EU RAT Device ID # 1929

LoD value 200 TCID50/ml

BfArM Test-ID: AT563/21

Hoyotek COVID-19 Antigen Rapid Test Cassette Nasopharyngeal Swab

1. Product description

Brand: Hoyotek

Scope: 30x tubes, 30x swabs, 30x test cassettes, 30x Reagenzien.

Bfarm-ID # **AT563/21**

CE-Standard: EN ISO 13485:2016

Size: 22cm*15cm*8cm

Durability: 12 months

Packaging: 30 tests

Characteristics:

- BfArM listed / EU RAT listed

- clinical sensitivity 96%

- clinical specifity 99%

- fast and reliable test results in 15 minutes

- 5 languages IFU (English, German, Spanish, French, Italian).

Carton box 60x47x42cm, 20kg per box, 40 packs or 1200 tests per box.

2. Pictures


Hoyotek
COVID-19
Corona Virus Antigen Rapid Test (Colloidal Gold)
Corona Virus (COVID-19)Antigen
Rapid Test (Colloidal Gold)
Inhalt
ISO
CE


COVID-19
Nasopharyngealabstrich
30 Tests
PASS
Hoyotek
ISO
CE
Inhalt
30 Testkassetten
30 Sterilisierte Tupfer
30 Extraktionsreagenzien
1 Gebrauchsanweisungen
1 Reagenzröhrchenständer

3. Certificates

QAdvis EAR European Authorized Representative

Your Regulatory Partner

Certificate of CE registration

QAD 1056

Manufacturer name and address: Hoyotek Biomedical Co. Ltd.
Floor 4, Zone C, Workshop No.1, China civil Aviation science and technology industrialization base No. 225, Jinger Road, Tianjin Airport Economic Zone, China

Product name:	**Model:**
Corona Virus (COVID-19) Antigen Rapid Test (colloidal gold)	HYT-G01
Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test (colloidal gold)	HYT-G02
Corona Virus (COVID-19) Combined (IgM/IgG/Neutralizing antibody) Rapid Test (colloidal gold)	HYT-G03

QAdvis EAR as a European Authorized Representative designated by the manufacturer certifies that the products listed above have been notified and filed at the Competent Authority, Swedish Medical Products Agency, as CE-marked In Vitro Diagnostic Medical Devices in accordance with the In Vitro Diagnostic Medical Devices Directive 98/79/EC, article 10.3.

The manufacturer has provided QAdvis EAR with Declaration of Conformity declaring conformance with the requirements in In Vitro Diagnostic Medical Devices Directive 98/79/EC.

Registration data at Swedish Medical Products Agency:

Reference number: 1607413694862
Initial notification to Swedish Medical Products Agency for the products listed above on 2020-12-08.

Date: 2020-12-08

Bing Wu
EAR manager

QAdvis EAR, Ideon Science Park, Scheelevägen 17, SE-223 70 Lund, Sweden. Phone: +46 8 621 01 05

QAdvis is a member of European Association of Authorised Representatives

EC REP

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4. EU-Declaration of Conformity

Declaration of conformity

Hoyotek

Manufacturer:	Hoyotek Biomedical Co., Ltd. Floor 4, Zone C, Workshop No.1, China civil Aviation science and technology industrialization base No. 225, Jinger Road, Tianjin Airport Economic Zone.
European Representative:	QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden
Product Name:	Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold) Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold) Corona Virus (COVID-19) Combined (IgM/IgG/Neutralizing antibody) Rapid Test (Colloidal Gold)
Product Model:	HYT-G01, HYT-G02, HYT-G03
Classification:	Other IVD Devices
Conformity assessment Route:	IVDD 98/79/EC Annex III

We, Hoyotek Biomedical Co., Ltd hereby declare that the devices mentioned above comply with applicable parts of the Swedish In-Vitro Diagnostic Medical Device Act SFS 1993:584, and the Swedish national legislation LVFS 2001:7, transposing the European In-Vitro Diagnostic Medical Devices Directive, IVDD 98/79/EC.

Verification to:	Standard ISO13485:2016, EN ISO14971:2012, EN ISO15223-1:2016, EN ISO18113-1:2011, EN ISO 18113-2:2011, EN ISO18113-3:2011 Related to Directive(s): 98/79/EC (in Vitro Diagnostic Medical Devices)

Approved by:

General Manager : Wu Bo

Tianjin Wu Bo 2020.11.12

Name	Signature
Function	Place and Date of issue

5. Instructions for use in German + English

Hoyotek®

CE

Corona Virus (COVID-19)
Antigen Rapid Test (Colloidal Gold)
Gebrauchsanweisung
(NUR FÜR DIE PROFESSIONELLE VERWENDUNG)

【Produktname】
Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)
【Modell Code】
HYT-G01-01: Nasal/ Nasopharyngeal Abstrich
【Verpackungsspezifikationen】
HYT-G01-01: 30 Tests/ box, 1 Test/ box

【Verwendungszweck】
Das COVID-19 Antigen Rapid Test Kit (Swab) wird zum qualitativen Nachweis von Nukleocapsid-Protein-Antigenen, durch Nasen oder Nasopharyngeal-Tupferproben vom menschlichen Körper genutzt. Es wird nur als Ergänzungstest für den Nukleinsäuretest des neuartigen Coronavirus oder in Kombination mit dem Nukleinsäuretest in Verdachtsfällen verwendet. Es kann nicht als Grundlage für die Diagnose und den Ausschluss einer durch eine neuartige Coronavirus-Infektion verursachten Lungenentzündung verwendet werden. Die Ergebnisse dieses Kits dienen nur als klinische Referenz. Wenn das Testergebnis positiv ist, ist eine weitere Bestätigung erforderlich. Wenn das Testergebnis negativ ist, kann die Möglichkeit einer Infektion nicht ausgeschlossen werden. Eine umfassende Analyse des Zustands des Patienten sollte in Kombination mit klinischen Symptomen und anderen Labortests durchgeführt werden.Der COVID-19-Antigen-Schnelltest ist für medizinische Fachkräfte oder geschulte Bediener vorgesehen, die sich mit Antigen Schnelltests auskennen.

【Testprinzip】
Der COVID-19 Antigen Rapid Test ist ein Lateral-Flow-Immunoassay, der auf dem Prinzip der Doppelantikörper-Sandwich-Technologie und der kolloidalen Gold-Methode basiert. Der monoklonale SARS-CoV-2-Nukleokapsid-Protein-Antikörper, der mit Farbmikropartikeln konjugiert ist, wird als Detektor verwendet und auf das Konjugationspad gesprüht. Während des Tests interagiert das SARS-CoV-2- Antigen in der Probe, falls vorhanden, mit dem SARS-CoV-2-Antikörper, der mit Farbmikropartikeln konjugiert ist, wodurch ein Antigen-Antikörper-markierter Komplex gebildet wird. Dieser Komplex wandert über die Kapillarwirkung auf der Membran bis zur Testlinie, wo er vom vorbeschichteten monoklonalen SARS-CoV-2-Nukleokapsid-Protein- Antikörper eingefangen wird. Eine farbige Testlinie (T) ist im Ergebnisfenster sichtbar. Das Fehlen der T-Linie deutet auf keine SARS-CoV-2-Antigen in der Probe bzw. ein negatives Ergebnis hin. Die Kontrolllinie (C) wird zur Verfahrenskontrolle verwendet und sollte immer angezeigt werden, wenn das Testverfahren ordnungsgemäß ausgeführt wird.

