bundesamt für Sicherheit im Gesundheitswesen
Traisengasse 5
1200 Wien
Per Email an medizinprodukte@basg.gv.at

Hiermit bestätige ich

Firma: Anbio (Xiamen) Biotechnology Co.,Ltd.

Name: Xiao Hu

Anschrift: No.2016, Wengjiao West Road, Xinyang Street, Haicang District, Xiamen, Fujian 361026, China

als Verantwortlicher für das Inverkehrbringen, dass hinsichtlich der nachstehend beschriebenen Schnelltests zum Nachweis eines Vorliegens einer Infektion mit SARS-CoV-2, die durch den Hersteller für eine Probennahme im anterior nasalen Bereich oder andere ähnlich minimal invasive Probennahmen in Verkehr gebracht und mit einer CE-Kennzeichnung gemäß dem Medizinproduktegesetz oder auf der Grundlage der Richtlinie 98/79/EG ergangenen nationalen Vorschriften anderer Vertragsparteien des Abkommens über den Europäischen Wirtschaftsraum versehen sind, jedoch vom Hersteller bisher nicht zur Eigenanwendung in Verkehr gebracht wurde, ein Sicherheits- und Leistungsniveau erreicht wird, das die Funktionstauglichkeit und die Einsatztauglichkeit für den geplanten Zweck (Eigenanwendung) gewährleistet.

Schnelltest zum Nachweis eines Vorliegens einer Infektion mit SARS-CoV-2

Nr.	Genaue Bezeichnung des Medizinproduktes	Name und Anschrift des Herstellers gemäß § 2 Abs. 7 österreichisches Medizinproduktegesetz	Name und Anschrift des Bevollmächtigten gemäß § 2 Abs. 8a österreichisches Medizinproduktegesetz
1	Rapid COVID-19 Antigen Test (Colloidal Gold)	Anbio (Xiamen) Biotechnology Co.,Ltd.	Lotus BL B.V.
2		No.2016, Wengjiao West Road, Xinyang Street, Haicang District, Xiamen, Fujian 361026, China	Koningin Julianaplein 10, 1e Verd, 2595 AA Den Haag, Niederlande

01.02.2021

Datum 01.02.2021 Unterschrift Xiao Hu

厦门)生物科技有限公司

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex III.

Manufacturer: Anbio (Xiamen) Biotechnology Co.,Ltd.
Address: No.2016, Wengjiao West Road, Xinyang Street, Haicang District,361026 Xiamen, Fujian, China.

European Representative: Lotus NL B.V.

Contact person: Peter **E-mail:** peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague, Netherlands.

In Vitro Diagnostic Directive:

- **Rapid COVID-19 Antigen Test (Colloidal Gold)**

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:04/09/2020

Place:Xiamen,China

Name of authorized signatory: Danny Wang
Position held in the company: General Manager
Seal/Stamp:

Anbio (Xiamen) Biotechnology Co.,Ltd.

COVID-19 Antigen Schnelltest (kolloidales Gold)

Gebrauchsanleitung

【Produktname】COVID-19 Antigen Schnelltest (kolloidales Gold)

【 Zweckbestimmung】für den professionellen Einsatz in der in-vitro Diagnostik, befristet zugelassen nach

§ 11 MPG in Deutschland BfArM GZ: 5640-S-079/21 und Laientestung

【Spezifikation】1 Test/ Kit, 10 Tests/ Kit, 20 Tests/Kit.

【Anwendungsbereich】

Der COVID-19-Antigen Schnelltest ist ein kolloidaler Gold-Immunochromatographie Assay zum qualitativen Nachweis von Nucleokapsid-Antigenen aus SARS-CoV-2 im menschlichen Nasen-, Rachenabstrichen oder Speichel, bei denen der Verdacht auf COVID-19 besteht.

Die neuen Coronaviren gehören zur Gattung β-Genius dieser Virenklasse. COVID-19 ist eine akute Infektionskrankheit der Atemwege. Menschen sind im moderate bis sehr anfällig. Derzeit sind die mit dem neuartigen Coronavirus infizierten Patienten die Hauptinfektionsquelle, aber auch asymptomatisch infizierte Menschen können infektiös sein. Nach der aktuellen epidemiologischen Untersuchung beträgt die Inkubationszeit 1 bis 14 Tage, meist 3 bis 7 Tage. Hauptsymptome sind Fieber, Müdigkeit und trockener Husten. In einigen Fällen treten verstopfte Nase, laufende Nase, Halsschmerzen, Myalgie und Durchfall auf.

Die Ergebnisse beziehen sich auf die Identifizierung von SARS-CoV-2 Nucleokapsid-Antigen. Das Antigen ist im Allgemeinen in Proben der oberen Atemwege oder Proben der unteren Atemwege während der akuten Phase der Infektion nachweisbar. Die positiven Ergebnisse weisen auf das Vorhandensein viraler Antigene hin, aber eine klinische Korrelation mit der Anamnese und anderen diagnostischen Informationen ist erforderlich, um den Infektionsstatus zu bestimmen. Positive Ergebnisse schließen eine bakterielle Infektion oder eine Co-Infektion mit anderen Viren nicht aus. Das nachgewiesene Antigen ist möglicherweise nicht die eindeutige Ursache der Krankheit. Negative Ergebnisse schließen eine SARS-CoV-2-Infektion nicht aus und sollten nicht als alleinige Grundlage für Entscheidungen zur Behandlung oder zum Patientenmanagement, einschließlich Entscheidungen zur Infektionskontrolle, verwendet werden. Negative Ergebnisse sollten im Zusammenhang mit den jüngsten Expositionen, der Anamnese und dem Vorhandensein klinischer Anzeichen und Symptome eines Patienten im Einklang mit SARS-CoV-2 betrachtet und gegebenenfalls mit einem molekularen Assay (RT_PCR) für das Patientenmanagement bestätigt werden.

【Testprinzip】

Dieses Reagenz basiert auf einem kolloidalen Gold-Immunochromatographie Assay.

Während des Tests werden Probenextrakte auf die Testkarten aufgebracht. Wenn der Extrakt SARS-CoV-2-Antigen enthält, bindet das Antigen an den monoklonalen SARS-CoV-2-Antikörper. Während des lateralen Flusses bewegt sich der Komplex entlang der Nitrocellulosemembran zum Ende des absorbierenden Papiers. Beim Passieren der Testlinie (Linie T, beschichtet mit einem anderen monoklonalen SARS-CoV-2- Antikörper) wird der Komplex von SARS-CoV-2 eingefangen Antikörper auf der Testlinie zeigt eine rote Linie; Beim Passieren der Linie C wird kolloidales goldmarkiertes Ziegen-Anti-Kaninchen-IgG durch die Kontrolllinie eingefangen (Linie C, beschichtet mit Kaninchen-IgG), die eine rote Linie zeigt.

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【Hauptbestandteile】

Die folgenden Komponenten sind im COVID-19 Antigen Schnelltest-Kit enthalten:

Mitgelieferte Materialien:

Probentyp	Materialien
Nasenabstriche, Rachenabstriche und Speichel	1. COVID-19-Antigen-Testkassette 2. Extraktionslösung 3. Bedienungsanleitung 4. Abnahme-Zubehör (Stäbchen, Reservoir)
(Nur) Speichel	1.COVID-19-Antigen-Testkassette) 2.Speichelsammelgerät (mit 1ml Extraktionslösung) 3.Bedienungsanleitung 4.Einweg-Tupfer

Benötigt, jedoch nicht im Test-Kit enthalten:

1.Timer
2.Röhrchen-Rack für Proben
3.Persönliche Schutzausrüstung

【Lagerbedingungen und Haltbarkeit】

1. Lagern Sie das Produkt bei 2-30°C, die Haltbarkeit beträgt vorläufig 24 Monate.
2.Die Testkarte sollte direkt nach dem Öffnen des Beutels verwendet werden.
3.Reagenzien und Geräte müssen bei der Prüfung Raumtemperatur (15–30°C) haben.

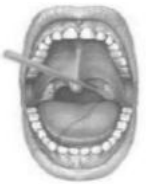
【Handhabung der Probensammlung】

1. Abstrich-Probenentnahme:

<u>Nasopharyngeal oder Rachen-Abstrichproben:</u>

Nasopharyngeal: Nach dem Putzen der Nase, legen Sie den Kopf des Patienten leicht in den Nacken. Führen Sie den Tupfer fast horizontal entlang der Nasenscheidewand tief in die Nase bis zur Rachenwand. Belassen Sie den Tupfer dort für wenige Sekunden und ziehen Sie ihn dann in rotierender Bewegung heraus.

Rachen: Lassen Sie den Patienten den Kopf leicht neigen, den Mund öffnen und "aaaah" Geräusche machen, damit die Rachenmandeln beidseitig freigelegt werden. Halten Sie den Tupfer fest und wischen Sie an den Rachenmandeln auf beiden Seiten des Patienten mindestens dreimal mit mäßiger Kraft hin und her.



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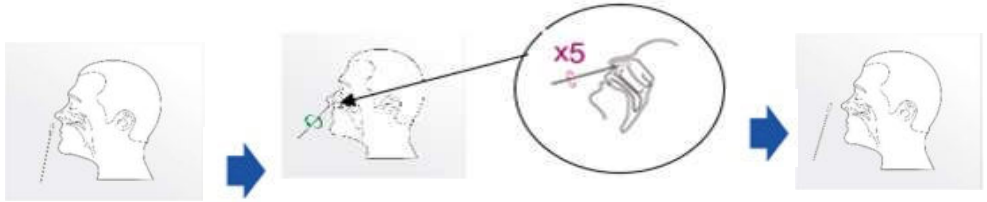
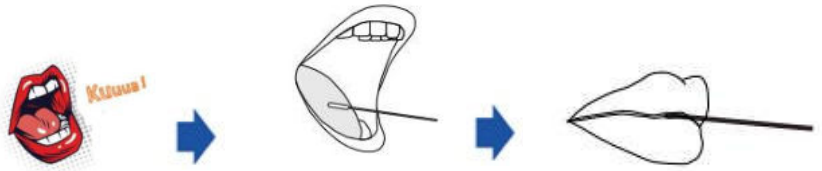
Nasen Abstrichproben:

a. Führen Sie den Stäbchen (Tupfer) in ein Nasenloch des Patienten ein. Die Tupferspitze sollte bis zu 2,5 cm vom Rand des Nasenlochs entfernt eingeführt werden.
b. Rollen Sie den Tupfer fünfmal entlang der Schleimhaut im Nasenloch, um sicherzustellen, dass sowohl Schleim als auch Zellen gesammelt werden.
c. Wiederholen Sie diesen Vorgang mit demselben Tupfer im anderen Nasenloch, um sicherzustellen, dass eine ausreichende Probe aus beiden Nasenhöhlen entnommen wird. Ziehen Sie den Tupfer aus der Nasenhöhle.



Speichel Probenentnahme durch Abstrich



Husten Sie tief, machen Sie das Geräusch von “kuuua”

Legen Sie den Tupfer auf Ihre Zunge

Halten Sie den Tupfer für 10-20 Sekunden im Mund, befeuchten Sie den Tupfer mit Speichel

2. ***Die Entnahme von Tupferproben***

a. Legen Sie den Tupfer mit der entnommenen Probe in das Extraktionsröhrchen, halten Sie den Tupferkopf fest und drücken Sie ihn mit Kraft gegen die Röhrchen-Oberfläche, während Sie den Tupfer etwa 10 Sekunden lang (10-15 Mal) drehen, um das Antigen vom Tupferkopf in die Extraktionslösung freizusetzen.

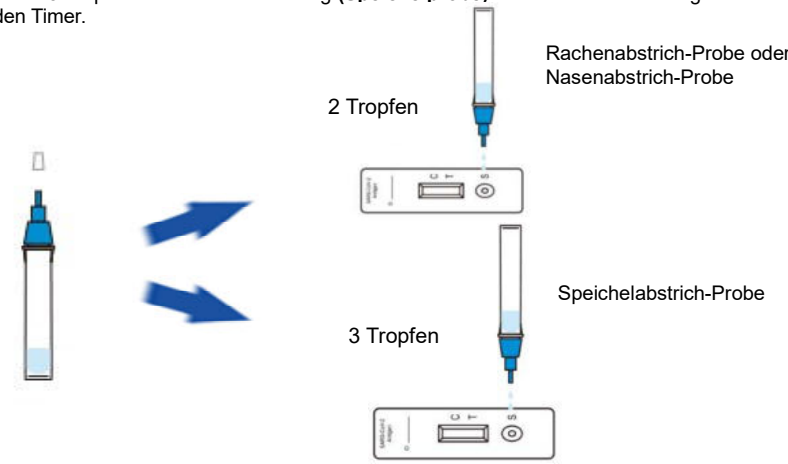
b. Entfernen des Tupfers: Drücken Sie den Tupferkopf beim Entfernen des Tupfers zusammen, um so viel Flüssigkeit wie möglich aus dem Tupfer zu entfernen. Entsorgen Sie die Tupfer gemäß den Vorschriften für die Entsorgung von Bioabfall.
c. Schrauben Sie die Düsenkappe auf das Extraktionsröhrchen.

3. Probentransport und -lagerung
Die Proben sollten so schnell wie möglich nach der Entnahme getestet werden. Abstriche oder Speichelproben können in der Extraktionslösung bis zu 24 Stunden bei Raumtemperatur oder 2° bis 8°C gelagert werden. Nicht einfrieren.

【Testmethode】

1. Der Test sollte bei Raumtemperatur (15-30°C) durchgeführt werden.
2. Proben hinzufügen

1) Abstrichprobe:
Öffnen Sie den Deckel, träufeln Sie 2 Tropfen der Extraktionslösung **(Rachen-Abstrichprobe oder Nasen-Abstrichprobe)** oder 3 Tropfen der Extraktionslösung **(Speichelprobe)** in die Probenvertiefung der Testkassette und starten Sie den Timer.



2) Speichelprobe (aus dem Speichelsammelgerät): Öffnen Sie den Deckel und nehmen Sie ein Röhrchen Flüssigkeit mit einem Einweg-Tropfer auf. Tropfen Sie 3 Tropfen Extraktionslösung in die Probenvertiefung der Testkassette und starten Sie den Timer.

3. Lesen Sie die Ergebnisse nach 15 bis 20 Minuten ab.

【Interpretation der Testergebnisse】

Negativ (-):

Nur Linie C ist gefärbt (s. Abb. unten), was darauf hindeutet, dass die Probe kein SARS-CoV-2-Antigen enthält.

Positiv (+):

Sowohl auf Linie C als auch auf Linie T sind Färbungen zu sehen (s. Abb. unten), was darauf hindeutet, dass die Probe SARS-CoV-2-Antigen enthält.

Ungültig:

Auf Linie C ist keine Färbung zu sehen (s. Abb. unten). Der Test ist ungültig oder es ist ein Anwendungsfehler aufgetreten. Wiederholen Sie den Test mit einer neuen Testkassette.

Negativ **Positiv** **Ungültig**

【Melden der Ergebnisse】

Positiver Test:

Positiv für das Vorhandensein von SARS-CoV-2-Antigen. Positive Ergebnisse weisen auf das Vorhandensein viraler Antigene hin, aber eine klinische Korrelation mit der Anamnese und anderen diagnostischen Informationen ist erforderlich, um den Infektionsstatus zu bestimmen. Positive Ergebnisse schließen eine bakterielle Infektion oder eine Co-Infektion mit anderen Viren nicht aus. Der nachgewiesene Wirkstoff ist möglicherweise nicht die eindeutige Ursache der Krankheit.

Negativer Test:

Negative Ergebnisse sind sicher, müssen aber gut interpretiert werden. Negative Testergebnisse schließen eine Infektion mit anderen Viren oder Pathogenen nicht aus und sollten nicht als alleinige Grundlage für Behandlungs- oder andere Patientenmanagemententscheidungen verwendet werden. Einschließlich Entscheidungen zur Infektionskontrolle, insbesondere bei Vorhandensein klinischer Anzeichen und Symptome im Einklang mit COVID-19 oder bei solchen, die dies getan haben in Kontakt mit dem Virus. Es wird empfohlen, diese Ergebnisse gegebenenfalls durch eine molekulare Testmethode für die Kontrolle des Patientenmanagements zu bestätigen.

Ungültig:

Ergebnisse nicht verwenden und weitergeben. Wiederholen Sie den Test.