【Hauptbestandteile】

Komponenten	Verpackungsspezififi kationen		Material
	1 test/box	30 tests/box	
Corona Virus (COVID-19) Antigen Testkassette	1 Stück	30 Stück	monoklonale SARSCoV-2- NukleokapsidProtein-Antikörper mit Farbmikropartikeln konjugiert
Probenextraktionslösung und Tupfer	0.5ml ×1 Flasche	0.5ml ×30 Flasche	Na_2HPO_4, NaH_2PO_4, NaCl, $C_{58}H_{114}O_{26}$

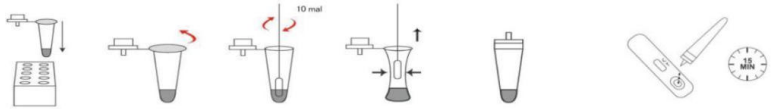
【Aufbewahrungsbedingungen und Haltbarkeit】
1.2-30 ℃ trocken, lichtgeschützt 12 Monate haltbar.
2.Das Produkt sollte trocken unter 2-30 ℃ gelagert und vor Licht geschützt werden. Unter der Bedingung von 2-30 ℃ liegt die Luftfeuchtigkeit unter 60%. Innerhalb von einer Stunde nach dem Öffnen verbrauchen. Ist die Luftfeuchtigkeit über 60%, sollte das Produkt sofort verwendet werden.
3.Produktionsdatum und Gültigkeitsdauer sind auf dem Etikett angegeben.

【Probensammlung und -handhabung】
Probensammlung
•Unzureichende Probenentnahme oder unsachgemäße Probenhandhabung kann zu einem falschen Ergebnis führen.
• Vor dem Sammeln des Nasenabstrichs sollte der Patient angewiesen werden seine Nase zu putzen.
• Nasenabstrich:
1.Führen Sie den gesamten weichen Bereich des Tupfers in ein Nasenloch des Patienten. Der Tupfer sollte bis zu 2,5 cm (1 Zoll) eingeführt werden (gemessen vom Rand des Nasenlochs).
2.Rollen Sie den Tupfer 5-mal entlang der Schleimhaut im Nasenloch, um sicherzustellen, dass sowohl Schleim als auch Zellen gesammelt werden.
3.Wiederholen Sie diesen Vorgang mit dem gleichen Tupfer für das andere Nasenloch, um sicherzustellen, dass eine geeignete Probe aus beiden Nasenhöhlen entnommen wird.
4.Ziehen Sie den Tupfer rotierend aus der Nasenhöhle.

• Nasopharyngeal-Abstrich:
1. Legen Sie den Kopf des Patienten ca. 70 Grad zurück in den Nacken.
2. Führen Sie den Tupfer vorsichtig und langsam in das Nasenloch des Patienten ein, bis er die hintere Nasopharynx erreicht.
3. Drücken Sie den Tupfer vorsichtig weiter, bis ein Widerstand auftritt oder eine vergleichbare Distanz des Tupfers vom Nasenloch bis zum Ohr des Patienten gewährleistet ist. Das zeigt den Kontakt mit der Nasopharynx an.
4. Drehen Sie den Tupfer vorsichtig für 3-5-mal.
5. Lassen Sie den Tupfer für einige Sekunden an der Nasopharynx, um Sekrete zu absorbieren.
6. Ziehen Sie den Tupfer rotierend heraus.

Probentransport und -lagerung:
Die Proben sollten so schnell wie möglich getestet werden. Wenn der Transport der Proben erforderlich ist, werden folgende Transportmedien empfohlen, die vorab getestet wurden und gezeigt haben, dass sie die Leistung des Tests nicht beeinflussen: Hanks balance Mkd Salzlösung, M5-Medien oder Kochsalze. Alternativ können Proben gekühlt (2-8 °C) oder bei Raumtemperatur (15-30 °C) in einem sauberen, trocknen und geschlossenen Behälter bis zu 8 Stunden vor dem Test gelagert werden.

【Probenvorbereitung】
1. Reißen Sie die Aluminiumfolie des Extraktionsröhrchen ab und legen Sie es auf den Arbeitsplatz.
2. Führen Sie den Tupfer in das Extraktionsröhrchen ein, das das Reagenz enthält. Drehen Sie den Tupfer mindestens 10-mal, während Sie den Tupfer gegen den Boden und die Seite des Extraktionsröhrchen drücken.
3. Drücken Sie das Extraktionsröhrchen mit den Fingern und rollen Sie den Tupferkopf gegen die Innenseite, so dass beim Entfernen so viel Flüssigkeit wie möglich freigegeben wird. Die extrahierte Lösung wird als Probe verwendet.
4. Setzen Sie die Tropfspitze fest auf das Probenextraktionsröhrchen.
5. Geben Sie vier Tropfen der Lösung (ca. 100uL) in die Testkassette und starten Sie dann die Stoppuhr. Die Ergebnisse sollten innerhalb von 13-15 Minuten abgelesen werden.



【Interpretation der Testergebnisse】
1. Positiv: Zwei rote Linien erscheinen an der T-Linie und der C-Linie. Es zeigt an, dass das COVID-19-Antigen in der Probe nachgewiesen wird. Das bedeutet, dass der Patient sich möglicherweise in einem frühen Stadium der Infektion befindet oder derzeit infiziert ist. Die endgültige Bestätigung sollte mit klinischen Symptomen kombiniert werden.
2. Negativ: Im Erkennungsfenster wird nur eine rote Qualitätskontrolllinie (C-Linie) angezeigt. Es zeigt an, dass in der Probe kein COVID-19-Antigen nachgewiesen werden konnte.
3. Ungültiges Ergebnis: Das Kontrollfenster hat keinen roten Streifen. Führen sie den Test ein weiteres
Mal durch und folgen sie genau den entsprechenden Anweisungen. Wenn das Testergebnis immer noch ungültig ist, wenden Sie sich bitte an den örtlichen Lieferanten oder den Kundendienst unseres Unternehmens.