【Grenzen des Tests】

1.Die klinische Performance wurde mit gefrorenen Proben bewertet, und die Testleistung kann bei frischen. Proben unterschiedlich sein.
2.Benutzer sollten die Proben nach der Probenentnahme so schnell wie möglich testen.
3.Positive Testergebnisse schließen eine Co-Infektion mit anderen Krankheitserregern nicht aus.
4.Die Ergebnisse des SARS-CoV-2-Antigen-Tests sollten mit der Krankengeschichte, den epidemiologischen Daten und anderen Daten korreliert werden, die dem Kliniker, der den Patienten bewertet, zur Verfügung stehen.
5.Ein falsch negatives Testergebnis kann auftreten, wenn der Gehalt an viralem Antigen in einer Probe unter der Nachweisgrenze des Tests liegt oder wenn die Probe nicht ordnungsgemäß gesammelt oder transportiert wurde. Ein negatives Testergebnis schließt daher die Möglichkeit einer COVID-19-Infektion nicht gänzlich aus.
6.Die Menge an Antigen in einer Probe kann mit zunehmender Krankheitsdauer abnehmen. Proben, die nach dem 5. Krankheitstag entnommen wurden, sind im Vergleich zu einem RT-PCR-Assay eher negativ.
7.Die Nichtbeachtung des Testverfahrens kann die Testleistung beeinträchtigen und / oder das Testergebnis ungültig machen.
8. Der Inhalt dieses Kits darf nur zum qualitativen Nachweis von SARS-CoV-2-Antigenen aus Rachenabstrichen, Nasentupfer- sowie Speichelproben verwendet werden. Der Test ist nur von geschultem Personal in persönlicher Schutzausrüstung durchzuführen.
9.Das Reagenz kann sowohl lebensfähiges als auch nicht lebensfähiges SARS-CoV-2-Antigen nachweisen. Die Nachweisleistung hängt von der Antigenbelastung ab und korreliert möglicherweise nicht mit anderen Diagnosemethoden, die an derselben Probe durchgeführt wurden.
10.Negative Testergebnisse sollen nicht für andere Corona Viren, andere virale Antigene - oder Bakterieninfektionen gelten.
11.Positive und negative Vorhersagewerte hängen stark von den Prävalenzraten ab. Positive Testergebnisse repräsentieren eher falsch positive Ergebnisse in Zeiten geringer / keiner COVID-19-Aktivität, wenn die Prävalenz der Krankheit niedrig ist. Falsch negative Testergebnisse sind wahrscheinlicher, wenn die Prävalenz der durch SARS-CoV-2 verursachten Krankheit hoch ist.
12.Dieses Gerät wurde nur für die Verwendung mit menschlichem Probenmaterial bewertet.
13.Die Leistung dieses Tests wurde nicht für die Anwendung bei Patienten ohne Anzeichen und Symptome einer Atemwegsinfektion bewertet. Die Leistung kann bei asymptomatischen Personen unterschiedlich sein.

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Vorderer Nasenabstrich | Rachenabstrich | Lutschtest

3in1 SARS-COV-2
Antigen Schnelltest Kit

Sonderzulassung nach §11 Absatz 1 MPG von Antigen-Tests zur Eigenanwendung durch Laien (Selbsttests) **5640-S-058/21**

99,52%* Genauigkeit

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CE

Studie 4：Gesamt Bewertung & Überblick

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		PCR Ergebnis		
		Positiv	Negativ	Gesamt
Schnelltest COVID-19 Antigen (kolloidales Gold) Ergebnis	Positiv	1087(a)	0(b)	1087(a+b)
	Negativ	9(c)	793(d)	793(c+d)
	Gesamt	1096(a+c)	793(b+d)	1889(a+b+c+d)

Koinzidenzrate und 95 % Konfidenzintervall

	Koinzidenzrate	95 % Konfidenzintervall
Klinische Sensitivität	99,18%	98,45%~99,62%
Klinische Spezifizität	100%	99,54%~100%
Gesamt Koinzidenzrate	99,52%	99,10%~99,78%

2. Nachweisgrenze (NG)

Die Nachweisgrenze für den COVID-19-Antigen-Schnelltest (kolloidales Gold) lag bei 4,25 x10^2 TCID50/ml. Die Nachweisgrenze wurde mit limitierenden Verdünnungen des hitzeinaktivierten SARS-CoV-2-Antigens ermittelt.

3. Kreuzreaktivität

Der COVID-19-Antigen-Schnelltest (Kolloidales Gold) kreuzt sich nicht mit den folgenden verbreiteten Atemwegserregern.

S.N.	Potenzieller Kreuzreaktant	Arten	Getestete Konzentration
1	H1N1(2009)	A-H1N1-2009	10^6pfu/mL
2	Saisonales H1N1-Influenzavirus	A-H1N1	10^6pfu/mL
3	H3N2-Influenzavirus	A-H3N2	10^6pfu/mL
4	Aviäres Influenza-H5N1-Virus	A-H5N1	10^6pfu/mL
5	Aviäres Influenza-H7N9-Virus	A-H7N9	10^6pfu/mL
6	Influenza-B-Yamagata	B-Yamagata	10^6pfu/mL
7	Influenza-B-Victoria	B-Victoria	10^6pfu/mL
8	Respiratorisches Synzytialvirus Typ A	RSV-A2	10^6pfu/mL
9	Respiratorisches Synzytialvirus Typ B	RSV-B	10^6pfu/mL
10	Enterovirus A	CV-A10	10^6pfu/mL
11	Enterovirus B	Echovirus 6	10^6pfu/mL
12	Enterovirus C	CV-A21	10^6pfu/mL
13	Enterovirus D	EV-D68	10^6pfu/mL
14	Parainfluenza-Virus Typ 1	HPIVs-1	10^6pfu/mL
15	Parainfluenza-Virus Typ 2	HPIVs-2	10^6pfu/mL
16	Parainfluenza-Virus Typ 3	HPIVs-3 VR-93	10^6pfu/mL
17	Rhinovirus A	HRV-9 VR-489	10^6pfu/mL
18	Rhinovirus B	HRV-52 VR-1162 HRV-3	10^6pfu/mL
19	Rhinovirus C	HRV-16 VR-283	10^6pfu/mL
20	Adenovirus Typ 1	HAdV-1 VR-1	10^6pfu/mL
21	Adenovirus Typ 2	HAdV-2 VR-846	10^6pfu/mL
22	Adenovirus Typ 3	HAdV-3	10^6pfu/mL
23	Adenovirus Typ 4	HAdV-4 VR-1572	10^6pfu/mL
24	Adenovirus Typ 5	HAdV-5 VR-1578/1516	10^6pfu/mL
25	Adenovirus Typ 7	HAdV-7 VR-7	10^6pfu/mL
26	Adenovirus Typ 55	HAdV-55	10^6pfu/mL
27	Menschliches Metapneumovirus	HMPV	10^6pfu/mL
28	Epstein-Barr-Virus	HHV-4 VR-1492	10^6pfu/mL
29	Masern-Virus	MV VR-24	10^6pfu/mL
30	Menschliches Zytomegalie-Virus	HHV-5 VR-977	10^6pfu/mL
31	Rotavirus	RV VR-2018	10^6pfu/mL

32	Norovirus	NOR	10^6pfu/mL
33	Mumps-Virus	MuV VR-106	10^6pfu/mL
34	Varizella-Zoster-Virus	VZV VR-1367	10^6pfu/mL
35	Legionellen	33152	10^7cfu/mL
36	Bordetella pertussis	BAA-589	10^7cfu/mL
37	Haemophilus influenzae	Hib	10^7cfu/mL
38	Staphylococcus aureus	CGMCC 1.2910	10^7cfu/mL
39	Streptococcus pneumoniae	CGMCC 1.8722	10^7cfu/mL
40	Streptococcus pyogenes	CGMCC 1.8868	10^7cfu/mL
41	Klebsiella pneumoniae	CGMCC 1.1736	10^7cfu/mL
42	Mycobacterium tuberculosis	25177	10^7cfu/mL
43	Mycoplasma pneumoniae	39505	10^7cfu/mL
44	Chlamydia pneumoniae	VR-2282	10^7cfu/mL
45	Aspergillus fumigatus	AF293	10^7cfu/mL
46	Candida albicans	SC5314	10^7cfu/mL
47	Candida glabrata	ATCC 2001	10^7cfu/mL
48	Cryptococcus neoformans	H99	10^7cfu/mL
49	Cryptococcus gutii	R265	10^7cfu/mL
50	Pneumocystis jirovecii (PJP)	CGMCC 1.9054	10^7cfu/mL
51	Coronavirus 229E	VR-740	10^6pfu/mL
52	Coronavirus OC43	VR-1558	10^6pfu/mL
53	Coronavirus NL63	COV-NL63	10^6pfu/mL
54	Coronavirus HKU1	COV-HKU1	10^6pfu/mL
55	Coronavirus MERS	MERS	10^8TU/mL
56	Coronavirus SARS	SARS	10^8TU/mL
57	Gepoolte menschliche Nasenspülung	/	10^7cfu/mL

4. Störsubstanzen / Interferenzen

Die folgenden potenziell Störsubstanzen haben keine Auswirkung auf den COVID-19-Antigen-Schnelltest (Kolloidales Gold). Die letzten Testkonzentrationen der Störsubstanzen sind in der nachstehenden Tabelle dokumentiert.

S.N.	Substanzname	Konzentration
1	Vollblut	4%(v/v)
2	Mucin	0.5%(v/v)
3	Ricola (Menthol)	1.5mg/mL
4	Sucrets (Dyclonin)	1.5mg/mL
5	Sucrets (Menthol)	1.5mg/mL
6	Chloraseptikum (Menthol)	1.5mg/mL
7	Chloraseptikum (Benzocain)	1.5mg/mL
8	Naso GEL (NeilMed)	5%(v/v)
9	CVS Nasentropfen (Phenylephrin)	15%(v/v)
10	Afrin (Oxymetazolin)	15%(v/v)
11	CVS Nasenspray (Cromolyn)	15%(v/v)
12	Nasengel (Oxymetazolin)	10%(v/v)
13	Zicam	5%(v/v)
14	Homöopathie (Alkalol)	1:10
15	Freund des Fischers	1.5mg/mL
16	Phenol-Spray gegen Halsschmerzen	15%(v/v)
17	Tobramycin	4μg/mL
18	Mupirocin	10mg/mL
19	Fluticason-Propionat	5%(v/v)
20	Tamiflu (Oseltamivirphosphat)	5mg/mL

5. Hook-Effekt

Die Konzentration beträgt 3,40 x 10^5 $TCID_{50}$/mL, die Testergebnisse sind alle positiv, und es gibt keinen nachweisbaren Hook-Effekt.

【Vorsichtsmaßnahmen】

1. Für die Verwendung in der In-vitro-Diagnostik.
2. Dieser Test wurde nur zum Nachweis von Proteinen aus SARS-CoV-2 zugelassen, nicht für andere Viren oder Krankheitserreger.
3. Verwenden Sie dieses Kit nicht über das auf dem Außenkarton angegebene Verfallsdatum hinaus.
4. Verwenden Sie das Kit nicht zur Bewertung von Patientenproben, wenn entweder der Positivkontrollabstrich oder der Negativkontrollabstrich nicht die erwarteten Ergebnisse liefert.
5. Die Testergebnisse sollen visuell bestimmt werden.
6. Um fehlerhafte Ergebnisse zu vermeiden, müssen die Proben wie im Abschnitt zum Testverfahren angegeben verarbeitet werden.
7. Verwenden Sie keine Kit-Komponenten wieder.
8. Die ordnungsgemäße Entnahme, Lagerung und der ordnungsgemäße Transport der Proben sind für die Durchführung dieses Tests von entscheidender Bedeutung.

9. Eine spezielle Schulung oder Anleitung wird empfohlen, wenn der Bediener keine Erfahrung mit Probenentnahme und Handhabung hat. Tragen Sie beim Sammeln und Bewerten von Proben Schutzkleidung wie Labormantel, Einweghandschuhe und Augenschutz. Pathogene Mikroorganismen, einschließlich Hepatitis-Viren und Human Immuno-Deficiency Virus (HIV), können in klinischen Proben vorhanden sein. Bei der Handhabung, Lagerung und Entsorgung aller Proben und aller mit Blut oder anderen Körperflüssigkeiten kontaminierten Gegenstände sollten stets die üblichen Vorsichtsmaßnahmen und institutionellen Richtlinien befolgt werden.
10. Entsorgen Sie gebrauchte Testkits gemäß den Anforderungen von Bund, Ländern und Gemeinden als biologisch gefährliche Abfälle.

11. Weitere Informationen zu Gefahrensymbolen, Sicherheit, Handhabung und Entsorgung der Komponenten in diesem Kit finden Sie im Sicherheitsdatenblatt (SDB).
12. Tragen Sie beim Umgang mit dem Inhalt dieses Kits geeignete Schutzkleidung, Handschuhe und Augen- / Gesichtsschutz.

【Anleitung Version 】

Version: V4.1

Katalog- Nr.：A6061204

【Verzeichnis der CE-Zeichen】

IVD	In-Vitro-Diagnostikum, nicht schlucken		Nur einmal verwenden
	Verwendbar bis		Vor dem Verwenden Gebrauchsanleitung beachten
	Achtung, bitte Anweisungen im Anhang beachten		Hersteller
30°C 2°C	Temperaturgrenze	LOT	Chargennummer
EC REP	Zugelassener Vertreter der Europäischen Union		Produkt trocken lagern
	Vor Sonneneinstrahlung schützen		Nicht verwenden, wenn die Verpackung beschädigt ist
	Herstellungsdatum		Biologische Risiken
CE	Produkt entspricht der EU- Richtlinie 98/79/EG für In- Vitro-Diagnostika		

CE IVD

【Hersteller】

Anbio (Xiamen) Biotechnology Co.,Ltd.
Adresse: No.2016, Wengjiao West Road, Xinyang Street, Haicang District, Xiamen, Fujian, China.
Tel.:+86-592-6312399, E-Mail:info@anbio.com

EC REP Lotus NL B.V.
Adresse: Koningin Julianaplein 10, 1e Verd,2595AA, Den Haag, Niederlande
Email: peter@lotusnl.com

【Importeur / Distributor】

AMEYA GmbH, Gregor Mendel Strasse 46, 1190 Wien, Austria
Email: office@ameya.at
Tel. +43 1 523 3000 01

CE IVD

02.03.2021

Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests

Ziel

Vergleich verschiedener Antigenschnelltests mit identischem Probenmaterial

Material

Pools von naso- und oropharyngealen Abstrichen.

Trockene Tupfer wurden in PBS aufgenommen, feuchte Tupfer waren bereits in Transportmedium unterschiedlicher Zusammensetzung. Pools sind zufällige Mischungen aus bis zu 10 Proben vergleichbarer CT Werte, die 1:10 in negativen Proben in PBS verdünnt wurden. Die CT Werte eines Pools wurden mit verschiedenen PCR Assays bestimmt und die mutmassliche Anzahl an RNA-Kopien mit Hilfe des INSTAND Standards berechnet. Bei den verwendeten PCRs entspricht ein CT Wert von 25 etwa 10^6 RNA Kopien / mL. Es wurden jeweils 18 Proben mit CT<25, 23 Proben mit CT zwischen 25 und 30 und 9 Proben mit CT>30 analysiert. Vermehrung des Virus in Zellkultur wurde als mögliches Korrelat für Infektiosität als weiteres Merkmal der Proben bestimmt.

Durchführung

Die Pools wurden aliquotiert, eingefroren, versendet, und zur Evaluierung der Tests aufgetaut. Für jeden Test wurden 50µL des Pools mit den vom Test bereitgestellten Komponenten z.B. Tupfer, analysiert. An der vergleichenden Evaluierung beteiligte Labors sind u. a. Robert Koch-Institut, Paul-Ehrlich-Institut, Konsiliarlabor für Coronaviren (Charité), Institut für Mikrobiologie der Bundeswehr.

Zusammenfassung

Diese vergleichende Evaluierung einer großen Anzahl von SARS-CoV-2 Antigenschnelltests (point of care tests; POCT) verschiedenen Designs und verschiedener Hersteller mit demselben Probenset ermöglicht einen Überblick über den derzeitigen Stand der Technik hinsichtlich ihrer Sensitivität. Die Ergebnisse lassen keine Rückschlüsse auf die Spezifität der Tests zu.

Diejenigen POCT, die bislang in die vergleichende Evaluierung eingegangen sind und hier als dem derzeitigen Stand der Technik entsprechend bewertet wurden, sind in der folgenden Tabelle aufgeführt. Weitere Tests, die als nicht dem Stand der Technik entsprechend bewertet wurden, wurden aus der Liste des BfArM entfernt. Die Untersuchungen werden kontinuierlich fortgeführt, die Tabelle entsprechend ergänzt.

Es sei ausdrücklich darauf hingewiesen, dass diese vergleichende Evaluierung nur eine Stichprobe der beim BfArM gelisteten und somit erstattungsfähigen SARS-CoV-2 Antigenschnelltests berücksichtigen kann, und manche Tests bislang (noch) nicht berücksichtigt werden konnten, trotz entsprechendem Interesse seitens Herstellern / Vertreibern.

Kontakt:

E-Mail: sarscov2ivd@pei.de

Stand 02.03.2021

Übersicht SARS-CoV-2 Antigenschnelltests, die als „dem derzeitigen Stand der Technik entsprechend“ bewertet wurden

Testname	Hersteller (Vertrieb)
Panbio™COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	Abbott Rapid Diagnostics Jena GmbH
RIDA®QUICK SARS-CoV-2 Antigen	R-Biopharm AG
SARS-CoV-2 Rapid Antigen Test	SD BIOSENSOR (Roche Diagnostics GmbH)
NADAL® COVID-19 Ag Schnelltest	nal von minden gmbh
STANDARD™ F COVID-19 Ag FIA	SD BIOSENSOR
STANDARD™ Q COVID-19 Ag Test	SD BIOSENSOR
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX SWISS SA
MEDsan® SARS-CoV-2 Antigen Rapid Test	MEDsan GmbH
TestNOW® - COVID-19 Antigen	Affimedix
NowCheck® COVID-19 Ag Test	BIONOTE
Coronavirus Ag Rapid Test Cassette (Swab)	Zhejiang Orient Gene Biotech Co.,Ltd
Sofia SARS Antigen FIA	Quidel Corporation
COVID-19 Ag Test Kit	Guangdong Wesail Biotech Co., Ltd.
CLINITEST® Rapid COVID-19 Antigen Test	Siemens Healthineers
ESPLINE® SARS-CoV-2	Fujirebio Inc. (Mast Diagnostica GmbH)
BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson
GenBody COVID-19 Ag	IVC Pragen Healthcare
LumiraDx SARS-CoV-2 Ag Test	LumiraDX
Exdia COVID-19-Ag-Test	Precision Biosensor Inc. (Axon Lab AG)
SARS-CoV-2 Ag Rapid Test (FIA)	Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)
SARS-CoV-2 Antigen Schnelltest	Xiamen Boson Biotech Co., Ltd
COVID-19 Antigen Schnelltest (Colloidal Gold)	Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)
mö-screen Corona Antigen Test	Mölab GmbH
Rapid SARS-CoV-2 Antigen Test Card	MP Biomedicals Germany GmbH
Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)
AMP Rapid Test SARS-CoV-2 Ag	Ameda Labordiagnostik GmbH
Clungene COVID-19 Antigen Rapid Test	Hangzhou Clongene Biotech Co., Ltd.
DIA-COVID® COVID-19 Ag Rapid Test Kit	GenSure Biotech Inc.
SARS-CoV-2 Antigen Rapid Test Kit	Beijing Lepu Medical Technology Co., Ltd
Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	Qingdao Hightop Biotech Co., Ltd.
Rapid Covid-19 Antigen Test (Colloidal Gold)	Anbio (Xiamen) Biotechnology Co., Ltd
Safecare COVID-19 Ag Rapid Test Kit (Swab)	Safecare Biotech Hangzhou Co., Ltd.
QuickProfile Covid-19 Antigen Test Card	LumiQuick Diagnostics, Inc.

Testname	Hersteller (Vertrieb)
Covid 19 Antigen Schnelltest	BioRepair GmbH
Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Shenzhen Lvshiyuan Biotechnology Co., Ltd.
CAT Antigen Covid Rapid Test	Oncosem Onkolojik Sistemler San. Ve Tic. A.S.
ScheBo SARS-CoV-2 Quick Antigen	ScheBo Biotech AG
Nova Test SARS-CoV-2 Antigen Rapid Test Kit	Atlas Link Technology Co.,Ltd.
Toda Coronadiag Ag	Toda Pharma
Humasis COVID-19 Ag Test	Humasis Co., Ltd.
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)	Beijing Hotgen Biotech Co., Ltd.
COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	AmonMed (Xiamen) Biotechnology Co., Ltd.
Canea COVID-19 Antigen Schnelltest	Core Technology Co., Ltd.
fluorecare COVID-19 SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd
Testsealabs® Rapid Test Kit COVID-19 Antigen Test Cassette	Hangzhou Testsea Biotechnology Co., Ltd
Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	Hangzhou Lysun Biotechnology Co., Ltd.
Wizbiotech SARS-CoV-2 Antigen Rapid Test	Xiamen WIZ Biotech Co., Ltd.
SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	PerGrande BioTech Development Co., Ltd.
salocor SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal swab)	Salofa OY
Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Genrui Biotech Inc.
Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	Guangzhou Wondfo Biotech Co. Ltd
Aesku Rapid SARS-CoV-2 Rapid Test	Aesku Diagnostics GmbH
Rapid Response COVID-19 Rapid Test Device	BTNX, Inc. (Biotrend Chemikalien Gmbh)
Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	Azure Biotech Inc.
Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	Labnovation Technologies, Inc.
V-Chek SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)	SGA Mühendislik DAN. EG. Icve DIS.Ltd.STI
SGTi-flex COVI-19 Ag	Sugentech, Inc.
softec SARS COV-2 (Covid-19) Antigen Test Kit	Zet Medikal Tekstil Dis Ticaret Ltd. STI.
Genedia W Covid-19 Ag	Green Cross Medical Science Corp. (Weko Pharma GmbH)
COVID-19 (SARS CoV-2) Antigen Test Kit (Colloidal Gold)	Anhui Deepblue Medical Technology Co. , Ltd.
FREND™ COVID-19 Ag	NanoEntek Inc

Clinical Evaluation Report

Product name: Rapid COVID-19 Antigen Test (Colloidal Gold)

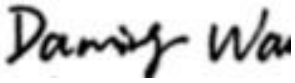
Company name: Anbio (Xiamen) Biotechnology Co., Ltd.

Duration of experiment: September 01, 2020 to February 05, 2021

Draft / Date： Xinhui Zheng / February 05, 2021

Reviewed By / Date: Jieli Zhang / February 05, 2021

Approved By / Date： Daming Wang / February 05, 2021

Signature: 

Sign on: February 05, 2021

Place: Xiamen, China

Contents

1. Objective

Anbio (Xiamen) Biotechnology Co., Ltd. intends to introduce Rapid COVID-19 Antigen Test (Colloidal Gold) into the market. The objective of this study was designed to evaluate the user performance of COVID-19 Antigen Colloidal Gold Test.
The test results of samples from clinical cases were compared with RT-PCR results of cases to verify the clinical performance of the test reagent.

2. Background information for clinical evaluation

The novel coronaviruses belong to the β genus of Coronaviridae. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.
Results are for the identification of SARS-CoV-2 nucleocapsid antigen. The antigen is generally detectable in upper respiratory samples or lower respiratory samples during the acute phase of infection. The positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. The positive results do not rule out bacterial infection or co-infection with other viruses. The antigen detected may not be the definite cause of disease. The negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2 and confirmed with a molecular assay, if necessary, for patient management.

3. Materials and Equipment

(1) Rapid COVID-19 Antigen Test (Colloidal Gold)
Lot: #2020086131 (A1), #2020086132 (A2), #2020086133 (A3)
Manufacturer: Anbio (Xiamen) Biotechnology Co., Ltd.
(2) Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV
Lot: #S1572054
Manufacturer: BGI Genomics Co, Ltd.
(3) Real time fluorescence quantitative PCR
Type: ABI 7500
Manufacturer: Applied Biosystems
(4) Clinical specimens

4. Evaluation Sites

(1) POC in Guangzhou, China
(2) POC in Xiamen, China
(3) POC in Beijing, China

The above POC sites are the designated laboratory for COVID-19 testing, and each POC site is operated by 3 - 5 professionals.

5. Number of clinical specimens

Tab1a Number of clinical specimens

Group	RT-PCR result (nasopharyngeal swab)	Sample type	Number	Collection Day
1	Positive	Nasal swab	*At least 100 cases*	2020/9/1 to 2021/2/3
		Throat swab	*At least 100 cases*	
		Saliva	*At least 100 cases*	
2	Negative	Nasal swab	*At least 100 cases*	2020/9/1 to 2021/2/3
		Throat swab	*At least 100 cases*	
		Saliva	*At least 100 cases*	

6. Criteria for Participant

(1) Gender: Male or female.
(2) Age: No restriction, neonates are excluded.
(3) Days from Symptom Onset

Days from Symptom Onset	0-3 days	4-7 days	＞7 days
Percentage	40%	40%	20%

(4) Mild patients: Minor respiratory symptoms, no fever and there is no pneumonia in imaging.
Moderate patients: Respiratory symptoms, Fever and pneumonia can be seen on imaging.
Severe patients: Breathless, RR≥30 times/min, or Finger oxygen saturation≤93% when inhaling air in resting state, or PaO_2/FiO^2≤300mmHg, or Lung imaging showed that the lesions progressed significantly by 50% within 24-48 hours.
Critically ill patients: Respiratory failure occurs and requires mechanical ventilation, or shock, or combined occurrence of other organ failure requires ICU monitoring and treatment.
(5) Test within 48 hours after sample collection.

7. Clinical specimens' storage

(1) Applicable clinical specimen's type: Throat swab specimen, nasal swab specimen, saliva specimen
(2) Storage: Samples should be tested as soon as possible after collection. Processed samples (add Extraction Solution) are stable for up to 24 hours at room temperature or 2°C to 8°C and cannot be frozen.
(3) The specimens must be balanced to room temperature before testing.

8. Operation

8.1 Limit of Detection (LoD)

(1) LOD of human throat swab specimen matrix
The LOD for the Rapid COVID-19 Antigen Test for rapid detection of SARS-CoV-2 was established using limiting dilutions of heat-inactivated SARS-CoV-2 virus. The material was supplied frozen at a

concentration of $3.40x10^5$ $TCID_{50}$/mL.

In this study, designed to estimate the LOD of the assay when using a direct throat swab, the starting material was spiked into a volume of pooled human throat swab obtained from healthy donors and confirmed negative for SARS-CoV-2. An initial range finding study was performed testing devices in triplicate using a 10-fold dilution series of 3 replicates per concentration. At each dilution, 50 µL samples were added to swabs and then tested in the assay using the procedure appropriate for patient throat swab specimens. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LOD was further refined with a 2-fold dilution series of 3 replicates per concentration.

Choose 3 concentrations (negative, LOD, 2 LOD) repeat the test for each concentration 20 times. Calculate the positive rate, the lowest concentration where the positive rate is greater than or equal to 95% is LOD.

This study included the use of three different lots of the Rapid COVID-19 Antigen Test.

(2) LOD of human nasal swab specimen matrix

The LOD for the Rapid COVID-19 Antigen Test for rapid detection of SARS-CoV-2 was established using limiting dilutions of heat-inactivated SARS-CoV-2 virus. The material was supplied frozen at a concentration of $3.40x10^5$ $TCID_{50}$/mL.

In this study, designed to estimate the LOD of the assay when using a direct nasal swab, the starting material was spiked into a volume of pooled human nasal swab obtained from healthy donors and confirmed negative for SARS-CoV-2. An initial range finding study was performed testing devices in triplicate using a 10-fold dilution series of 3 replicates per concentration. At each dilution, 50 µL samples were added to swabs and then tested in the assay using the procedure appropriate for patient nasal swab specimens. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LOD was further refined with a 2-fold dilution series of 3 replicates per concentration.

Choose 3 concentrations (negative, LOD, 2 LOD) repeat the test for each concentration 20 times. Calculate the positive rate, the lowest concentration where the positive rate is greater than or equal to 95% is LOD.

This study included the use of three different lots of the Rapid COVID-19 Antigen Test.

(3) LOD of human saliva specimen matrix

The LOD for the Rapid COVID-19 Antigen Test for rapid detection of SARS-CoV-2 was established using limiting dilutions of heat-inactivated SARS-CoV-2 virus. The material was supplied frozen at a concentration of $3.40x10^5$ $TCID_{50}$/mL.

In this study, designed to estimate the LOD of the assay when using a direct saliva, the starting material was spiked into a volume of pooled human saliva obtained from healthy donors and confirmed negative for SARS-CoV-2. An initial range finding study was performed testing devices in triplicate using a 10-fold dilution series of 3 replicates per concentration. At each dilution, 50 µL samples were added to swabs and then tested in the assay using the procedure appropriate for patient nasal swab specimens. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LOD was further refined with a 2-fold dilution series of 3 replicates per concentration.

Choose 3 concentrations (negative, LOD, 2 LOD) repeat the test for each concentration 20 times. Calculate the positive rate, the lowest concentration where the positive rate is greater than or equal to 95% is LOD.

This study included the use of three different lots of the Rapid COVID-19 Antigen Test.

(4) Clinical sample verification

Test clinically confirmed population samples to determine the $TCID_{50}$ of each sample. Select 30 samples with concentration between 2.215 $x10^2$ $TCID_{50}$/mL and 4.24 $x10^2$ $TCID_{50}$/mL, select 30 samples with concentration between 4.25 $x10^2$ $TCID_{50}$/mL and 8.5 $x10^2$ $TCID_{50}$/mL for testing.

8.2 Cross-Reactivity

8.2.1 Cross reactivity sample preparation

(1) Preparation of throat swab samples(negative): In a certain amount of pooled human throat swabs obtained from healthy donors and confirmed negative for SARS-CoV-2, add interfering substances (according to the final concentration in Table 1).

(2) Preparation of throat swab samples (positive): a certain amount of pooled human throat swabs obtained from donors and confirm that the SARS-CoV-2 concentrations are 3 LOD and 1.5 LOD, add interfering substances (according to the final concentration in Table 1).

(3) Preparation of nasal swab samples (negative): In a certain amount of pooled human nasal swabs obtained from healthy donors and confirmed negative for SARS-CoV-2, add interfering substances (according to the final concentration in Table 1).

(4) Preparation of nasal swab samples (positive): a certain amount of pooled human nasal swabs obtained from donors and confirm that the SARS-CoV-2 concentrations are 3 LOD and 1.5 LOD, add interfering substances (according to the final concentration in Table 1).

(5) Preparation of saliva samples (negative): In a certain amount of pooled human saliva obtained from healthy donors and confirmed negative for SARS-CoV-2, add interfering substances (according to the final concentration in Table 1).

(6) Preparation of saliva samples(positive): a certain amount of pooled human saliva obtained from donors and confirm that the SARS-CoV-2 concentrations are 3 LOD and 1.5 LOD, add interfering substances (according to the final concentration in Table 1).

8.2.2 Test clinical specimens with three lots of Rapid COVID-19 Antigen Test (Colloidal Gold) according to the Instruction for Use. Each sample was tested 3 times per batch. Record the results respectively. Positive signals are recorded as “+” and negative signals are recorded as “-”.

8.2.3 Check if there were “-” for C line, which indicates invalid test results. If any invalid test were observed, the invalid results should be abandoned, and the specimen should be tested again. If the second test of the specimen were still invalid, the specimen should be abandoned from the experiment.

8.2.4 Check if there was “+” for T line, which indicates a positive result. Otherwise it is a negative result. Count and record the number of positive result(s) (Np) and negative result(s) (Nn).

8.2.5 Calculate the ratio of negative results versus total tests (Nn%) with formula Nn%= Nn/(Np+Nn)*100%; calculate the ratio of negative results versus total tests (Np%) with formula Np%= Np/(Np+Nn)*100%.