【Einschränkungen der Testmethode】
1.Dieses Produktinspektionsergebnis dient nur als klinische Referenz und sollte nicht als einzige Grundlage für die klinische Diagnose und Behandlung dienen. Das klinische Management von Patienten sollte mit seinen Symptomen oder Anzeichen, anderen Anamnesen und Laboruntersuchungen, dem Ansprechen auf die Behandlung und epidemiologischen Informationen wie der umfassenden Betrachtung kombiniert werden.
2.Aufgrund der methodischen Beschränkungen von Antigen-Nachweisreagenzien liegt die Minimumnachweisgrenze (Analyseempfindlichkeit) im Allgemeinen unter der von Nukleinsäurereagenzien. Daher sollten Experimentatoren negativen Ergebnissen mehr Aufmerksamkeit schenken. Andere Testergebnisse müssen auch berücksichtigt werden, um

ein umfassendes Urteil zu fällen. Es wird empfohlen, Nukleinsäuretests oder Methoden zur Virusisolierung und Kulturidentifizierung zu verwenden, um negative Ergebnisse im Zweifelsfall zu überprüfen.
3.Analyse falscher negativer Ergebnisse:
a.Unangemessene Probenentnahme, -transport und -behandlung, sowie zu geringe Virus Tröpfchen in der Probe.können zu falschen negativen Ergebnissen führen.
b.Genetische Variationen im Virus können zu Veränderungen der Antigendeterminanten führen, was zu falschen negativen Ergebnissen führt, die mit größerer Wahrscheinlichkeit bei monoklonalen Antikörperreagenzien auftreten.
c.Bei einem neu auftretenden, neuartigen Ausbruch des neuen Coronavirus werden der optimale zu testende Probentyp und die optimale Probeentnahmezeit nach der Infektion (maximaler Virustiter) möglicherweise nicht bestätigt, sodass mehrere Proben an mehreren Stellen desselben Patienten die Möglichkeit verringern falsche negative Ergebnisse zu erhalten.

【Leistungsmerkmale】
1.Das Erscheinungsbild ist flach, das Material ist fest angebracht, der Inhalt ist vollständig, die Verpackung ist intakt und unbeschädigt. Die Kennzeichen sind klar und identifizierbar. Der Probenextrakt weist keine sichtbaren Verunreinigungen auf.
2.Die Bewegungsgeschwindigkeit des Probenverdünnungsmittels ≥ 10 mm pro Minute.
3.Konformitätsrate von Produkten zur positiven Qualitätskontrolle: Inspektion von 5 positiven Qualitätskontrollprodukten, P1 ～ P5 Corona-Virus (COVID-19) Antigen muss positiv sein, die Konformitätsrate zur positiven internen Qualitätskontrolle sollte 5/5 (+ / +) betragen.
4.Konformitätsrate von Produkten mit negativer Qualitätskontrolle: Inspektion von 10 Produkten mit negativer Qualitätskontrolle, N1 ～ N10 Corona-Virus (COVID-19) Antigen muss negativ sein, die Konformitätsrate mit negativer interner Qualitätskontrolle sollte 10/10 (- / -) betragen.
5.Minimale Nachweisgrenze: Referenzprodukt für die niedrigste Nachweisgrenze des Testers, S1 ～ S5: S1 ～ S4 erfordert, dass das Coronavirus (COVID-19) --Antigentests positiv ist und S5 erfordert, dass alle Coronavirus-Antigenetests (COVID-19) negativ sind.
6.Wiederholbarkeit: Tester macht 2 Kopien des Referenzprodukts. Die Teste wurden jeweils 10-mal wieder geprüft, und die Testergebnisse waren alle positiv.
7.Die Kreuzreaktion des Erregers: Es findet keine Reaktion mit dem Grippe-A-Virus und dem Grippe-B-Virus statt.

【Leistungsdiagnostik】
Die Leistung des Kits wurde an Patienten mit Verdacht auf COVID-19 ermittelt, die zwischen März 2020 und Januar 2021 während der täglichen klinischen Praxis im National CDC von Hunan und Shenyang Sixth People's Hospital (China) entnommen wurden. Die Proben wurden von qualifiziertem Personal entnommen.
Von 500 Patienten wurde ein Nasopharyngealabstrich für die molekulare Diagnose mittels RT-PCR für den Antigen-Schnelltest entnommen. Das Kit zeigte eine diagnostische Sensitivität von 96 % und eine diagnostische Spezifität von 99 % im Vergleich zu den RT-PCR-Ergebnissen.

Ergebnisse der klinischen Leistung			
CoronaVirus (COVID-19) Antigen	PCR Komparator		Insgesamt
	Positiv	Negativ	
Positiv	96	4	100
Negativ	4	396	400
Insgesamt	100	400	500

Positive Percent Agreement (PPA)= 96/100(96%) （95%CI: 90.07%-98.9%）
Negative Percent Agreement (NPA)= 396/400 (99%) （95%CI:97.46%-99.73%）

Von 400 Patienten wurde ein Nasenabstrich für die molekulare Diagnose mittels RT-PCR für den Antigen-Schnelltest entnommen. Das Kit zeigte eine diagnostische Sensitivität von 95.24 % und eine diagnostische Spezifität von 98.18 % im Vergleich zu den RT-PCR-Ergebnissen.

Corona Virus (COVID-19) Antigen	PCR Komparator		Insgesamt
	Positiv	Negativ	
Positiv	120	5	125
Negativ	6	269	275
Insgesamt	126	274	400

Positive Percent Agreement (PPA)= 120/126(95.24%) （95%CI: 89.92%~98.23%）
Negative Percent Agreement (NPA)= 269/274 (98.18%) （95%CI:95.79%~99.41%）

1.Untersuchung der Interferenz
Die folgenden Substanzen wurden in der angegebenen Konzentration untersucht, es gibt keine Interferenzen.

OTC Throat drop (Halls)	15%	Budesonide	2 mg/mL
OTC Throat drop (Ricola)	15%	Menthol	10 mg/mL
OTC Nasal spray (Afrin)	15%	Mucin	10μg/mL
OTC Nasal spray (VicksSinex)	15%	Mometasone	1 mg/mL
Acetyl salicylic acid	10mg/mL	lbuprofen	3 mM
Acetaminophen	15mg/mL	Flunisolide	120μg/mL
Afrin Nasal Spray (Oxymetazoline）	4%（v/v）	Tobramycin	80μg/mL
Sodium Cromoglycate	12 mg/mL	Fluticasone	0.4ng/mL
Whole Blood	5%（v/v）	Ritonavir	8.0mg/mL
Chlorpheniramine	5 mg/mL	Abidor	420mg/mL
maleate Dexamethason	1 mg/mL	Peramivir	1.0mmol/L
Doxycycline hyclate	50μM	Quinine	150μM

2.Kreuzreaktionen
Es gibt keine Kreuzreaktion und Interferenz mit den nachstehend aufgeführten potenziellen kreuzreagierenden Mikroorganismen.