8.2.6 Information about Cross Reactivity of potential reactants

Tab1 List of cross reactivity species

S.N.	Potential cross-reactant	Species	Concentration tested
1	H1N1(2009)	A-H1N1-2009	10^6pfu/mL
2	Seasonal H1N1 influenza virus	A-H1N1	10^6pfu/mL
3	H3N2 influenza virus	A-H3N2	10^6pfu/mL
4	H5N1 avian influenza virus	A-H5N1	10^6pfu/mL
5	H7N9 avian influenza virus	A-H7N9	10^6pfu/mL
6	Influenza B Yamagata	B-Yamagata	10^6pfu/mL
7	Influenza B Victoria	B-Victoria	10^6pfu/mL
8	Respiratory syncytial virus type A	RSV-A2	10^6pfu/mL
9	Respiratory syncytial virus type B	RSV-B	10^6pfu/mL
10	Enterovirus A	CV-A10	10^6pfu/mL
11	Enterovirus B	Echovirus 6	10^6pfu/mL
12	Enterovirus C	CV-A21	10^6pfu/mL
13	Enterovirus D	EV-D68	10^6pfu/mL
14	Parainfluenza virus type 1	HPIVs-1	10^6pfu/mL
15	Parainfluenza virus type 2	HPIVs-2	10^6pfu/mL
16	Parainfluenza virus type 3	HPIVs-3 VR-93	10^6pfu/mL
17	Rhinovirus A	HRV-9 VR-489	10^6pfu/mL
18	Rhinovirus B	HRV-52 VR-1162 HRV-3 VR-1113	10^6pfu/mL
19	Rhinovirus C	HRV-16 VR-283	10^6pfu/mL
20	Adenovirus type 1	HAdV-1 VR-1	10^6pfu/mL
21	Adenovirus type 2	HAdV-2 VR-846	10^6pfu/mL
22	Adenovirus type 3	HAdV-3	10^6pfu/mL
23	Adenovirus type 4	HAdV-4 VR-1572	10^6pfu/mL
24	Adenovirus type 5	HAdV-5 VR-1578/1516	10^6pfu/mL

25	Adenovirus type 7	HAdV-7 VR-7	10^6pfu/mL
26	Adenovirus type 55	HAdV-55	10^6pfu/mL
27	Human metapneumovirus	HMPV	10^6pfu/mL
28	Epstein-Barr virus	HHV-4 VR-1492	10^6pfu/mL
29	Measles virus	MV VR-24	10^6pfu/mL
30	Human cytomegalovirus	HHV-5 VR-977	10^6pfu/mL
31	Rotavirus	RV VR-2018	10^6pfu/mL
32	Norovirus	NOR	10^6pfu/mL
33	Mumps virus	MuV VR-106	10^6pfu/mL
34	Varicella-zoster virus	VZV VR-1367	10^6pfu/mL
35	Legionella	33152	10^7cfu/mL
36	Bordetella pertussis	BAA-589	10^7cfu/mL
37	Haemophilus influenzae	Hib	10^7cfu/mL
38	Staphylococcus aureus	CGMCC 1.2910	10^7cfu/mL
39	Streptococcus pneumoniae	CGMCC 1.8722	10^7cfu/mL
40	Streptococcus pyogenes	CGMCC 1.8868	10^7cfu/mL
41	Klebsiella pneumoniae	CGMCC 1.1736	10^7cfu/mL
42	Mycobacterium tuberculosis	25177	10^7cfu/mL
43	Mycoplasma pneumoniae	39505	10^7cfu/mL
44	Chlamydia pneumoniae	VR-2282	10^7cfu/mL
45	Aspergillus fumigatus	AF293	10^7cfu/mL
46	Candida albicans	SC5314	10^7cfu/mL
47	Candida glabrata	ATCC 2001	10^7cfu/mL
48	Cryptococcus neoformans	H99	10^7cfu/mL
49	Cryptococcus gutii	R265	10^7cfu/mL
50	Pneumocystis jirovecii (PJP)	CGMCC 1.9054	10^7cfu/mL
51	Coronavirus229E	VR-740	10^6pfu/mL
52	CoronavirusOC43	VR-1558	10^6pfu/mL
53	CoronavirusNL63	COV-NL63	10^6pfu/mL
54	Coronavirus HKU1	COV-HKU1	10^6pfu/mL

55	Coronavirus MERS	MERS	10^8TU/mL
56	Coronavirus SARS	SARS	10^8TU/mL
57	Pooled human nasal wash	/	10^7cfu/mL

8.3 Interference Substances Study

8.3.1 Interference sample preparation

(1) Preparation of throat swab samples（negative): In a certain amount of pooled human throat swabs obtained from healthy donors and confirmed negative for SARS-CoV-2, add interfering substances (according to the final concentration in Table 2).

(2) Preparation of nasal swab samples（negative): In a certain amount of pooled human nasal swabs obtained from healthy donors and confirmed negative for SARS-CoV-2, add interfering substances (according to the final concentration in Table 2).

(3) Preparation of saliva samples（negative): In a certain amount of pooled human saliva obtained from healthy donors and confirmed negative for SARS-CoV-2, add interfering substances (according to the final concentration in Table 2).

(4) Preparation of throat swab samples (positive): a certain amount of pooled human throat swabs obtained from donors and confirm that the SARS-CoV-2 concentration is 3 LOD, add interfering substances (according to the final concentration in Table 2).

(5) Preparation of nasal swab samples (positive): a certain amount of pooled human nasal swabs obtained from donors and confirm that the SARS-CoV-2 concentration is 3 LOD, add interfering substances (according to the final concentration in Table 2).

(6) Preparation of saliva samples (positive): a certain amount of pooled human saliva obtained from donors and confirm that the SARS-CoV-2 concentration is 3 LOD, add interfering substances (according to the final concentration in Table 2).

8.3.2 Test the interference samples with three lots of Rapid COVID-19 Antigen Test (Colloidal Gold) according to the Instruction for Use. Each sample was tested 5 times per batch. Record the results respectively. Positive signals are recorded as “+” and negative signals are recorded as “-”.

8.3.3 Check if there were “-” for C line, which indicates invalid test results (Ri). Count the total number of Ri.

8.3.4 Check if there were “+” for T line while testing negative samples. Any “+” should be regard as false positive (Fp). Count the total number of Fp. Check if there were “-” for T line while testing positive samples. Any “-” should be regard as false negative (Fn). Count the total number of Fn.

8.4 Clinical Trials

(1) Specimens collection and information record

The main researchers of the clinical institutions designate special personnel to select the eligible cases according to the enrollment criteria, and collect the clinical information of the enrolled specimens, including: age, gender, clinical symptoms, clinical classification(mild or moderate), sample collection time and other information. The specimens are numbered according to the sequence before and after grouping, i.e. Specimens number.

(2) Specimens blinding

The main researchers of the clinical institution designated the person to randomly number the specimens in the group with the random number generating tool, record the random number of the specimens and the corresponding specimens number, and the person arranged the specimens

according to the sequence of the random number, and handed them to the test operator for testing according to this sequence, noting that the person and the test operator cannot be the same person.

(3) Testing

The test operator shall test the specimens and operate according to the instructions. RT-PCR test is used for in-vitro qualitative detection of novel coronavirus (2019-nCoV) ORF1ab, N gene and E gene in nasopharyngeal swab, oropharyngeal swab, sputum, and alveolar lavage fluid samples.

(4) Unblinding

At the end of the test, according to the corresponding relationship between random number and specimens' number, record the test results.

(5) Result determination

The test results should be statistically analyzed with clinical diagnosis to evaluate the clinical application performance of the product.

9. Control method

(1) Before the start of clinical research, the enterprise shall train the researchers to make them familiar with and master the operation method and technical performance of the product, to minimize the test error.

(2) Researchers should strictly follow the product's operation specifications and related requirements for testing to ensure that the testing error can be minimized.

(3) The supervisors shall check the relevant activities and documents of the clinical trial, whether the trial is conducted in accordance with the test scheme, standard operating procedures and relevant regulations, and whether the test data is recorded in a timely, clear, accurate and complete manner.

10. Data management

(1) Traceability of data, filling, and transfer of case report form

Ensure the traceability of clinical trial data. According to the original observation records of the subjects, the researchers recorded the data in the case report form in a timely, complete, accurate and clear manner. The supervisor shall monitor whether the trial is carried out in accordance with the plan, confirm that the case report form is filled in correctly and completely, and is consistent with the original data. In case of any mistake or omission, the researcher shall be required to correct it in time. The original record shall be kept clear and visible during modification, and the correction shall be signed and dated by the researcher.

(2) Data entry and modification

To ensure the accuracy of data, two data entry personnel are responsible for independent entry and proofreading. During the data analysis, for the questions in the case report form, the researcher should answer and return them as soon as possible, and the statistician should modify, confirm, and input them according to the researcher's answers.

(3) Lock of database

At the end of the test, after data entry, the researcher and the sponsor check the data, and lock the data after confirming that the data set is correct, and then lock the data for statistical analysis.

11. Results and Statistical Analysis

11.1 Results for Limit of Detection (LoD)

(1) LOD of human throat swab specimen matrix

Tab2 Results of 10-fold dilution series

	$TCID_{50}$	A1			A2			A3		
1	$3.40x10^5$/mL	+	+	+	+	+	+	+	+	+
2	$3.40x10^4$/mL	+	+	+	+	+	+	+	+	+
3	$3.40x10^3$/mL	+	+	+	+	+	+	+	+	+
4	$3.40x10^2$/mL	-	+	-	-	-	-	-	+	-
5	3.40x10/mL	-	-	-	-	-	-	-	-	-
6	3.40/mL	-	-	-	-	-	-	-	-	-

Tab3 Results of 2-fold dilution series

	$TCID_{50}$	A1			A2			A3		
1	$3.40x10^3$/mL	+	+	+	+	+	+	+	+	+
2	$1.70x10^3$/mL	+	+	+	+	+	+	+	+	+
3	$8.5x10^2$/mL	+	+	+	+	+	+	+	+	+
4	$4.25x10^2$/mL	+	+	+	+	+	+	+	+	+
5	$3.40x10^2$/mL	-	-	+	-	+	-	-	-	-
6	$2.125x10^2$/mL	-	-	-	-	-	-	-	-	-

Tab4 Repeat test results

	$8.5x10^2$ $TCID_{50}$/mL			$4.25x10^2$ $TCID_{50}$/mL			$3.40x10^2$ $TCID_{50}$/mL		
	A1	A2	A3	A1	A2	A3	A1	A2	A3
1	+	+	+	+	+	+	-	-	-
2	+	+	+	+	+	+	-	-	-
3	+	+	+	+	+	+	-	-	-
4	+	+	+	+	+	+	-	-	-
5	+	+	+	+	+	+	-	-	-
6	+	+	+	+	+	+	-	-	-
7	+	+	+	+	+	+	-	-	-
8	+	+	+	+	+	+	-	-	-
9	+	+	+	+	+	+	-	-	-
10	+	+	+	+	+	+	+	-	-
11	+	+	+	+	+	+	-	+	-
12	+	+	+	+	+	+	-	-	-
13	+	+	+	+	+	+	-	-	-
14	+	+	+	+	+	+	-	-	-
15	+	+	+	+	+	+	-	-	-
16	+	+	+	+	+	+	+	-	-
17	+	+	+	+	+	+	-	-	-
18	+	+	+	+	+	+	-	-	-
19	+	+	+	+	+	+	-	-	-
20	+	+	+	+	+	+	-	-	-
Positive rate	100% (60/60)			100% (60/60)			5% (3/60)		

(2) LOD of human nasal swab specimen matrix

Tab5 Results of 10-fold dilution series

	$TCID_{50}$	A1			A2			A3		
1	$3.40x10^5$/mL	+	+	+	+	+	+	+	+	+
2	$3.40x10^4$/mL	+	+	+	+	+	+	+	+	+
3	$3.40x10^3$/mL	+	+	+	+	+	+	+	+	+
4	$3.40x10^2$/mL	-	-	-	+	-	-	-	-	-
5	3.40x10/mL	-	-	-	-	-	-	-	-	-
6	3.40/mL	-	-	-	-	-	-	-	-	-

Tab6 Results of 2-fold dilution series

	$TCID_{50}$	A1			A2			A3		
1	$3.40x10^3$/mL	+	+	+	+	+	+	+	+	+
2	$1.70x10^3$/mL	+	+	+	+	+	+	+	+	+
3	$8.5x10^2$/mL	+	+	+	+	+	+	+	+	+
4	$4.25x10^2$/mL	+	+	+	+	+	+	+	+	+
5	$3.40x10^2$/mL	-	-	-	-	-	+	+	-	-
6	$2.125x10^2$/mL	-	-	-	-	-	-	-	-	-

Tab7 Repeat test results for LOD

	$8.5x10^2$ $TCID_{50}$/mL			$4.25x10^2$ $TCID_{50}$/mL			$3.40x10^2$ $TCID_{50}$/mL		
	A1	A2	A3	A1	A2	A3	A1	A2	A3
1	+	+	+	+	+	+	-	-	-
2	+	+	+	+	+	+	-	-	+
3	+	+	+	+	+	+	-	-	-
4	+	+	+	+	+	+	+	-	-
5	+	+	+	+	+	+	-	-	-
6	+	+	+	+	+	+	-	-	-
7	+	+	+	+	-	+	-	-	-
8	+	+	+	+	+	-	-	-	-
9	+	+	+	+	+	+	-	-	-
10	+	+	+	+	+	+	+	-	-
11	+	+	+	+	+	+	-	+	-
12	+	+	+	+	+	+	-	-	-
13	+	+	+	+	+	+	-	-	-
14	+	+	+	+	+	+	-	+	-
15	+	+	+	+	+	+	-	-	+
16	+	+	+	+	+	+	+	-	-
17	+	+	+	+	+	+	-	-	-
18	+	+	+	+	+	+	-	-	-
19	+	+	+	+	+	+	-	-	-
20	+	+	+	+	+	+	-	-	-
Positive rate	100% (60/60)			96.7% (58/60)			11.67% (7/60)		

(3) LOD of human saliva specimen matrix

Tab8 Results of 10-fold dilution series

	$TCID_{50}$	A1			A2			A3		
1	$3.40x10^5$/mL	+	+	+	+	+	+	+	+	+
2	$3.40x10^4$/mL	+	+	+	+	+	+	+	+	+
3	$3.40x10^3$/mL	+	+	+	+	+	+	+	+	+
4	$3.40x10^2$/mL	-	+	-	-	-	-	-	+	-
5	3.40x10/mL	-	-	-	-	-	-	-	-	-
6	3.40/mL	-	-	-	-	-	-	-	-	-

Tab9 Results of 2-fold dilution series

	$TCID_{50}$	A1			A2			A3		
1	$3.40x10^3$/mL	+	+	+	+	+	+	+	+	+
2	$1.70x10^3$/mL	+	+	+	+	+	+	+	+	+
3	$8.5x10^2$/mL	+	+	+	+	+	+	+	+	+
4	$4.25x10^2$/mL	+	+	+	+	+	+	+	+	+
5	$3.40x10^2$/mL	-	-	+	-	+	-	-	-	-
6	$2.125x10^2$/mL	-	-	-	-	-	-	-	-	-

Tab10 Repeat test results for LOD

	$8.5x10^2$ $TCID_{50}$/mL			$4.25x10^2$ $TCID_{50}$/mL			$3.40x10^2$ $TCID_{50}$/mL		
	A1	A2	A3	A1	A2	A3	A1	A2	A3
1	+	+	+	+	+	+	-	-	-
2	+	+	+	+	+	+	-	-	-
3	+	+	+	+	+	+	-	-	-
4	+	+	+	+	+	+	-	-	-
5	+	+	+	+	+	+	-	-	-
6	+	+	+	+	+	+	-	-	-
7	+	+	+	+	-	+	-	-	-
8	+	+	+	+	+	-	-	-	-
9	+	+	+	+	+	+	-	-	-
10	+	+	+	+	+	+	+	-	-
11	+	+	+	+	+	+	-	+	-
12	+	+	+	+	+	+	-	-	-
13	+	+	+	+	+	+	-	-	-
14	+	+	+	+	+	+	-	-	-
15	+	+	+	+	+	+	-	-	-
16	+	+	+	+	+	+	+	-	-
17	+	+	+	+	+	+	-	-	-
18	+	+	+	+	+	+	-	-	-
19	+	+	+	+	+	+	-	-	-
20	+	+	+	+	+	+	-	-	-
Positive rate	100% (60/60)			96.7% (58/60)			5% (3/60)		

(4) Clinical sample verification

Tab11 Throat swab specimen ($2.215x10^2$ $TCID_{50}$/mL~$4.24x10^2$ $TCID_{50}$/mL) test results

Test	A1	A2	A3	Test	A1	A2	A3
1	-	-	-	16	-	-	-
2	-	-	-	17	-	-	-
3	-	-	-	18	-	-	-
4	-	-	-	19	-	-	-
5	-	-	-	20	-	-	-
6	-	-	-	21	-	-	-
7	-	-	-	22	-	-	-
8	-	-	-	23	-	-	-
9	-	-	-	24	-	-	-
10	-	-	-	25	-	-	-
11	-	-	-	26	-	-	-
12	-	-	-	27	-	-	-
13	-	-	-	28	-	-	-
14	-	-	-	29	-	-	-
15	-	-	-	30	-	-	-

Tab12 Throat swab specimen ($4.25x10^2$ $TCID_{50}$/mL~$8.5x10^2$ $TCID_{50}$/mL) test results

Test	A1	A2	A3	Test	A1	A2	A3
1	+	+	+	16	+	+	+
2	+	+	+	17	+	+	+
3	+	+	+	18	+	+	+
4	+	+	+	19	+	+	+
5	+	+	+	20	+	+	+
6	+	+	+	21	+	+	+
7	+	+	+	22	+	+	+
8	+	+	+	23	+	+	+
9	+	+	+	24	+	+	+
10	+	+	+	25	+	+	+
11	+	+	+	26	+	+	+
12	+	+	+	27	+	+	+
13	+	+	+	28	+	+	+
14	+	+	+	29	+	+	+
15	+	+	+	30	+	+	+

Tab13 Nasal swab specimen ($2.215x10^2$ $TCID_{50}$/mL~$4.24x10^2$ $TCID_{50}$/mL) test results

Test	A1	A2	A3	Test	A1	A2	A3
1	-	-	-	16	-	-	-
2	-	-	-	17	-	-	-
3	-	-	-	18	-	-	-
4	-	-	-	19	-	-	-
5	-	-	-	20	-	-	-
6	-	-	-	21	-	-	-
7	-	-	-	22	-	-	-

8	-	-	-	23	-	-	-
9	-	-	-	24	-	-	-
10	-	-	-	25	-	-	-
11	-	-	-	26	-	-	-
12	-	-	-	27	-	-	-
13	-	-	-	28	-	-	-
14	-	-	-	29	-	-	-
15	-	-	-	30	-	-	-

Tab14 Nasal swab specimen ($4.25x10^2$ $TCID_{50}$/mL~$8.5x10^2$ $TCID_{50}$/mL) test results

Test	A1	A2	A3	Test	A1	A2	A3
1	+	+	+	16	+	+	+
2	+	+	+	17	+	+	+
3	+	+	+	18	+	+	+
4	+	+	+	19	+	+	+
5	+	+	+	20	+	+	+
6	+	+	+	21	+	+	+
7	+	+	+	22	+	+	+
8	+	+	+	23	+	+	+
9	+	+	+	24	+	+	+
10	+	+	+	25	+	+	+
11	+	+	+	26	+	+	+
12	+	+	+	27	+	+	+
13	+	+	+	28	+	+	+
14	+	+	+	29	+	+	+
15	+	+	+	30	+	+	+

Tab15 Saliva specimen ($2.215x10^2$ $TCID_{50}$/mL~$4.24x10^2$ $TCID_{50}$/mL) test results

Test	A1	A2	A3	Test	A1	A2	A3
1	-	-	-	16	-	-	-
2	-	-	-	17	-	-	-
3	-	-	-	18	-	-	-
4	-	-	-	19	-	-	-
5	-	-	-	20	-	-	-
6	-	-	-	21	-	-	-
7	-	-	-	22	-	-	-
8	-	-	-	23	-	-	-
9	-	-	-	24	-	-	-
10	-	-	-	25	-	-	-
11	-	-	-	26	-	-	-
12	-	-	-	27	-	-	-
13	-	-	-	28	-	-	-
14	-	-	-	29	-	-	-
15	-	-	-	30	-	-	-

Tab16 Saliva specimen ($4.25x10^2$ $TCID_{50}$/mL~$8.5x10^2$ $TCID_{50}$/mL) test results

Test	A1	A2	A3	Test	A1	A2	A3
1	+	+	+	16	+	+	+
2	+	+	+	17	+	+	+
3	+	+	+	18	+	+	+
4	+	+	+	19	+	+	+
5	+	+	+	20	+	+	+
6	+	+	+	21	+	+	+
7	+	+	+	22	+	+	+
8	+	+	+	23	+	+	+
9	+	+	+	24	+	+	+
10	+	+	+	25	+	+	+
11	+	+	+	26	+	+	+
12	+	+	+	27	+	+	+
13	+	+	+	28	+	+	+
14	+	+	+	29	+	+	+
15	+	+	+	30	+	+	+

11.2 Results for Cross Reactivity Study

(1) Test results of throat swab specimens

Tab17 Test results of throat swab specimens with common respiratory infections

S.N.	A1			A2			A3		
1	-	-	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-
18	-	-	-	-	-	-	-	-	-
19	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-
21	-	-	-	-	-	-	-	-	-

22	-	-	-	-	-	-	-	-	-
23	-	-	-	-	-	-	-	-	-
24	-	-	-	-	-	-	-	-	-
25	-	-	-	-	-	-	-	-	-
26	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-	-	-
28	-	-	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	-	-
31	-	-	-	-	-	-	-	-	-
32	-	-	-	-	-	-	-	-	-
33	-	-	-	-	-	-	-	-	-
34	-	-	-	-	-	-	-	-	-
35	-	-	-	-	-	-	-	-	-
36	-	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-	-
38	-	-	-	-	-	-	-	-	-
39	-	-	-	-	-	-	-	-	-
40	-	-	-	-	-	-	-	-	-
41	-	-	-	-	-	-	-	-	-
42	-	-	-	-	-	-	-	-	-
43	-	-	-	-	-	-	-	-	-
44	-	-	-	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-	-
46	-	-	-	-	-	-	-	-	-
47	-	-	-	-	-	-	-	-	-
48	-	-	-	-	-	-	-	-	-
49	-	-	-	-	-	-	-	-	-
50	-	-	-	-	-	-	-	-	-
51	-	-	-	-	-	-	-	-	-
52	-	-	-	-	-	-	-	-	-
53	-	-	-	-	-	-	-	-	-
54	-	-	-	-	-	-	-	-	-
55	-	-	-	-	-	-	-	-	-
56	-	-	-	-	-	-	-	-	-
57	-	-	-	-	-	-	-	-	-

Tab18 Test Results of Nn% (throat swab)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	0	9	100%
Seasonal H1N1 influenza virus	9	0	9	100%
H3N2 influenza virus	9	0	9	100%
H5N1 avian influenza virus	9	0	9	100%
H7N9 avian influenza virus	9	0	9	100%

Influenza B Yamagata	9	0	9	100%
Influenza B Victoria	9	0	9	100%
Respiratory syncytial virus type A	9	0	9	100%
Respiratory syncytial virus type B	9	0	9	100%
Enterovirus A	9	0	9	100%
Enterovirus B	9	0	9	100%
Enterovirus C	9	0	9	100%
Enterovirus D	9	0	9	100%
Parainfluenza virus type 1	9	0	9	100%
Parainfluenza virus type 2	9	0	9	100%
Parainfluenza virus type 3	9	0	9	100%
Rhinovirus A	9	0	9	100%
Rhinovirus B	9	0	9	100%
Rhinovirus C	9	0	9	100%
Adenovirus type 1	9	0	9	100%
Adenovirus type 2	9	0	9	100%
Adenovirus type 3	9	0	9	100%
Adenovirus type 4	9	0	9	100%
Adenovirus type 5	9	0	9	100%
Adenovirus type 7	9	0	9	100%
Adenovirus type 55	9	0	9	100%
Human metapneumovirus	9	0	9	100%
Epstein-Barr virus	9	0	9	100%
Measles virus	9	0	9	100%
Human cytomegalovirus	9	0	9	100%
Rotavirus	9	0	9	100%
Norovirus	9	0	9	100%
Mumps virus	9	0	9	100%
Varicella-zoster virus	9	0	9	100%
Legionella	9	0	9	100%
Bordetella pertussis	9	0	9	100%
Haemophilus influenzae	9	0	9	100%
Staphylococcus aureus	9	0	9	100%
Streptococcus pneumoniae	9	0	9	100%
Streptococcus pyogenes	9	0	9	100%
Klebsiella pneumoniae	9	0	9	100%
Mycobacterium tuberculosis	9	0	9	100%
Mycoplasma pneumoniae	9	0	9	100%
Chlamydia pneumoniae	9	0	9	100%
Aspergillus fumigatus	9	0	9	100%
Candida albicans	9	0	9	100%

Candida glabrata	9	0	9	100%
Cryptococcus neoformans	9	0	9	100%
Cryptococcus gutii	9	0	9	100%
Pneumocystis jirovecii (PJP)	9	0	9	100%
Coronavirus229E	9	0	9	100%
CoronavirusOC43	9	0	9	100%
CoronavirusNL63	9	0	9	100%
Coronavirus HKU1	9	0	9	100%
Coronavirus MERS	9	0	9	100%
Coronavirus SARS	9	0	9	100%
Pooled human nasal wash	9	0	9	100%

Tab19 Test results of throat swab specimens (1.5 LOD)

S.N.	A1			A2			A3		
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+
18	+	+	+	+	+	+	+	+	+
19	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+
21	+	+	+	+	+	+	+	+	+
22	+	+	+	+	+	+	+	+	+
23	+	+	+	+	+	+	+	+	+
24	+	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+	+
26	+	+	+	+	+	+	+	+	+
27	+	+	+	+	+	+	+	+	+
28	+	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+
30	+	+	+	+	+	+	+	+	+

31	+	+	+	+	+	+	+	+	+
32	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	+
34	+	+	+	+	+	+	+	+	+
35	+	+	+	+	+	+	+	+	+
36	+	+	+	+	+	+	+	+	+
37	+	+	+	+	+	+	+	+	+
38	+	+	+	+	+	+	+	+	+
39	+	+	+	+	+	+	+	+	+
40	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+
42	+	+	+	+	+	+	+	+	+
43	+	+	+	+	+	+	+	+	+
44	+	+	+	+	+	+	+	+	+
45	+	+	+	+	+	+	+	+	+
46	+	+	+	+	+	+	+	+	+
47	+	+	+	+	+	+	+	+	+
48	+	+	+	+	+	+	+	+	+
49	+	+	+	+	+	+	+	+	+
50	+	+	+	+	+	+	+	+	+
51	+	+	+	+	+	+	+	+	+
52	+	+	+	+	+	+	+	+	+
53	+	+	+	+	+	+	+	+	+
54	+	+	+	+	+	+	+	+	+
55	+	+	+	+	+	+	+	+	+
56	+	+	+	+	+	+	+	+	+
57	+	+	+	+	+	+	+	+	+

Tab20 Test Results of Np% (1.5 LOD)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	9	0	100%
Seasonal H1N1 influenza virus	9	9	0	100%
H3N2 influenza virus	9	9	0	100%
H5N1 avian influenza virus	9	9	0	100%
H7N9 avian influenza virus	9	9	0	100%
Influenza B Yamagata	9	9	0	100%
Influenza B Victoria	9	9	0	100%
Respiratory syncytial virus type A	9	9	0	100%
Respiratory syncytial virus type B	9	9	0	100%
Enterovirus A	9	9	0	100%
Enterovirus B	9	9	0	100%

Enterovirus C	9	9	0	100%
Enterovirus D	9	9	0	100%
Parainfluenza virus type 1	9	9	0	100%
Parainfluenza virus type 2	9	9	0	100%
Parainfluenza virus type 3	9	9	0	100%
Rhinovirus A	9	9	0	100%
Rhinovirus B	9	9	0	100%
Rhinovirus C	9	9	0	100%
Adenovirus type 1	9	9	0	100%
Adenovirus type 2	9	9	0	100%
Adenovirus type 3	9	9	0	100%
Adenovirus type 4	9	9	0	100%
Adenovirus type 5	9	9	0	100%
Adenovirus type 7	9	9	0	100%
Adenovirus type 55	9	9	0	100%
Human metapneumovirus	9	9	0	100%
Epstein-Barr virus	9	9	0	100%
Measles virus	9	9	0	100%
Human cytomegalovirus	9	9	0	100%
Rotavirus	9	9	0	100%
Norovirus	9	9	0	100%
Mumps virus	9	9	0	100%
Varicella-zoster virus	9	9	0	100%
Legionella	9	9	0	100%
Bordetella pertussis	9	9	0	100%
Haemophilus influenzae	9	9	0	100%
Staphylococcus aureus	9	9	0	100%
Streptococcus pneumoniae	9	9	0	100%
Streptococcus pyogenes	9	9	0	100%
Klebsiella pneumoniae	9	9	0	100%
Mycobacterium tuberculosis	9	9	0	100%
Mycoplasma pneumoniae	9	9	0	100%
Chlamydia pneumoniae	9	9	0	100%
Aspergillus fumigatus	9	9	0	100%
Candida albicans	9	9	0	100%
Candida glabrata	9	9	0	100%
Cryptococcus neoformans	9	9	0	100%
Cryptococcus gutii	9	9	0	100%
Pneumocystis jirovecii (PJP)	9	9	0	100%
Coronavirus229E	9	9	0	100%
CoronavirusOC43	9	9	0	100%
CoronavirusNL63	9	9	0	100%
Coronavirus HKU1	9	9	0	100%

Coronavirus MERS	9	9	0	100%
Coronavirus SARS	9	9	0	100%
Pooled human nasal wash	9	9	0	100%

Tab21 Test results of throat swab specimens (3 LOD)

S.N.	A1			A2			A3		
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+
18	+	+	+	+	+	+	+	+	+
19	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+
21	+	+	+	+	+	+	+	+	+
22	+	+	+	+	+	+	+	+	+
23	+	+	+	+	+	+	+	+	+
24	+	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+	+
26	+	+	+	+	+	+	+	+	+
27	+	+	+	+	+	+	+	+	+
28	+	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+
30	+	+	+	+	+	+	+	+	+
31	+	+	+	+	+	+	+	+	+
32	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	+
34	+	+	+	+	+	+	+	+	+
35	+	+	+	+	+	+	+	+	+
36	+	+	+	+	+	+	+	+	+
37	+	+	+	+	+	+	+	+	+
38	+	+	+	+	+	+	+	+	+

39	+	+	+	+	+	+	+	+	+
40	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+
42	+	+	+	+	+	+	+	+	+
43	+	+	+	+	+	+	+	+	+
44	+	+	+	+	+	+	+	+	+
45	+	+	+	+	+	+	+	+	+
46	+	+	+	+	+	+	+	+	+
47	+	+	+	+	+	+	+	+	+
48	+	+	+	+	+	+	+	+	+
49	+	+	+	+	+	+	+	+	+
50	+	+	+	+	+	+	+	+	+
51	+	+	+	+	+	+	+	+	+
52	+	+	+	+	+	+	+	+	+
53	+	+	+	+	+	+	+	+	+
54	+	+	+	+	+	+	+	+	+
55	+	+	+	+	+	+	+	+	+
56	+	+	+	+	+	+	+	+	+
57	+	+	+	+	+	+	+	+	+

Tab22 Test Results of Np% (3 LOD)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	9	0	100%
Seasonal H1N1 influenza virus	9	9	0	100%
H3N2 influenza virus	9	9	0	100%
H5N1 avian influenza virus	9	9	0	100%
H7N9 avian influenza virus	9	9	0	100%
Influenza B Yamagata	9	9	0	100%
Influenza B Victoria	9	9	0	100%
Respiratory syncytial virus type A	9	9	0	100%
Respiratory syncytial virus type B	9	9	0	100%
Enterovirus A	9	9	0	100%
Enterovirus B	9	9	0	100%
Enterovirus C	9	9	0	100%
Enterovirus D	9	9	0	100%
Parainfluenza virus type 1	9	9	0	100%
Parainfluenza virus type 2	9	9	0	100%
Parainfluenza virus type 3	9	9	0	100%
Rhinovirus A	9	9	0	100%
Rhinovirus B	9	9	0	100%
Rhinovirus C	9	9	0	100%

Adenovirus type 1	9	9	0	100%
Adenovirus type 2	9	9	0	100%
Adenovirus type 3	9	9	0	100%
Adenovirus type 4	9	9	0	100%
Adenovirus type 5	9	9	0	100%
Adenovirus type 7	9	9	0	100%
Adenovirus type 55	9	9	0	100%
Human metapneumovirus	9	9	0	100%
Epstein-Barr virus	9	9	0	100%
Measles virus	9	9	0	100%
Human cytomegalovirus	9	9	0	100%
Rotavirus	9	9	0	100%
Norovirus	9	9	0	100%
Mumps virus	9	9	0	100%
Varicella-zoster virus	9	9	0	100%
Legionella	9	9	0	100%
Bordetella pertussis	9	9	0	100%
Haemophilus influenzae	9	9	0	100%
Staphylococcus aureus	9	9	0	100%
Streptococcus pneumoniae	9	9	0	100%
Streptococcus pyogenes	9	9	0	100%
Klebsiella pneumoniae	9	9	0	100%
Mycobacterium tuberculosis	9	9	0	100%
Mycoplasma pneumoniae	9	9	0	100%
Chlamydia pneumoniae	9	9	0	100%
Aspergillus fumigatus	9	9	0	100%
Candida albicans	9	9	0	100%
Candida glabrata	9	9	0	100%
Cryptococcus neoformans	9	9	0	100%
Cryptococcus gutii	9	9	0	100%
Pneumocystis jirovecii (PJP)	9	9	0	100%
Coronavirus229E	9	9	0	100%
CoronavirusOC43	9	9	0	100%
CoronavirusNL63	9	9	0	100%
Coronavirus HKU1	9	9	0	100%
Coronavirus MERS	9	9	0	100%
Coronavirus SARS	9	9	0	100%
Pooled human nasal wash	9	9	0	100%