MERS-Coronavirus	Florida/USA-2_Saudi Arabia_2014	5 x 10^4 TCID50/ml
Influenza A	H1N1 Denver	2 x 10^5 TCID50/ml
	H1N1 WS/33	1.5 x 10^5 TCID50/ml
	H1N1 Pdm-09	2 x 10^5 TCID50/ml
	H1N1 New Caledonia	1 x 10^5 TCID50/ml
	H1N1 New jersey	2 x 10^5 TCID50/ml
Influenza B	Nevada/03/2011	2 x 10^5 TCID50/ml
	B/Lee/40	5 x 10^5 TCID50/ml
	B/Taiwan/2/62	1 x 10^5 TCID50/ml
Human Coronavirus	229E	1 x 10^5 TCID50/ml
	OC43	1 x 10^5 TCID50/ml
	NL63	1 x 10^5 TCID50/ml
Respiratory syncytial virus	Type A	1 x 10^5 TCID50/ml
	Type B	1 x 10^5 TCID50/ml
Human Metapneumovirus (hMPV)	hMPV 3 Type B1 / Peru2-2002	1 x 10^5 TCID50/ml
	hMPV 16 Type A1 / IA10-2003	1 x 10^5 TCID50/ml
Parainfluenza virus	Type 1	1 x 10^5 TCID50/ml
	Type 2	1 x 10^5 TCID50/ml
	Type 3	1 x 10^5 TCID50/ml
	Type 4A	1 x 10^5 TCID50/ml
Rhinovirus	A16	1 x 10^5 TCID50/ml
	Type B42	1 x 10^5 TCID50/ml
Enterovirus	Type 68	1 x 10^5 TCID50/ml
	(09/2014 isolate 4)	1 x 10^4 TCID50/ml
Mycobacterium tuberculosis	K	1 x 10^4 TCID50/ml
	Erdman	1 x 10^4 TCID50/ml
	HN878	1 x 10^4 TCID50/ml
	CDC1551	1 x 10^4 TCID50/ml
	H37Rv	1 x 10^4 TCID50/ml

Neuartiger monoklonaler Coronavirus-Antikörper ist ein Protein, das das Nucleocapsid-Protein erkennt und genetische Varianten von Stämmen nachweisen kann

【Vorsichtsmaßnahmen】

1.Der Test sollte nur bei Raumtemperatur durchgeführt werden, da extreme Temperaturen die Genauigkeit der Ergebnisse beeinträchtigen kann.
2.Die durch den Schnelltest erhaltenen positiven Ergebnisse sollten durch andere Methoden bestätigt werden.
3.Der Schnelltest sollte versiegelt und an einem trockenen Ort aufbewahrt werden. Der Tupfer sollte so bald wie möglich nach dem Herausnehmen aus der Verpackung genutzt werden. Vermeiden Sie es, ihn zu lange in die Luft zu legen, da dies zur Verfälschung der Ergebnisse aufgrund von Feuchtigkeit führen kann.
4.Die Tiefe der Testlinienfarbe hängt nicht unbedingt mit dem Antigen in der Probe zusammen. Die Interpretation des Ergebnis nach 15 Minuten ist ungültig.
5.Wenn der COVID-19-Antigengehalt in der Probe sehr hoch ist, kann die C-Linienzone geschwächt sein, was ein normales Phänomen ist.
6.Die Ergebnisse des Schnelltests dienen nur als klinische Referenz und sollten nicht die einzige Grundlage für die klinische Diagnose und Behandlung sein.
7.Benutzte Proben und Tests sollten als potenzielle Infektionserreger behandelt werden.
8.Die Auftrittszeit der Kontrolllinie sollte nicht als Zeitbasis für die Beurteilung der Ergebnisse der Testlinie herangezogen werden. Die Ergebnisse der Farbwiedergabe sollten innerhalb einer Frist von 13 bis 15 Minuten beobachtet und beurteilt werden.
9.Der Schnelltest wird nur für die In-vitro-Diagnose verwendet.
10.Dieses Produkt muss von professionell geschultem Personal bedient werden, z. B. von medizinischem Personal mit klinischer Erfahrung.

Hoyotek Biomedical Co., Ltd.
Floor 4, Zone C, Workshop No.1, Basis für chinesische Zivilluftfahrt der Wissenschaft, Technologie und Industrialisierung, No. 225, Jinger Road, Tianjin Wirtschaftszone am Flughafen. 300308 Tianjin China.

QAdvis EAR AB
Ideon Science Park
Scheelevägen 17, SE-223 70 Lund, Sweden

【Symbolindex】

	Zum Einmalgebrauch	IVD	Nur zur In-Vitro-Diagnose
	Bei 2-30℃ lagern		Vor Nutzung Packungsbeilage lesen
	Zu verbrauchen bis	LOT	Chargennummer
	Bei Verpackungsbeschädigung nicht benutzen	Σ	Enthält ausreichend Utensilien für <n> Tests
	Von Sonnenlicht fernhalten		Trocken halten
	Herstellungsdatum		Hersteller
EC REP	Benannte Stelle		

Versionsnummer: 04

Datum des Inkrafttretens: 3. Dezember, 2021

Hoyotek®

CE

Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold) Instruction for use (ONLY FOR PROFESSIONAL USE)

【Product name】
Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)
【Model code】
HYT-G01-01: Nasal/ Nasopharyngeal swab
【Packing specification】
HYT-G01-01: 30 Tests/ box, 1 Test/ box

【Intended use】
The COVID-19 Antigen Rapid Test Kit (Swab) intended for qualitative detection of nucleocapsid protein antigen in direct nasal or nasopharyngeal swab specimens from the human body. It is only used as a supplementary test for the nucleic acid test of novel coronavirus or in cooperation with nucleic acid test in suspected cases. It cannot be used as a basis for the diagnosis and exclusion of pneumonia caused by novel coronavirus infection and is not suitable for general screening. For medical institution use only, and biosecurity protection should be done in laboratory when testing of novel coronavirus. The results of this kit are only for clinical reference. If the test result is positive, further confirmation is needed. If the test result is negative, the possibility of infection cannot be excluded. Comprehensive analysis of the patient's condition should be carried out in combination with clinical symptoms and other laboratory tests.

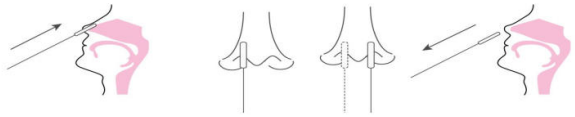
【Test principle】
The COVID-19 Antigen Rapid Test is a lateral flow immunoassay based on the principle of double antibody sandwich technology and the colloidal gold method. The SARS-CoV-2 nucleocapsid protein monoclonal antibody conjugated with colored microparticles is used as a detector and sprayed onto the conjugation pad. During the test, the SARS-CoV-2 antigen in the sample, if present, interacts with the SARS-CoV-2 antibody conjugated with colored microparticles, forming an antigen-antibody-labeled complex. This complex migrates via capillary action on the membrane to the test line, where it is captured by the pre-coated monoclonal SARS-CoV-2 nucleocapsid protein antibody. A colored test line (T) is visible in the results window. The absence of the T-line indicates no SARS-CoV-2 antigen in the sample or a negative result. The control line (C) is used as a procedural control and should always be displayed when the test procedure is being carried out properly.