(2) Test results of nasal swab specimens

Tab23 Test results of nasal swab specimens with common respiratory infections

S.N.	A1			A2			A3		
1	-	-	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-
18	-	-	-	-	-	-	-	-	-
19	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-
21	-	-	-	-	-	-	-	-	-
22	-	-	-	-	-	-	-	-	-
23	-	-	-	-	-	-	-	-	-
24	-	-	-	-	-	-	-	-	-
25	-	-	-	-	-	-	-	-	-
26	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-	-	-
28	-	-	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	-	-
31	-	-	-	-	-	-	-	-	-
32	-	-	-	-	-	-	-	-	-
33	-	-	-	-	-	-	-	-	-
34	-	-	-	-	-	-	-	-	-
35	-	-	-	-	-	-	-	-	-
36	-	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-	-
38	-	-	-	-	-	-	-	-	-
39	-	-	-	-	-	-	-	-	-
40	-	-	-	-	-	-	-	-	-

41	-	-	-	-	-	-	-	-	-
42	-	-	-	-	-	-	-	-	-
43	-	-	-	-	-	-	-	-	-
44	-	-	-	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-	-
46	-	-	-	-	-	-	-	-	-
47	-	-	-	-	-	-	-	-	-
48	-	-	-	-	-	-	-	-	-
49	-	-	-	-	-	-	-	-	-
50	-	-	-	-	-	-	-	-	-
51	-	-	-	-	-	-	-	-	-
52	-	-	-	-	-	-	-	-	-
53	-	-	-	-	-	-	-	-	-
54	-	-	-	-	-	-	-	-	-
55	-	-	-	-	-	-	-	-	-
56	-	-	-	-	-	-	-	-	-
57	-	-	-	-	-	-	-	-	-

Tab24 Test Results of Nn% (nasal swab)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	0	9	100%
Seasonal H1N1 influenza virus	9	0	9	100%
H3N2 influenza virus	9	0	9	100%
H5N1 avian influenza virus	9	0	9	100%
H7N9 avian influenza virus	9	0	9	100%
Influenza B Yamagata	9	0	9	100%
Influenza B Victoria	9	0	9	100%
Respiratory syncytial virus type A	9	0	9	100%
Respiratory syncytial virus type B	9	0	9	100%
Enterovirus A	9	0	9	100%
Enterovirus B	9	0	9	100%
Enterovirus C	9	0	9	100%
Enterovirus D	9	0	9	100%
Parainfluenza virus type 1	9	0	9	100%
Parainfluenza virus type 2	9	0	9	100%
Parainfluenza virus type 3	9	0	9	100%
Rhinovirus A	9	0	9	100%
Rhinovirus B	9	0	9	100%
Rhinovirus C	9	0	9	100%
Adenovirus type 1	9	0	9	100%
Adenovirus type 2	9	0	9	100%

Adenovirus type 3	9	0	9	100%
Adenovirus type 4	9	0	9	100%
Adenovirus type 5	9	0	9	100%
Adenovirus type 7	9	0	9	100%
Adenovirus type 55	9	0	9	100%
Human metapneumovirus	9	0	9	100%
Epstein-Barr virus	9	0	9	100%
Measles virus	9	0	9	100%
Human cytomegalovirus	9	0	9	100%
Rotavirus	9	0	9	100%
Norovirus	9	0	9	100%
Mumps virus	9	0	9	100%
Varicella-zoster virus	9	0	9	100%
Legionella	9	0	9	100%
Bordetella pertussis	9	0	9	100%
Haemophilus influenzae	9	0	9	100%
Staphylococcus aureus	9	0	9	100%
Streptococcus pneumoniae	9	0	9	100%
Streptococcus pyogenes	9	0	9	100%
Klebsiella pneumoniae	9	0	9	100%
Mycobacterium tuberculosis	9	0	9	100%
Mycoplasma pneumoniae	9	0	9	100%
Chlamydia pneumoniae	9	0	9	100%
Aspergillus fumigatus	9	0	9	100%
Candida albicans	9	0	9	100%
Candida glabrata	9	0	9	100%
Cryptococcus neoformans	9	0	9	100%
Cryptococcus gutii	9	0	9	100%
Pneumocystis jirovecii (PJP)	9	0	9	100%
Coronavirus229E	9	0	9	100%
CoronavirusOC43	9	0	9	100%
CoronavirusNL63	9	0	9	100%
Coronavirus HKU1	9	0	9	100%
Coronavirus MERS	9	0	9	100%
Coronavirus SARS	9	0	9	100%
Pooled human nasal wash	9	0	9	100%

Tab25 Test results of nasal swab specimens (1.5 LOD)

S.N.	A1			A2			A3		
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+

6	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+
18	+	+	+	+	+	+	+	+	+
19	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+
21	+	+	+	+	+	+	+	+	+
22	+	+	+	+	+	+	+	+	+
23	+	+	+	+	+	+	+	+	+
24	+	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+	+
26	+	+	+	+	+	+	+	+	+
27	+	+	+	+	+	+	+	+	+
28	+	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+
30	+	+	+	+	+	+	+	+	+
31	+	+	+	+	+	+	+	+	+
32	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	+
34	+	+	+	+	+	+	+	+	+
35	+	+	+	+	+	+	+	+	+
36	+	+	+	+	+	+	+	+	+
37	+	+	+	+	+	+	+	+	+
38	+	+	+	+	+	+	+	+	+
39	+	+	+	+	+	+	+	+	+
40	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+
42	+	+	+	+	+	+	+	+	+
43	+	+	+	+	+	+	+	+	+
44	+	+	+	+	+	+	+	+	+
45	+	+	+	+	+	+	+	+	+
46	+	+	+	+	+	+	+	+	+
47	+	+	+	+	+	+	+	+	+
48	+	+	+	+	+	+	+	+	+
49	+	+	+	+	+	+	+	+	+

50	+	+	+	+	+	+	+	+	+
51	+	+	+	+	+	+	+	+	+
52	+	+	+	+	+	+	+	+	+
53	+	+	+	+	+	+	+	+	+
54	+	+	+	+	+	+	+	+	+
55	+	+	+	+	+	+	+	+	+
56	+	+	+	+	+	+	+	+	+
57	+	+	+	+	+	+	+	+	+

Tab26 Test Results of Np% (1.5 LOD)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	9	0	100%
Seasonal H1N1 influenza virus	9	9	0	100%
H3N2 influenza virus	9	9	0	100%
H5N1 avian influenza virus	9	9	0	100%
H7N9 avian influenza virus	9	9	0	100%
Influenza B Yamagata	9	9	0	100%
Influenza B Victoria	9	9	0	100%
Respiratory syncytial virus type A	9	9	0	100%
Respiratory syncytial virus type B	9	9	0	100%
Enterovirus A	9	9	0	100%
Enterovirus B	9	9	0	100%
Enterovirus C	9	9	0	100%
Enterovirus D	9	9	0	100%
Parainfluenza virus type 1	9	9	0	100%
Parainfluenza virus type 2	9	9	0	100%
Parainfluenza virus type 3	9	9	0	100%
Rhinovirus A	9	9	0	100%
Rhinovirus B	9	9	0	100%
Rhinovirus C	9	9	0	100%
Adenovirus type 1	9	9	0	100%
Adenovirus type 2	9	9	0	100%
Adenovirus type 3	9	9	0	100%
Adenovirus type 4	9	9	0	100%
Adenovirus type 5	9	9	0	100%
Adenovirus type 7	9	9	0	100%
Adenovirus type 55	9	9	0	100%
Human metapneumovirus	9	9	0	100%
Epstein-Barr virus	9	9	0	100%
Measles virus	9	9	0	100%
Human cytomegalovirus	9	9	0	100%

Rotavirus	9	9	0	100%
Norovirus	9	9	0	100%
Mumps virus	9	9	0	100%
Varicella-zoster virus	9	9	0	100%
Legionella	9	9	0	100%
Bordetella pertussis	9	9	0	100%
Haemophilus influenzae	9	9	0	100%
Staphylococcus aureus	9	9	0	100%
Streptococcus pneumoniae	9	9	0	100%
Streptococcus pyogenes	9	9	0	100%
Klebsiella pneumoniae	9	9	0	100%
Mycobacterium tuberculosis	9	9	0	100%
Mycoplasma pneumoniae	9	9	0	100%
Chlamydia pneumoniae	9	9	0	100%
Aspergillus fumigatus	9	9	0	100%
Candida albicans	9	9	0	100%
Candida glabrata	9	9	0	100%
Cryptococcus neoformans	9	9	0	100%
Cryptococcus gutii	9	9	0	100%
Pneumocystis jirovecii (PJP)	9	9	0	100%
Coronavirus229E	9	9	0	100%
CoronavirusOC43	9	9	0	100%
CoronavirusNL63	9	9	0	100%
Coronavirus HKU1	9	9	0	100%
Coronavirus MERS	9	9	0	100%
Coronavirus SARS	9	9	0	100%
Pooled human nasal wash	9	9	0	100%

Tab 27 Test results of nasal swab specimens (3 LOD)

S.N.	A1			A2			A3		
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+	+

15	+	+	+	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+
18	+	+	+	+	+	+	+	+	+
19	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+
21	+	+	+	+	+	+	+	+	+
22	+	+	+	+	+	+	+	+	+
23	+	+	+	+	+	+	+	+	+
24	+	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+	+
26	+	+	+	+	+	+	+	+	+
27	+	+	+	+	+	+	+	+	+
28	+	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+
30	+	+	+	+	+	+	+	+	+
31	+	+	+	+	+	+	+	+	+
32	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	+
34	+	+	+	+	+	+	+	+	+
35	+	+	+	+	+	+	+	+	+
36	+	+	+	+	+	+	+	+	+
37	+	+	+	+	+	+	+	+	+
38	+	+	+	+	+	+	+	+	+
39	+	+	+	+	+	+	+	+	+
40	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+
42	+	+	+	+	+	+	+	+	+
43	+	+	+	+	+	+	+	+	+
44	+	+	+	+	+	+	+	+	+
45	+	+	+	+	+	+	+	+	+
46	+	+	+	+	+	+	+	+	+
47	+	+	+	+	+	+	+	+	+
48	+	+	+	+	+	+	+	+	+
49	+	+	+	+	+	+	+	+	+
50	+	+	+	+	+	+	+	+	+
51	+	+	+	+	+	+	+	+	+
52	+	+	+	+	+	+	+	+	+
53	+	+	+	+	+	+	+	+	+
54	+	+	+	+	+	+	+	+	+
55	+	+	+	+	+	+	+	+	+
56	+	+	+	+	+	+	+	+	+
57	+	+	+	+	+	+	+	+	+

Tab28 Test Results of Np% (3 LOD)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	9	0	100%
Seasonal H1N1 influenza virus	9	9	0	100%
H3N2 influenza virus	9	9	0	100%
H5N1 avian influenza virus	9	9	0	100%
H7N9 avian influenza virus	9	9	0	100%
Influenza B Yamagata	9	9	0	100%
Influenza B Victoria	9	9	0	100%
Respiratory syncytial virus type A	9	9	0	100%
Respiratory syncytial virus type B	9	9	0	100%
Enterovirus A	9	9	0	100%
Enterovirus B	9	9	0	100%
Enterovirus C	9	9	0	100%
Enterovirus D	9	9	0	100%
Parainfluenza virus type 1	9	9	0	100%
Parainfluenza virus type 2	9	9	0	100%
Parainfluenza virus type 3	9	9	0	100%
Rhinovirus A	9	9	0	100%
Rhinovirus B	9	9	0	100%
Rhinovirus C	9	9	0	100%
Adenovirus type 1	9	9	0	100%
Adenovirus type 2	9	9	0	100%
Adenovirus type 3	9	9	0	100%
Adenovirus type 4	9	9	0	100%
Adenovirus type 5	9	9	0	100%
Adenovirus type 7	9	9	0	100%
Adenovirus type 55	9	9	0	100%
Human metapneumovirus	9	9	0	100%
Epstein-Barr virus	9	9	0	100%
Measles virus	9	9	0	100%
Human cytomegalovirus	9	9	0	100%
Rotavirus	9	9	0	100%
Norovirus	9	9	0	100%
Mumps virus	9	9	0	100%
Varicella-zoster virus	9	9	0	100%
Legionella	9	9	0	100%
Bordetella pertussis	9	9	0	100%
Haemophilus influenzae	9	9	0	100%

Staphylococcus aureus	9	9	0	100%
Streptococcus pneumoniae	9	9	0	100%
Streptococcus pyogenes	9	9	0	100%
Klebsiella pneumoniae	9	9	0	100%
Mycobacterium tuberculosis	9	9	0	100%
Mycoplasma pneumoniae	9	9	0	100%
Chlamydia pneumoniae	9	9	0	100%
Aspergillus fumigatus	9	9	0	100%
Candida albicans	9	9	0	100%
Candida glabrata	9	9	0	100%
Cryptococcus neoformans	9	9	0	100%
Cryptococcus gutii	9	9	0	100%
Pneumocystis jirovecii (PJP)	9	9	0	100%
Coronavirus229E	9	9	0	100%
CoronavirusOC43	9	9	0	100%
CoronavirusNL63	9	9	0	100%
Coronavirus HKU1	9	9	0	100%
Coronavirus MERS	9	9	0	100%
Coronavirus SARS	9	9	0	100%
Pooled human nasal wash	9	9	0	100%

(3) Test results of saliva specimens

Tab29 Test results of saliva specimens with common respiratory infections

S.N.	A1			A2			A3		
1	-	-	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-	-	-
12	-	-	-	-	-	-	-	-	-
13	-	-	-	-	-	-	-	-	-
14	-	-	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	-	-	-	-
18	-	-	-	-	-	-	-	-	-
19	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-

21	-	-	-	-	-	-	-	-	-
22	-	-	-	-	-	-	-	-	-
23	-	-	-	-	-	-	-	-	-
24	-	-	-	-	-	-	-	-	-
25	-	-	-	-	-	-	-	-	-
26	-	-	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-	-	-
28	-	-	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-	-	-
31	-	-	-	-	-	-	-	-	-
32	-	-	-	-	-	-	-	-	-
33	-	-	-	-	-	-	-	-	-
34	-	-	-	-	-	-	-	-	-
35	-	-	-	-	-	-	-	-	-
36	-	-	-	-	-	-	-	-	-
37	-	-	-	-	-	-	-	-	-
38	-	-	-	-	-	-	-	-	-
39	-	-	-	-	-	-	-	-	-
40	-	-	-	-	-	-	-	-	-
41	-	-	-	-	-	-	-	-	-
42	-	-	-	-	-	-	-	-	-
43	-	-	-	-	-	-	-	-	-
44	-	-	-	-	-	-	-	-	-
45	-	-	-	-	-	-	-	-	-
46	-	-	-	-	-	-	-	-	-
47	-	-	-	-	-	-	-	-	-
48	-	-	-	-	-	-	-	-	-
49	-	-	-	-	-	-	-	-	-
50	-	-	-	-	-	-	-	-	-
51	-	-	-	-	-	-	-	-	-
52	-	-	-	-	-	-	-	-	-
53	-	-	-	-	-	-	-	-	-
54	-	-	-	-	-	-	-	-	-
55	-	-	-	-	-	-	-	-	-
56	-	-	-	-	-	-	-	-	-
57	-	-	-	-	-	-	-	-	-

Tab30 Test Results of Nn% (saliva)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	0	9	100%
Seasonal H1N1 influenza virus	9	0	9	100%
H3N2 influenza virus	9	0	9	100%
H5N1 avian influenza virus	9	0	9	100%