【Product components】

Components	Packing Specifications		Material
	1 test/box	30 tests/box	
Corona Virus (COVID-19) Antigen Rapid Test Card	1 bag	30 bags	Colloidal gold labeled mouse anti-Corona Virus (COVID-19) nucleocapsid protein monoclonal antibody; Mouse anti-Corona Virus (COVID-19) nucleocapsid protein monoclonal antibody; Goat anti-mouse polyclonal antibody;
Sample extraction solution and swab	0.5ml ×1 bottle	0.5ml ×30 bottles	Na_2HPO_4, NaH_2PO_4, NaCl, $C_{58}H_{114}O_{26}$

【Storage conditions and expiry date】
1.Storage between 2-30 ℃, keep away from light, valid for 12 months.
2.The product should be stored in dry condition under 2-30 ℃ and kept away from direct light. Under the condition of 18-30 ℃, the humidity is below 60. Therefore, the product has to be used within 1 hour after opening. If the Humidity is above 60%, it should be used immediately.
3.Production date and validity period are shown in the label.

【Specimen collection and handling】
Specimen Collection
• Inadequate specimen collection or improper specimen handling may yield a false result.
• Prior to collecting the nasal swab, the patient should be instructed to blow their nose.
• Nasal Swabbing:
1. Insert the entire soft end of the swab into the nostril, about up to 2.5 cm (1 inch) from the edge of the nostril.
2. Slowly rotate the swab 5 times over the surface of the nostril to ensure that both mucus and cells are collected.
3. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
4. Slowly remove the swab from the nostril while rotating it.



Nasopharyngeal Swabbing:

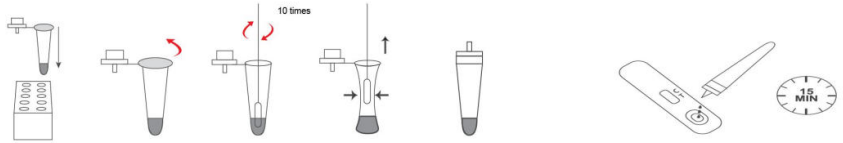
1. Tilt the patient's head back approximately 70 degrees.
2. Gently and slowly insert the swab into the patient's nostril until it reaches the posterior nasopharynx.
3. Gently keep pushing the swab until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.
4. Gently rotate the swab for 3-5 times.
5. Leave the swab in place for several seconds to absorb secretions.
6. Slowly remove swab while rotating it.

• Specimens Transport and Storage:

Specimens should be tested as soon as possible. If transport of the samples is required, the following transport media are recommended, which have been tested and shown not to interfere with the performance of the test: Hank's balance Mkd salt solution, M5 media, or saline. Alternatively, samples may be stored refrigerated (2-8 ℃) or at room temperature (15-30℃) in a clean, dry and closed container for up to 8 hours before testing.

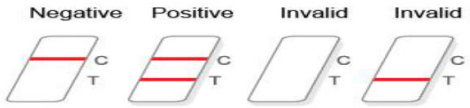
【Specimen Preparation】

1. Tear off the aluminum foil of the extraction tube and put it on the workstation.
2. Insert the swab into the extraction tube which contains buffer. Rotate the swab at least 10times while pressing the swab against the bottom and side of the extraction tube.
3. Pinch the extraction tube with fingers and roll the swab head against the inside of the Extraction tube when you remove it to release as much liquid as possible. The extracted solution will be used as test specimen.
4. Insert a dropper tip into the specimen extraction tube tightly.
5. Add four drops of the solution (approx. 100 uL) into the test cassette and then start the timer. Result should be read at 13-15 minutes.



【Interpretation of assay result】

1. Positive: Two red lines appear at T-line and C-line. It indicates that COVID-19 antigen is detected in the sample, the patient may be in early stage of infection or is currently infected. The final confirmation should be combined with clinical symptoms.
2. Negative: Only one red quality control line (C) appears in the detection window. It indicates that no COVID-19 antigen is detected in the sample.
3. Invalid results：The control window has no red stripe. If you get an invalid result, please repeat the test again, in strict accordance with the instructions. If the test result is invalid again, please contact local suppliers or customer service with our company for technical consultation.



【Limitations of the test method】

1. This product inspection result is only for clinical reference and should not serve as the only basis for clinical diagnosis and treatment. The clinical management of patients should be combined with its symptoms or signs, other medical history and laboratory examination, treatment response and epidemiological information such as the comprehensive consideration.
2. Due to the methodological limitations of antigen detection reagents, the minimum detection limit (analytical sensitivity) is generally below that of nucleic acid reagents. Therefore, experimenters should pay more attention to negative results. Other test results must also be considered in order to make a comprehensive judgment. It is recommended that nucleic acid tests or virus isolation and culture identification methods be used to verify negative results when in doubt. Analysis of t possibility of wrong negative results:
   (a) Improper sampling, transport and treatment, and insufficient virus droplets in samples may lead to false negative resul
   (b) Genetic variation in the virus may lead to changes in antigenic determinants, resulting in false negative results, whi are more likely to occur with monoclonal antibody reagents.
   (c) For an emergent novel Corona virus, the optimal type of sample to be tested and the optimal sampling time af infection (peak viral titer) may not be confirmed. Therefore, multiple sampling at multiple sites in the same patient w reduce the possibility of false negative results.

【Product performance indicator】

1. Smooth appearance, solid material attachment, complete contents, complete packaging no damage, clearly identifiable signs, no visible impurities were found in the sample extract.
2. The moving speed of sample diluent≥10mm per minute.
3. Compliance rate of positive quality control products: inspection 5 positive quality control products, P1～P5 Corona Virus (COVID-19) Antigen is required to be positive; the positive internal quality control compliance rate should be 5/5 (+/+).
4. Compliance rate of negative quality control products: inspection of 10 negative quality control products, N1～N10 Corona Virus (COVID-19) Antigen is required to be negative; the negative internal quality control compliance rate should be 10/10 (-/-).
5. Minimum detection limit: the minimum detection limit of quality control products S1-S5, S1～S4 Corona Virus (COVID-19) Antigen test results should be positive, S5 Corona Virus (COVID-19) Antigen test results should be negative.
6. Repeatability: test 2 internal repeatability quality control products, each test for 10 times, test results should be positive.
7. The cross reaction of the pathogen: there is no reaction with Flu A virus and Flu B virus.

【Diagnostic performance】

The performance of the kit was tested on samples from patients with suspected COVID-19 taken between March 2020 and January 2021 during daily clinical practice at the Hunan CDC and Shenyang Sixth People's Hospital (China). The samples were taken by qualified personnel.

500 nasopharyngeal swab samples were taken for molecular diagnosis using RT-PCR for the rapid antigen test. The test was shown to have 96 % diagnostic sensitivity and 99 % diagnostic specificity compared with the RT-PCR results.

Clinical Study Results			
Corona Virus (COVID-19) Antigen	PCR Comparator		Sub total
	Positive	Negative	
Positive	96	4	100
Negative	4	396	400
Sub total	100	400	500

Positive Percent Agreement (PPA)= 96/100(96%) （95%CI: 90.07%~98.9%）
Negative Percent Agreement (NPA)= 396/400 (99%) （95%CI:97.46%~99.73%）

400 nasal swab samples were taken for molecular for molecular diagnosis using RT-PCR for the rapid antigen test, The test was shown to have 95.24 % diagnostic sensitivity and 98.18 % diagnostic specificity compared with the RT-PCR results.