H7N9 avian influenza virus	9	0	9	100%
Influenza B Yamagata	9	0	9	100%
Influenza B Victoria	9	0	9	100%
Respiratory syncytial virus type A	9	0	9	100%
Respiratory syncytial virus type B	9	0	9	100%
Enterovirus A	9	0	9	100%
Enterovirus B	9	0	9	100%
Enterovirus C	9	0	9	100%
Enterovirus D	9	0	9	100%
Parainfluenza virus type 1	9	0	9	100%
Parainfluenza virus type 2	9	0	9	100%
Parainfluenza virus type 3	9	0	9	100%
Rhinovirus A	9	0	9	100%
Rhinovirus B	9	0	9	100%
Rhinovirus C	9	0	9	100%
Adenovirus type 1	9	0	9	100%
Adenovirus type 2	9	0	9	100%
Adenovirus type 3	9	0	9	100%
Adenovirus type 4	9	0	9	100%
Adenovirus type 5	9	0	9	100%
Adenovirus type 7	9	0	9	100%
Adenovirus type 55	9	0	9	100%
Human metapneumovirus	9	0	9	100%
Epstein-Barr virus	9	0	9	100%
Measles virus	9	0	9	100%
Human cytomegalovirus	9	0	9	100%
Rotavirus	9	0	9	100%
Norovirus	9	0	9	100%
Mumps virus	9	0	9	100%
Varicella-zoster virus	9	0	9	100%
Legionella	9	0	9	100%
Bordetella pertussis	9	0	9	100%
Haemophilus influenzae	9	0	9	100%
Staphylococcus aureus	9	0	9	100%
Streptococcus pneumoniae	9	0	9	100%
Streptococcus pyogenes	9	0	9	100%
Klebsiella pneumoniae	9	0	9	100%
Mycobacterium tuberculosis	9	0	9	100%
Mycoplasma pneumoniae	9	0	9	100%
Chlamydia pneumoniae	9	0	9	100%
Aspergillus fumigatus	9	0	9	100%

Candida albicans	9	0	9	100%
Candida glabrata	9	0	9	100%
Cryptococcus neoformans	9	0	9	100%
Cryptococcus gutii	9	0	9	100%
Pneumocystis jirovecii (PJP)	9	0	9	100%
Coronavirus229E	9	0	9	100%
CoronavirusOC43	9	0	9	100%
CoronavirusNL63	9	0	9	100%
Coronavirus HKU1	9	0	9	100%
Coronavirus MERS	9	0	9	100%
Coronavirus SARS	9	0	9	100%
Pooled human nasal wash	9	0	9	100%

Tab31 Test results of saliva specimens (1.5 LOD)

S.N.	A1			A2			A3		
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+
18	+	+	+	+	+	+	+	+	+
19	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+
21	+	+	+	+	+	+	+	+	+
22	+	+	+	+	+	+	+	+	+
23	+	+	+	+	+	+	+	+	+
24	+	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+	+
26	+	+	+	+	+	+	+	+	+
27	+	+	+	+	+	+	+	+	+
28	+	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+

30	+	+	+	+	+	+	+	+	+
31	+	+	+	+	+	+	+	+	+
32	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	+
34	+	+	+	+	+	+	+	+	+
35	+	+	+	+	+	+	+	+	+
36	+	+	+	+	+	+	+	+	+
37	+	+	+	+	+	+	+	+	+
38	+	+	+	+	+	+	+	+	+
39	+	+	+	+	+	+	+	+	+
40	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+
42	+	+	+	+	+	+	+	+	+
43	+	+	+	+	+	+	+	+	+
44	+	+	+	+	+	+	+	+	+
45	+	+	+	+	+	+	+	+	+
46	+	+	+	+	+	+	+	+	+
47	+	+	+	+	+	+	+	+	+
48	+	+	+	+	+	+	+	+	+
49	+	+	+	+	+	+	+	+	+
50	+	+	+	+	+	+	+	+	+
51	+	+	+	+	+	+	+	+	+
52	+	+	+	+	+	+	+	+	+
53	+	+	+	+	+	+	+	+	+
54	+	+	+	+	+	+	+	+	+
55	+	+	+	+	+	+	+	+	+
56	+	+	+	+	+	+	+	+	+
57	+	+	+	+	+	+	+	+	+

Tab32 Test Results of Np% (1.5 LOD)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	9	0	100%
Seasonal H1N1 influenza virus	9	9	0	100%
H3N2 influenza virus	9	9	0	100%
H5N1 avian influenza virus	9	9	0	100%
H7N9 avian influenza virus	9	9	0	100%
Influenza B Yamagata	9	9	0	100%
Influenza B Victoria	9	9	0	100%
Respiratory syncytial virus type A	9	9	0	100%
Respiratory syncytial virus type B	9	9	0	100%
Enterovirus A	9	9	0	100%

Enterovirus B	9	9	0	100%
Enterovirus C	9	9	0	100%
Enterovirus D	9	9	0	100%
Parainfluenza virus type 1	9	9	0	100%
Parainfluenza virus type 2	9	9	0	100%
Parainfluenza virus type 3	9	9	0	100%
Rhinovirus A	9	9	0	100%
Rhinovirus B	9	9	0	100%
Rhinovirus C	9	9	0	100%
Adenovirus type 1	9	9	0	100%
Adenovirus type 2	9	9	0	100%
Adenovirus type 3	9	9	0	100%
Adenovirus type 4	9	9	0	100%
Adenovirus type 5	9	9	0	100%
Adenovirus type 7	9	9	0	100%
Adenovirus type 55	9	9	0	100%
Human metapneumovirus	9	9	0	100%
Epstein-Barr virus	9	9	0	100%
Measles virus	9	9	0	100%
Human cytomegalovirus	9	9	0	100%
Rotavirus	9	9	0	100%
Norovirus	9	9	0	100%
Mumps virus	9	9	0	100%
Varicella-zoster virus	9	9	0	100%
Legionella	9	9	0	100%
Bordetella pertussis	9	9	0	100%
Haemophilus influenzae	9	9	0	100%
Staphylococcus aureus	9	9	0	100%
Streptococcus pneumoniae	9	9	0	100%
Streptococcus pyogenes	9	9	0	100%
Klebsiella pneumoniae	9	9	0	100%
Mycobacterium tuberculosis	9	9	0	100%
Mycoplasma pneumoniae	9	9	0	100%
Chlamydia pneumoniae	9	9	0	100%
Aspergillus fumigatus	9	9	0	100%
Candida albicans	9	9	0	100%
Candida glabrata	9	9	0	100%
Cryptococcus neoformans	9	9	0	100%
Cryptococcus gutii	9	9	0	100%
Pneumocystis jirovecii (PJP)	9	9	0	100%
Coronavirus229E	9	9	0	100%
CoronavirusOC43	9	9	0	100%
CoronavirusNL63	9	9	0	100%

Coronavirus HKU1	9	9	0	100%
Coronavirus MERS	9	9	0	100%
Coronavirus SARS	9	9	0	100%
Pooled human nasal wash	9	9	0	100%

Tab33 Test results of saliva specimens (3 LOD)

S.N.	A1			A2			A3		
1	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+
11	+	+	+	+	+	+	+	+	+
12	+	+	+	+	+	+	+	+	+
13	+	+	+	+	+	+	+	+	+
14	+	+	+	+	+	+	+	+	+
15	+	+	+	+	+	+	+	+	+
16	+	+	+	+	+	+	+	+	+
17	+	+	+	+	+	+	+	+	+
18	+	+	+	+	+	+	+	+	+
19	+	+	+	+	+	+	+	+	+
20	+	+	+	+	+	+	+	+	+
21	+	+	+	+	+	+	+	+	+
22	+	+	+	+	+	+	+	+	+
23	+	+	+	+	+	+	+	+	+
24	+	+	+	+	+	+	+	+	+
25	+	+	+	+	+	+	+	+	+
26	+	+	+	+	+	+	+	+	+
27	+	+	+	+	+	+	+	+	+
28	+	+	+	+	+	+	+	+	+
29	+	+	+	+	+	+	+	+	+
30	+	+	+	+	+	+	+	+	+
31	+	+	+	+	+	+	+	+	+
32	+	+	+	+	+	+	+	+	+
33	+	+	+	+	+	+	+	+	+
34	+	+	+	+	+	+	+	+	+
35	+	+	+	+	+	+	+	+	+
36	+	+	+	+	+	+	+	+	+
37	+	+	+	+	+	+	+	+	+

38	+	+	+	+	+	+	+	+	+
39	+	+	+	+	+	+	+	+	+
40	+	+	+	+	+	+	+	+	+
41	+	+	+	+	+	+	+	+	+
42	+	+	+	+	+	+	+	+	+
43	+	+	+	+	+	+	+	+	+
44	+	+	+	+	+	+	+	+	+
45	+	+	+	+	+	+	+	+	+
46	+	+	+	+	+	+	+	+	+
47	+	+	+	+	+	+	+	+	+
48	+	+	+	+	+	+	+	+	+
49	+	+	+	+	+	+	+	+	+
50	+	+	+	+	+	+	+	+	+
51	+	+	+	+	+	+	+	+	+
52	+	+	+	+	+	+	+	+	+
53	+	+	+	+	+	+	+	+	+
54	+	+	+	+	+	+	+	+	+
55	+	+	+	+	+	+	+	+	+
56	+	+	+	+	+	+	+	+	+
57	+	+	+	+	+	+	+	+	+

Tab34 Test Results of Np% (3 LOD)

Cross reactant	Total tests	Positive results	Negative results	Nn%
H1N1(2009)	9	9	0	100%
Seasonal H1N1 influenza virus	9	9	0	100%
H3N2 influenza virus	9	9	0	100%
H5N1 avian influenza virus	9	9	0	100%
H7N9 avian influenza virus	9	9	0	100%
Influenza B Yamagata	9	9	0	100%
Influenza B Victoria	9	9	0	100%
Respiratory syncytial virus type A	9	9	0	100%
Respiratory syncytial virus type B	9	9	0	100%
Enterovirus A	9	9	0	100%
Enterovirus B	9	9	0	100%
Enterovirus C	9	9	0	100%
Enterovirus D	9	9	0	100%
Parainfluenza virus type 1	9	9	0	100%
Parainfluenza virus type 2	9	9	0	100%
Parainfluenza virus type 3	9	9	0	100%
Rhinovirus A	9	9	0	100%
Rhinovirus B	9	9	0	100%

Rhinovirus C	9	9	0	100%
Adenovirus type 1	9	9	0	100%
Adenovirus type 2	9	9	0	100%
Adenovirus type 3	9	9	0	100%
Adenovirus type 4	9	9	0	100%
Adenovirus type 5	9	9	0	100%
Adenovirus type 7	9	9	0	100%
Adenovirus type 55	9	9	0	100%
Human metapneumovirus	9	9	0	100%
Epstein-Barr virus	9	9	0	100%
Measles virus	9	9	0	100%
Human cytomegalovirus	9	9	0	100%
Rotavirus	9	9	0	100%
Norovirus	9	9	0	100%
Mumps virus	9	9	0	100%
Varicella-zoster virus	9	9	0	100%
Legionella	9	9	0	100%
Bordetella pertussis	9	9	0	100%
Haemophilus influenzae	9	9	0	100%
Staphylococcus aureus	9	9	0	100%
Streptococcus pneumoniae	9	9	0	100%
Streptococcus pyogenes	9	9	0	100%
Klebsiella pneumoniae	9	9	0	100%
Mycobacterium tuberculosis	9	9	0	100%
Mycoplasma pneumoniae	9	9	0	100%
Chlamydia pneumoniae	9	9	0	100%
Aspergillus fumigatus	9	9	0	100%
Candida albicans	9	9	0	100%
Candida glabrata	9	9	0	100%
Cryptococcus neoformans	9	9	0	100%
Cryptococcus gutii	9	9	0	100%
Pneumocystis jirovecii (PJP)	9	9	0	100%
Coronavirus229E	9	9	0	100%
CoronavirusOC43	9	9	0	100%
CoronavirusNL63	9	9	0	100%
Coronavirus HKU1	9	9	0	100%
Coronavirus MERS	9	9	0	100%
Coronavirus SARS	9	9	0	100%
Pooled human nasal wash	9	9	0	100%

11.3 Results for Interference Substances Study

(1) Results of throat swab samples

Tab35 Results of testing interference throat swab samples (negative)

	Substances	Concentration	A1					A2					A3				
1	Whole Blood	10%(v/v)	-	-	+	+	-	-	-	-	-	+	-	-	-	-	-
		4%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	Mucin	1%(v/v)	+	+	+	-	+	+	+	+	-	-	+	+	+	+	+
		0.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.25%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	Ricola (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	Sucrets (Dyclonin)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	Sucrets (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	Chloraseptic (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	Chloraseptic (Benzocaine)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	Naso GEL (NeilMed)	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	Afrin (Oxymetazoline)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	CVS Nasal Spray (Cromolyn)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	Nasal Gel (Oxymetazoline)	10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	Zicam	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	Homeopathic (Alkalol)	1:10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1:15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	Fisherman's Friend	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	Sore Throat Phenol Spray	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	Tobramycin	4μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	Mupirocin	10mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	Fluticasone Propionate	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	Tamiflu (Oseltamivir Phosphate)	5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Tab36 Results of testing interference throat swab samples (positive)

	Substances	Concentration	A1					A2					A3				
1	Whole Blood	10%(v/v)	+	-	+	+	+	-	-	-	+	+	+	-	-	+	+
		4%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
2	Mucin	1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.25%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
3	Ricola (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
4	Sucrets (Dyclonin)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
5	Sucrets (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
6	Chloraseptic (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Chloraseptic	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

	(Benzocaine)	1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
8	Naso GEL (NeilMed)	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
10	Afrin (Oxymetazoline)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
11	CVS Nasal Spray (Cromolyn)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
12	Nasal Gel (Oxymetazoline)	10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
13	Zicam	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Homeopathic (Alkalol)	1:10	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1:15	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1:20	+	+	+	+	+	+	+	+	+	+	+	+	+	+
15	Fisherman's Friend	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
16	Sore Throat Phenol Spray	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
17	Tobramycin	4μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
18	Mupirocin	10mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
19	Fluticasone Propionate	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
20	Tamiflu (Oseltamivir Phosphate)	5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Tab37 Results summary of interference experiment

Substances	Concentration	Ri	Fp	Fn
Whole Blood	10%(v/v)	0	20%	40%
	4%(v/v)	0	0	0
	1%(v/v)	0	0	0
Mucin	1%(v/v)	0	80%	0
	0.5%(v/v)	0	0	0
	0.25%(v/v)	0	0	0
Ricola (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sucrets (Dyclonin)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sucrets (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Chloraseptic (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Chloraseptic (Benzocaine)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Naso GEL (NeilMed)	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
CVS Nasal Drops (Phenylephrine)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Afrin (Oxymetazoline)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
CVS Nasal Spray (Cromolyn)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Nasal Gel (Oxymetazoline)	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
Zicam	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
Homeopathic (Alkalol)	1:10	0	0	0

	1:15	0	0	0
	1:20	0	0	0
Fisherman's Friend	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sore Throat Phenol Spray	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Tobramycin	4μg/mL	0	0	0
	2μg/mL	0	0	0
	1μg/mL	0	0	0
Mupirocin	10mg/mL	0	0	0
	5mg/mL	0	0	0
	2.5mg/mL	0	0	0
Fluticasone Propionate	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
Tamiflu (Oseltamivir Phosphate)	5mg/mL	0	0	0
	2.5mg/mL	0	0	0
	1mg/mL	0	0	0

(2) Results of nasal swab samples

Tab38 Results of testing interference nasal swab samples (negative)

	Substances	Concentration	A1					A2					A3				
1	Whole Blood	10%(v/v)	+	+	-	+	+	-	+	+	-	-	+	+	-	+	-
		4%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	Mucin	1%(v/v)	+	+	+	+	-	-	+	+	+	-	-	+	+	+	+
		0.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.25%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	Ricola (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	Sucrets (Dyclonin)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	Sucrets (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	Chloraseptic (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	Chloraseptic (Benzocaine)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	Naso GEL (NeilMed)	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	Afrin (Oxymetazoline)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	CVS Nasal Spray (Cromolyn)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	Nasal Gel (Oxymetazoline)	10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	Zicam	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	Homeopathic (Alkalol)	1:10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1:15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	Fisherman's Friend	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	Sore Throat Phenol Spray	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	Tobramycin	4μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	Mupirocin	10mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	Fluticasone Propionate	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	Tamiflu (Oseltamivir Phosphate)	5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Tab39 Results of testing interference nasal swab samples (positive)

	Substances	Concentration	A1					A2					A3				
1	Whole Blood	10%(v/v)	-	+	-	-	+	+	+	+	+	+	-	+	+	+	+

		4%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
2	Mucin	1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.25%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
3	Ricola (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
4	Sucrets (Dyclonin)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
5	Sucrets (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
6	Chloraseptic (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Chloraseptic (Benzocaine)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
8	Naso GEL (NeilMed)	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
10	Afrin (Oxymetazoline)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
11	CVS Nasal Spray (Cromolyn)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
12	Nasal Gel (Oxymetazoline)	10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
13	Zicam	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Homeopathic (Alkalol)	1:10	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1:15	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1:20	+	+	+	+	+	+	+	+	+	+	+	+	+	+
15	Fisherman's Friend	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+