Corona Virus (COVID-19) Antigen	PCR Comparator		Sub total
	Positive	Negative	
Positive	120	5	125
Negative	6	269	275
Sub total	126	274	400

Positive Percent Agreement (PPA)= 120/126(95.24%) （95%CI: 89.92%~98.23%）
Negative Percent Agreement (NPA)= 269/274 (98.18%) （95%CI:95.79%~99.41%）

1. Interference experiment

The following substances were tested at the concentration shown, and no interference was found.

OTC Throat drop (Halls)	15%	Budesonide	2 mg/mL
OTC Throat drop (Ricola)	15%	Menthol	10 mg/mL
OTC Nasal spray (Afrin)	15%	Mucin	10μg/mL
OTC Nasal spray (VicksSinex)	15%	Mometasone	1 mg/mL

Acetyl salicylic acid	10mg/mL	Ibuprofen	3 mM
Acetaminophen	15mg/mL	Flunisolide	120μg/mL
Afrin Nasal Spray (Oxymetazoline)	4%（v/v）	Tobramycin	80μg/mL
Sodium Cromoglycate	12 mg/mL	Fluticasone	0.4ng/mL
Whole Blood	5%（v/v）	Ritonavir	8.0mg/mL
Chlorpheniramine	5 mg/mL	Abidor	420mg/mL
maleate Dexamethason	1 mg/mL	Peramivir	1.0mmol/L
Doxycycline hyclate	50μM	Quinine	150μM

2. Cross-reactivity

There was no cross-reaction and interference with the potential cross-reacting microorganisms listed below:

MERS-Coronavirus	Florida/USA-2_Saudi Arabia_2014	5 x 10^4 $TCID_{50}$/ml
Influenza A	H1N1 Denver	2 x 10^5 $TCID_{50}$/ml
	H1N1 WS/33	1.5 x 10^5 $TCID_{50}$/ml
	H1N1 Pdm-09	2 x 10^5 $TCID_{50}$/ml
	H1N1 New Caledonia	1 x 10^5 $TCID_{50}$/ml
	H1N1 New jersey	2 x 10^5 $TCID_{50}$/ml
Influenza B	Nevada/03/2011	2 x 10^5 $TCID_{50}$/ml
	B/Lee/40	5 x 10^5 $TCID_{50}$/ml
	B/Taiwan/2/62	1 x 10^5 $TCID_{50}$/ml
Human Coronavirus	229E	1 x 10^5 $TCID_{50}$/ml
	OC43	1 x 10^5 $TCID_{50}$/ml
	NL63	1 x 10^5 $TCID_{50}$/ml
Respiratory syncytial virus	Type A	1 x 10^5 $TCID_{50}$/ml
	Type B	1 x 10^5 $TCID_{50}$/ml
Human Metapneumovirus (hMPV)	hMPV 3 Type B1 / Peru2-2002	1 x 10^5 $TCID_{50}$/ml
	hMPV 16 Type A1 / IA10-2003	1 x 10^5 $TCID_{50}$/ml
Parainfluenza virus	Type 1	1 x 10^5 $TCID_{50}$/ml
	Type 2	1 x 10^5 $TCID_{50}$/ml
	Type 3	1 x 10^5 $TCID_{50}$/ml
	Type 4A	1 x 10^5 $TCID_{50}$/ml
Rhinovirus	A16	1 x 10^5 $TCID_{50}$/ml
	Type B42	1 x 10^5 $TCID_{50}$/ml
Enterovirus	Type 68	1 x 10^5 $TCID_{50}$/ml
	(09/2014 isolate 4)	1 x 10^4 $TCID_{50}$/ml
Mycobacterium tuberculosis	K	1 x 10^4 $TCID_{50}$/ml
	Erdman	1 x 10^4 $TCID_{50}$/ml
	HN878	1 x 10^4 $TCID_{50}$/ml
	CDC1551	1 x 10^4 $TCID_{50}$/ml
	H37Rv	1 x 10^4 $TCID_{50}$/ml

Novel Coronavirus Monoclonal Antibody is a protein that recognizes nucleocapsid protein and can detect genetic variants of strains.

【Cautions】

1.The test should only be performed at room temperature, as extreme temperatures canaffect the accuracy of the results.
2.The positive samples obtained by the rapid test should be confirmed by other methods.
3.The rapid test should be sealed and kept in dry place. The test cassette should be tested as soon as possible after removal from the packaging. Avoid placing it in the air for too long due to moisture.
4.The deepness of the test line color is not necessarily associated with the titer of the antigen in the sample. The interpretation of the result after 15 minutes is invalid.
5.When COVID-19 antigen content in the sample is very high, the C-line zone may be weakened, which is a normal phenomenon.
6.The results of rapid test are only for clinical reference and should not be the only basis for clinical diagnosis and treatment.
7.Waste samples and test should be treated as potential infectious agents.
8.The appearing time of the Control Line should not be taken as the time basis for judging the results of test line. The color rendering results should be observed and judged within a time limit of 13-15 minutes.
9.The rapid test is only used for in vitro diagnosis.
10.This product must be operated by professionally trained personnel, such as medical staff with clinical experience.

Hoyotek Biomedical Co., Ltd.
Floor 4, Zone C, Workshop No.1, China civil Aviation science and technology industrialization base No. 225, Jinger Road, Tianjin Airport Economic Zone. 300308 Tianjin China.

EC REP QAdvis EAR AB
Ideon Science Par
Scheelevägen 17, SE-223 70 Lund, Sweden

【Index of symbol】

	Do not reuse		For in vitro diagnostic use only
	Store between 2-30℃		Consult instructions for use
	Use by		Lot number
	Do not use if package is damaged		Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturing date		Manufacturer

6. Clinical evaluation report

Clinical evaluation report

Company Name: Hoyotek Biomedical Co., Ltd.

Packing specification: 30 tests/box

Company Address: Floor 4, Zone C, Workshop No.1, China civil Aviation science and technology industrialization base No. 225, Jinger Road, Tianjin Airport Economic Zone.

Product Name: Corona Virus (COVID-19) antigen Rapid Test (Colloidal gold)

Clinical evaluation place: the National CDC of Hunan and Shenyang Sixth People's Hospital

Start date: Mar 10, 2020

End date: January 19, 2021

Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease (COVID-19), which is contagious in humans. SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N). The antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease Perform clinical evaluation of the Corona Virus (COVID-19) antigen Rapid Test (Colloidal gold) to determine its diagnostic sensitivity and specificity.