		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
16	Sore Throat Phenol Spray	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
17	Tobramycin	4μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
18	Mupirocin	10mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
19	Fluticasone Propionate	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
20	Tamiflu (Oseltamivir Phosphate)	5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Tab40 Results summary of interference experiment

Substances	Concentration	Ri	Fp	Fn
Whole Blood	10%(v/v)	0	60%	26.7%
	4%(v/v)	0	0	0
	1%(v/v)	0	0	0
Mucin	1%(v/v)	0	73.3%	0
	0.5%(v/v)	0	0	0
	0.25%(v/v)	0	0	0
Ricola (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sucrets (Dyclonin)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sucrets (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Chloraseptic (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Chloraseptic (Benzocaine)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Naso GEL (NeilMed)	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
CVS Nasal Drops	15%(v/v)	0	0	0

(Phenylephrine)	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Afrin (Oxymetazoline)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
CVS Nasal Spray (Cromolyn)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Nasal Gel (Oxymetazoline)	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
Zicam	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
Homeopathic (Alkalol)	1:10	0	0	0
	1:15	0	0	0
	1:20	0	0	0
Fisherman's Friend	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sore Throat Phenol Spray	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Tobramycin	4μg/mL	0	0	0
	2μg/mL	0	0	0
	1μg/mL	0	0	0
Mupirocin	10mg/mL	0	0	0
	5mg/mL	0	0	0
	2.5mg/mL	0	0	0
Fluticasone Propionate	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
Tamiflu (Oseltamivir Phosphate)	5mg/mL	0	0	0
	2.5mg/mL	0	0	0
	1mg/mL	0	0	0

(3) Results of saliva samples

Tab41 Results of testing interference saliva samples (negative)

	Substances	Concentration	A1					A2					A3				
1	Whole Blood	10%(v/v)	-	-	+	+	-	-	-	-	-	+	-	-	-	-	-
		4%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	Mucin	1%(v/v)	+	+	+	-	+	+	+	+	-	-	+	+	+	+	+
		0.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

		0.25%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	Ricola (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	Sucrets (Dyclonin)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	Sucrets (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	Chloraseptic (Menthol)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	Chloraseptic (Benzocaine)	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	Naso GEL (NeilMed)	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	Afrin (Oxymetazoline)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	CVS Nasal Spray (Cromolyn)	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	Nasal Gel (Oxymetazoline)	10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	Zicam	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	Homeopathic (Alkalol)	1:10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1:15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1:20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	Fisherman's Friend	1.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		0.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	Sore Throat Phenol Spray	15%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		10%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

17	Tobramycin	4μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1μg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	Mupirocin	10mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	Fluticasone Propionate	5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1%(v/v)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	Tamiflu (Oseltamivir Phosphate)	5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		2.5mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		1mg/mL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Tab42 Results of testing interference saliva samples (positive)

	Substances	Concentration	A1					A2					A3				
1	Whole Blood	10%(v/v)	+	-	+	+	+	-	-	-	+	+	+	-	-	+	+
		4%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
2	Mucin	1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.25%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
3	Ricola (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
4	Sucrets (Dyclonin)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
5	Sucrets (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
6	Chloraseptic (Menthol)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
7	Chloraseptic (Benzocaine)	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
8	Naso GEL (NeilMed)	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
10	Afrin (Oxymetazoline)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
11	CVS Nasal Spray (Cromolyn)	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
12	Nasal Gel (Oxymetazoline)	10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
13	Zicam	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
14	Homeopathic (Alkalol)	1:10	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1:15	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1:20	+	+	+	+	+	+	+	+	+	+	+	+	+	+
15	Fisherman's Friend	1.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		0.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
16	Sore Throat Phenol Spray	15%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		10%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
17	Tobramycin	4μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1μg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
18	Mupirocin	10mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
19	Fluticasone Propionate	5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1%(v/v)	+	+	+	+	+	+	+	+	+	+	+	+	+	+
20	Tamiflu (Oseltamivir Phosphate)	5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		2.5mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+
		1mg/mL	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Tab43 Results summary of interference experiment

Substances	Concentration	Ri	Fp	Fn
Whole Blood	10%(v/v)	0	20%	40%
	4%(v/v)	0	0	0
	1%(v/v)	0	0	0
Mucin	1%(v/v)	0	80%	0
	0.5%(v/v)	0	0	0
	0.25%(v/v)	0	0	0
Ricola (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sucrets (Dyclonin)	1.5mg/mL	0	0	0

	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sucrets (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Chloraseptic (Menthol)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Chloraseptic (Benzocaine)	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Naso GEL (NeilMed)	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
CVS Nasal Drops (Phenylephrine)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Afrin (Oxymetazoline)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
CVS Nasal Spray (Cromolyn)	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Nasal Gel (Oxymetazoline)	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
Zicam	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
Homeopathic (Alkalol)	1:10	0	0	0
	1:15	0	0	0
	1:20	0	0	0
Fisherman's Friend	1.5mg/mL	0	0	0
	1mg/mL	0	0	0
	0.5mg/mL	0	0	0
Sore Throat Phenol Spray	15%(v/v)	0	0	0
	10%(v/v)	0	0	0
	5%(v/v)	0	0	0
Tobramycin	4μg/mL	0	0	0
	2μg/mL	0	0	0
	1μg/mL	0	0	0
Mupirocin	10mg/mL	0	0	0
	5mg/mL	0	0	0

	2.5mg/mL	0	0	0
Fluticasone Propionate	5%(v/v)	0	0	0
	2.5%(v/v)	0	0	0
	1%(v/v)	0	0	0
Tamiflu (Oseltamivir Phosphate)	5mg/mL	0	0	0
	2.5mg/mL	0	0	0
	1mg/mL	0	0	0

11.4 Results for Clinical Trials

11.4.1 Results for Throat swab specimen

(1) Results analysis table

Tab2a Analysis table of clinical specimens' results (Throat Swab)

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	312 (a)	0(b)	312(a+b)
Antigen Test (Colloidal	Negative	3©	329(d)	332(c+d)
Gold) result	Total	315(a+c)	329(b+d)	644(a+b+c+d)

(2) Coincidence rate and 95% confidence interval

Tab2b Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	99.05%	97.24%~99.80%
Clinical specificity	100%	98.88%~100%
Total coincidence rate	99.53%	98.64%~99.90%

11.4.2 Results for Nasal swab specimen

(1) Results analysis table

Tab3a Analysis table of clinical specimens' results (Nasal Swab)

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	229(a)	0(b)	229(a+b)
Antigen Test (Colloidal	Negative	2©	341(d)	343(c+d)
Gold) result	Total	231(a+c)	341(b+d)	572(a+b+c+d)

(2) Coincidence rate and 95% confidence interval

Tab3b Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	99.13%	96.91%~99.89%
Clinical specificity	100%	98.92%~100%
Total coincidence rate	99.65%	98.74%~99.96%

11.4.3 Results for Saliva specimen

(1) Results analysis table

Tab4a Analysis table of clinical specimens' results (Saliva)

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	546(a)	0(b)	546(a+b)
Antigen Test (Colloidal	Negative	4©	123(d)	127(c+d)
Gold) result	Total	550(a+c)	123(b+d)	673(a+b+c+d)

(2) Coincidence rate and 95% confidence interval

Tab4b Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	99.27%	98.15%~99.80%
Clinical specificity	100%	97.05%~100%
Total coincidence rate	99.41%	98.49%~99.84%

11.4.4 Results for Total specimen

(1) Results analysis table

Tab5a Analysis table of clinical specimens' results

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	1087(a)	0(b)	1087(a+b)
Antigen Test (Colloidal	Negative	9©	793(d)	802(c+d)
Gold) result	Total	1096(a+c)	793(b+d)	1889(a+b+c+d)

(2) Coincidence rate and 95% confidence interval

Tab5b Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	99.18%	98.45%~99.62%
Clinical specificity	100%	99.54%~100%
Total coincidence rate	99.52%	99.10%~99.78%

(3) Statistical Analysis

Kappa value (K) calculation

K = 0.9902 > 0.75 indicates that the high consistency of two methods and equivalence of two such systems.

11.4.5 Separate analysis

(1) Clinical classification

Tab6a Analysis table of different Clinical classification

	Mild	Moderate	Severe	Critically ill
PCR result	676	285	79	56
Product result	669	283	79	56
PPA	98.96%	99.30%	100%	100%

(2) Clinical classification

Tab6b Analysis table of different days from symptom onset

	0-3 days	4-7 days	>7 days
PCR result	543	331	222
Product result	536	329	222
PPA	98.71%	99.40%	100%

12. Conclusion

12.1 Limit of Detection (LoD)

	Estimated LOD/Cut off	No. Positive/Total	% Positive
nasal swab specimen	4.25 x10^2 $TCID_{50}$/mL	58/60	96.7%
throat swab specimen	4.25 x10^2 $TCID_{50}$/mL	60/60	100%
saliva specimen	4.25 x102 $TCID_{50}$/mL	58/60	96.7%

The LOD / Cut-off value of the Rapid COVID-19 Antigen Test (Colloidal Gold) is 4.25 x10^2 $TCID_{50}$/mL.

12.2 Cross-Reactivity

None of the viral and microbial pathogens tested at the concentrations indicated interfere with the test results of negative or positive samples in Rapid COVID-19 Antigen Test (Colloidal Gold).

Non-interfering Viruses / Microbials

S.N.	Viruses / Microbials	Species	Concentration tested
1	H1N1(2009)	A-H1N1-2009	10^6pfu/mL

2	Seasonal H1N1 influenza virus	A-H1N1	10^6pfu/mL
3	H3N2 influenza virus	A-H3N2	10^6pfu/mL
4	H5N1 avian influenza virus	A-H5N1	10^6pfu/mL
5	H7N9 avian influenza virus	A-H7N9	10^6pfu/mL
6	Influenza B Yamagata	B-Yamagata	10^6pfu/mL
7	Influenza B Victoria	B-Victoria	10^6pfu/mL
8	Respiratory syncytial virus type A	RSV-A2	10^6pfu/mL
9	Respiratory syncytial virus type B	RSV-B	10^6pfu/mL
10	Enterovirus A	CV-A10	10^6pfu/mL
11	Enterovirus B	Echovirus 6	10^6pfu/mL
12	Enterovirus C	CV-A21	10^6pfu/mL
13	Enterovirus D	EV-D68	10^6pfu/mL
14	Parainfluenza virus type 1	HPIVs-1	10^6pfu/mL
15	Parainfluenza virus type 2	HPIVs-2	10^6pfu/mL
16	Parainfluenza virus type 3	HPIVs-3 VR-93	10^6pfu/mL
17	Rhinovirus A	HRV-9 VR-489	10^6pfu/mL
18	Rhinovirus B	HRV-52 VR-1162 HRV-3 VR-1113	10^6pfu/mL
19	Rhinovirus C	HRV-16 VR-283	10^6pfu/mL
20	Adenovirus type 1	HadV-1 VR-1	10^6pfu/mL
21	Adenovirus type 2	HadV-2 VR-846	10^6pfu/mL
22	Adenovirus type 3	HadV-3	10^6pfu/mL
23	Adenovirus type 4	HadV-4 VR-1572	10^6pfu/mL
24	Adenovirus type 5	HAdV-5 VR-1578/1516	10^6pfu/mL
25	Adenovirus type 7	HAdV-7 VR-7	10^6pfu/mL
26	Adenovirus type 55	HAdV-55	10^6pfu/mL
27	Human metapneumovirus	HMPV	10^6pfu/mL

28	Epstein-Barr virus	HHV-4 VR-1492	10^6pfu/mL
29	Measles virus	MV VR-24	10^6pfu/mL
30	Human cytomegalovirus	HHV-5 VR-977	10^6pfu/mL
31	Rotavirus	RV VR-2018	10^6pfu/mL
32	Norovirus	NOR	10^6pfu/mL
33	Mumps virus	MuV VR-106	10^6pfu/mL
34	Varicella-zoster virus	VZV VR-1367	10^6pfu/mL
35	Legionella	33152	10^7cfu/mL
36	Bordetella pertussis	BAA-589	10^7cfu/mL
37	Haemophilus influenzae	Hib	10^7cfu/mL
38	Staphylococcus aureus	CGMCC 1.2910	10^7cfu/mL
39	Streptococcus pneumoniae	CGMCC 1.8722	10^7cfu/mL
40	Streptococcus pyogenes	CGMCC 1.8868	10^7cfu/mL
41	Klebsiella pneumoniae	CGMCC 1.1736	10^7cfu/mL
42	Mycobacterium tuberculosis	25177	10^7cfu/mL
43	Mycoplasma pneumoniae	39505	10^7cfu/mL
44	Chlamydia pneumoniae	VR-2282	10^7cfu/mL
45	Aspergillus fumigatus	AF293	10^7cfu/mL
46	Candida albicans	SC5314	10^7cfu/mL
47	Candida glabrata	ATCC 2001	10^7cfu/mL
48	Cryptococcus neoformans	H99	10^7cfu/mL
49	Cryptococcus gutii	R265	10^7cfu/mL
50	Pneumocystis jirovecii (PJP)	CGMCC 1.9054	10^7cfu/mL
51	Coronavirus229E	VR-740	10^6pfu/mL
52	CoronavirusOC43	VR-1558	10^6pfu/mL
53	CoronavirusNL63	COV-NL63	10^6pfu/mL
54	Coronavirus HKU1	COV-HKU1	10^6pfu/mL
55	Coronavirus MERS	MERS	10^8TU/mL
56	Coronavirus SARS	SARS	10^8TU/mL
57	Pooled human nasal wash	/	10^7cfu/mL

12.3 Interference Substances Study

None of the substances tested at the concentrations indicated interfere with the test results of negative or positive samples in Rapid COVID-19 Antigen Test (Colloidal Gold). Whole blood at concentration of > 4% v/v or mucin at concentration of > 0.5% v/v do not interfere in the interpretation of the test.

Non-interfering Substances

S.N.	Substance Name	Concentration	S.N.	Substance Name	Concentration
1	Whole Blood	4%(v/v)	11	CVS Nasal Spray (Cromolyn)	15%(v/v)
2	Mucin	0.5%(v/v)	12	Nasal Gel (Oxymetazoline)	10%(v/v)
3	Ricola (Menthol)	1.5mg/mL	13	Zicam	5%(v/v)
4	Sucrets (Dyclonin)	1.5mg/mL	14	Homeopathic (Alkalol)	1:10
5	Sucrets (Menthol)	1.5mg/mL	15	Fisherman's Friend	1.5mg/mL
6	Chloraseptic (Menthol)	1.5mg/mL	16	Sore Throat Phenol Spray	15%(v/v)
7	Chloraseptic (Benzocaine)	1.5mg/mL	17	Tobramycin	4μg/mL
8	Naso GEL (NeilMed)	5%(v/v)	18	Mupirocin	10mg/mL
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)	19	Fluticasone Propionate	5%(v/v)
10	Afrin (Oxymetazoline)	15%(v/v)	20	Tamiflu (Oseltamivir Phosphate)	5mg/mL

12.4 Clinical Trials

(1) In summary, 1889 samples were tested in this clinical trial, included 644 throat swabs, 572 nasal swabs, and 673 saliva samples.

(2) Among them, there were 1880 cases with product test results consistent with RT-PCR result in this clinical trial, included 1087 cases were positive, 793 cases were negative.

(3) There were overall 9 cases of product test results inconsistent with RT-PCR result in this clinical trial due to the difference in methodologies used.

RT-PCR result	Product result	Number
+	T (-), N (-), S (-)	1
+	T (+), N (+), S (-)	2
+	T (-)	2
+	N (-)	1
+	S (-)	1
*Throat swab: T, Nasal swab: N, Saliva: S		

Tab56 Inconsistent results

No.	Sampling day	Age	Sex (F/M)	Days from Symptom Onset	Clinical classification	Throat swab result	Nasal swab result	Saliva result	PC	
									Chanel A (RdRP)	Chane (N ge
1	2020/9/11	83	M	5	Mild	-	-	-	41	38
2	2020/10/1	51	F	4	Mild	+	+	-	36	/
3	2020/10/9	37	M	2	Mild	+	+	-	40	39
4	2020/9/19	59	F	5	Mild	-	/	/	40	40
5	2020/12/23	73	F	2	Moderate	-	/	/	41	/

(4) The sensitivity, specificity and total coincidence rate of product testing and RT-PCR result are 99.18%,100% and 99.52%, respectively. The sensitivity is more than 98%, the specificity is more than 99%.

(5) K = 0.9902 > 0.75 indicates that the high consistency of two methods and equivalence of two such systems.