Detection principle

The product is based on the principle of sandwich and colloidal gold immunochromatography, the nitrocellulose membrane Test Zone is pre-coated with mouse anti-Corona Virus (COVID-19) monoclonal antibody, the Control Zone is pre-coated with goat anti-mouse polyclonal antibody, the gold conjugation pad is pre-coated with colloidal gold labeled mouse anti-Corona Virus (COVID-19) monoclonal antibody. When testing positive samples, COVID-19 Antigen the sample will be combined with colloidal gold (Au) labeled mouse anti-Corona Virus (COVID-19) monoclonal antibody and form into immune complexes (Au-mouse anti-Corona Virus (COVID-19) monoclonal antibody-[COVID-19-(Antigen)]), the complexes will move forward inside the nitrocellulose membrane by chromatography effect. When reaching Test Zone, the complexes will be combined with mouse anti-Corona Virus (COVID-19) monoclonal antibody, and form into "(Au-mouse anti-Corona Virus (COVID-19) monoclonal antibody-[COVID-19- (Antigen)])-[mouse anti-Corona Virus (COVID-19) monoclonal antibody]", thus agglutination color appears; The residual colloidal gold labeled mouse anti-Corona Virus (COVID-19) monoclonal antibody will be combined with goat anti-mouse polyclonal antibody at the Control Zone, and produce color under agglutination. When testing negative samples, there's no COVID-19 Antigen in the samples, no immune complexes will be formed and color only appears in the Control line.

Purpose

Perform clinical evaluation of the Corona Virus (COVID-19) antigen Rapid Test (Colloidal gold) to determine its diagnostic sensitivity and specificity.

Testing management

During the trial, the main investigator is responsible for the coordination and management of the entire clinical trial, and the main participants are responsible for the main trial work. During the clinical trial, the main researcher supervises the quality control of the testing laboratory. Any problems found in the test must be contacted with the main researcher in time and appropriate measures should be taken. The final test results are statistically analyzed by the person in charge of statistics, and the main investigator confirmed and wrote the report.

Methods

Synchronous blind test and methodological comparison design. The Nasopharyngeal swab and oropharyngeal swab samples and saliva samples were collected by hospital professional medical staff in accordance with the sampling methods of Corona Virus (COVID-19) antigen Rapid Test (Colloidal gold) and Sansure Biotech Inc novel coronavirus detection kit. The Nasopharyngeal swab and oropharyngeal swab samples are blindly numbered and grouped by the National CDC of Hunan and Shenyang Sixth People's Hospital. Nasopharyngeal swab samples are divided into one group, saliva samples are divided into one group, oropharyngeal swab samples are divided into one group, and then tested by laboratory inspectors

Discussion and Conclusion

Results

In this clinical trial, Nasopharyngeal swab specimens were obtained from e National CDC of Hunan and Shenyang Sixth People's Hospital and tested with the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) and the comparator device Sansure Biotech Inc novel coronavirus detection kit produced. Statistical analysis was performed to calculate the positive agreement rate and negative agreement rate.

In this study, The Corona Virus (COVID-19) antigen Rapid Test (Colloidal gold) produced by Hoyotek has a diagnostic sensitivity of 96% for detecting Nasopharyngeal swabs, 93% for detecting oropharyngeal swab, 91% for detecting Saliva. The diagnostic specificity of 99% for detecting Nasopharyngeal swabs, 97.5% for detecting oropharyngeal swab, and 97.3% for detecting Saliva.

The results showed that the investigational device, the Antigen Rapid Test Kit (Colloidal Gold), meets the needs of clinical testing.

Main Content

General design

This test uses a synchronous blind test and methodological comparison design. In order to eliminate the possible impact of the subjective biases and personal preferences of researchers on the test results during the clinical trial process, this test uses a blind test. That is, the test personnel in this test do not know the specific information of the sample, and the clinical information of the sample may not be released until the end of the test. After the samples were enrolled, the samples were coded by the blind editor authorized by the clinical trial, in which the blind editor was not involved in the test operation of the clinical trial. Testing personnel shall test the coded sample according to the reagent test specification. In the process of test operation, clinical test researchers should strictly follow the requirements of the product specification for test operation and interpretation check, and the results obtained in the test process should be truthfully recorded in the data collection table.

For the detection of SARS-CoV-2 Antigen, the Nasopharyngeal swab and r oropharyngeal swab samples were collected by hospital professional medical staff in accordance with the sampling methods of Corona

Virus (COVID-19) antigen Rapid Test (Colloidal gold) and Sansure Biotech Inc novel coronavirus detection kit. he Nasopharyngeal swab and oropharyngeal swab samples are blindly numbered and grouped by the National CDC of Hunan and Shenyang Sixth People's Hospital. Nasopharyngeal swab samples are divided into one group, saliva samples are divided into one group, oropharyngeal swab samples are divided into one group, and then tested by laboratory inspectors.

Measures to reduce and avoid bias

Subjects were screened strictly according to the blind grouping of the clinical trial protocol to reduce the selection bias.

Prior to the start of the trial, the lab operators were trained to correctly perform the tests and follow the trial protocol.

Clinical sample related requirements

1) DOs and DON'Ts of Sample Collection

• Do test sample immediately

• Use only swabs provided with the kit.

2) Sample storage

• Specimen Transport and Storage

• Freshly collected specimens should be processed within 1 hour, or stored at the manufacturer's recommended condition before testing.

• It is essential that correct specimen collection and preparation methods be followed.

Clinical sample selection

1) Inclusion criteria

Sample inclusion criteria: the sample should be a sample with clearly recorded source, including different age, gender and other factors. The collection and treatment of samples are in accordance with the reagent specification or relevant regulations. Sample information should be complete, including age, sex, sample collection date, clinical diagnosis such as confirmation or exclusion of SARS-CoV-2 infection.

2) Exclusion criteria

➢ Samples that are unable to complete the test process human factors (sample contamination during operation).

➢ Samples were contaminated with bacteria or/and nosebleed.

➢ Samples went through too many freeze-thaw cycles.

➢ Samples not kept at the requirement conditions.

➢ Samples that are unable to yield control signals with PCR reagent.

Quality control

Definition

Quality control is defined as the operation of techniques and activities, such as monitoring, under the quality assurance system to verify that the research quality meets the requirements. Quality control must be applied at every stage of data processing to ensure that all data is trusted and properly located.

1）Study monitoring

During the outbreak, authorized and qualified inspectors will conduct regular remote 6 primary data checks according to the monitoring plan to verify compliance with protocols and regulations and assist investigators.

2）Laboratory quality control

The laboratory of the testing shall establish a unified test index, standard operating procedures and quality control procedures.

3）Quality control of reagent testing process In each test, the control line shall have red strip (qualified quality control). If the control line does not have red strip (unqualified quality control), the cause shall be found out and retested until the quality control result is qualified, so as to ensure the reliability and stability of the system.

4）Qualification of researchers The researchers participating in the clinical trial must have the specialty, qualification and ability of the clinical trial, and pass the qualification examination. The personnel requirements should be relatively fixed.

Reagents and instruments for clinical research

The information of reagents for test is shown in Table 1:

Table 1 Reagent Information

S/N	Sample Name	Size	Lot No.	Company
1	Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)	30/box	20201001	Hoyotek

Determination of results: Operate according to the instructions. After the test, observe the color reaction of colloidal gold on the T line and C line to determine the test result of the new coronavirus (COVID-19) antigen.

The nucleic acid background of all swab samples are the results of the new coronavirus nucleic acid detection reagent produced by Sansure Biotech Inc.

Clinical Trial Results and Analysis

Clinical diagnostic sensitivity of reagents

Table 2 Results of 100 cases of samples tested positive for COVID-19

	Nasopharyngeal swabs Number of positive	oropharyngeal swab Number of positive	Saliva Number of positive
Hoyotek antigen detection results	96	93	91

Test result: The Corona Virus (COVID-19) antigen Rapid Test (Colloidal gold) produced by Hoyotek have a diagnostic sensitivity of 96% for detecting Nasopharyngeal swabs,93% for detecting oropharyngeal swab, and 91% for detecting Saliva.

Diagnostic Specificity

Table 6 Results of 400 Nasopharyngeal /oropharyngeal swab samples with negative COVID-19 nucleic acid test

	Nasopharyngeal swabs Number of positive	oropharyngeal swab Number of positive
Hoyotek antigen detection results	396	390

The Corona Virus (COVID-19) antigen Rapid Test (Colloidal gold) produced by Hoyotek detects 400 cases nucleic acid negative Nasopharyngeal swabs with a diagnostic specificity of 99%, oropharyngeal swabs with a diagnostic specificity of 97.5%

Table 7 Results of 151 saliva samples with negative COVID-19 nucleic acid test

	Number of negative	Number of positive
Hoyotek antigen detection results	147	4

The Corona Virus (COVID-19) antigen Rapid Test (Colloidal gold) produced by Hoyotek detects 151 cases nucleic acid negative saliva with a diagnostic specificity of 97.3%.

Conclusion:

This clinical trial has performed a full analysis of the experimental reagents through methodological comparisons, and the results all meet the criteria for clinical evaluation. All the results showed that SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) meet the needs of clinical test.

1) Appendix 1

S/N	age	Gender	Types	collecti on date	ORF-Lab Scope-Fam CT Value	N gene-ROX CT Value	internal standard - HEX CT	clinical symptoms

							Value	
1	63	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	22.41	30.02	27.74	Serious
2	29	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	33.39	31.85	26.93	slight
3	25	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	31.24	31.72	29.08	slight
4	62	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	37.85	31.51	29.75	slight
5	77	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	31.81	33.13	25.07	slight
6	36	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	40.26	33.05	28.06	slight
7	55	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	20.79	35.67	26.67	slight
8	73	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	36.33	30.90	26.88	Serious
9	25	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	39.29	35.33	28.45	slight
10	20	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	33.26	31.35	29.31	slight
11	68	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	23.95	37.44	27.03	medium
12	69	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/11	23.72	31.68	28.77	slight
13	25	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/12	31.27	37.58	26.62	slight
14	50	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/12	28.01	33.17	28.84	slight
15	39	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/12	23.73	33.01	27.06	slight
16	61	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/12	39.00	31.71	29.08	Serious
17	28	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	32.76	38.51	25.22	medium
18	21	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	35.23	35.20	26.15	medium
19	43	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	22.53	37.71	29.12	slight
20	36	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	32.78	33.34	25.99	slight
21	52	Man	Nasopharyngeal	2020/3/	20.99	32.77	29.93	slight

			swabs/Oropharyngeal /saliva	13				
22	32	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	26.50	38.17	26.06	slight
23	25	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	31.75	34.33	27.51	medium
24	74	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	26.03	37.82	26.08	Serious
25	38	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	36.66	36.54	26.55	slight
26	21	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	31.31	31.55	25.17	slight
27	26	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	22.33	31.93	27.44	slight
28	26	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/13	36.41	37.92	27.28	slight
29	77	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	22.10	32.95	27.60	slight
30	29	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	21.21	30.47	28.35	slight
31	71	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	28.19	34.37	29.11	Serious
32	46	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	30.30	30.73	28.10	slight
33	57	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	22.76	31.04	25.90	slight
34	47	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	25.78	31.86	27.84	slight
35	52	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	30.04	34.92	25.88	slight
36	64	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	34.65	36.35	27.29	slight
37	48	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	39.48	38.91	27.63	slight
38	70	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	30.05	33.50	27.64	slight
39	61	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	27.18	33.45	28.48	medium
40	37	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/14	34.31	35.49	28.83	medium
41	25	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/15	23.95	38.06	29.85	medium
42	65	Woman	Nasopharyngeal	2020/3/	21.48	32.03	29.12	slight

			swabs/Oropharyngeal /saliva	15				
43	28	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/15	36.04	37.41	27.41	medium
44	56	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/15	37.45	36.29	29.73	slight
45	37	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/15	26.58	30.73	27.56	slight
46	60	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/15	28.40	31.13	25.30	medium
47	59	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/15	33.43	31.60	25.87	slight
48	34	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/15	28.21	31.55	26.89	slight
49	52	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/15	31.12	30.08	26.24	slight
50	67	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/15	27.30	32.33	27.28	slight
51	40	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/16	36.97	36.03	29.81	slight
52	40	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/16	26.68	38.15	27.21	slight
53	32	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/16	23.84	32.68	25.27	slight
54	31	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/18	23.57	31.87	29.80	slight
55	22	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/18	33.51	35.89	26.22	slight
56	57	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/18	38.63	30.13	29.33	slight
57	64	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/18	29.22	36.18	29.48	slight
58	46	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/18	34.23	31.87	26.28	medium
59	72	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/18	36.49	33.51	27.48	slight
60	27	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/18	38.41	32.73	26.08	medium
61	43	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/19	28.00	34.32	26.70	slight
62	35	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/19	26.50	35.62	27.07	slight
63	56	Woman	Nasopharyngeal	2020/3/	33.93	30.81	28.58	slight

			swabs/Oropharyngeal /saliva	19				
64	28	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/19	35.01	36.48	29.61	slight
65	23	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/20	20.45	36.22	25.21	medium
66	48	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/20	35.26	37.81	29.78	slight
67	31	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/20	21.84	36.38	25.69	slight
68	21	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/20	22.96	30.29	26.02	slight
69	28	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/20	26.19	38.33	25.46	slight
70	71	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/20	26.16	38.32	29.06	slight
71	46	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/20	32.88	37.66	28.91	slight
72	25	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/20	31.88	38.06	28.06	slight
73	51	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/21	23.99	36.61	27.81	medium
74	31	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/22	24.22	31.53	28.28	slight
75	37	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/22	22.18	33.66	25.19	slight
76	29	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/22	36.01	31.97	29.95	slight
77	20	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/22	39.52	30.48	25.91	slight
78	75	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/22	21.72	31.29	25.23	slight
79	62	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/22	36.51	34.46	28.05	slight
80	35	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/22	37.66	38.92	26.56	medium
81	60	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/22	33.17	35.72	28.40	slight
82	59	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/22	20.30	37.31	27.77	slight
83	22	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/22	39.77	38.09	29.43	slight
84	26	Woman	Nasopharyngeal	2020/3/	37.71	32.68	26.56	medium

			swabs/Oropharyngeal /saliva	23				
85	37	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	33.48	34.11	25.15	slight
86	35	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	39.43	37.81	27.50	slight
87	48	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	21.70	30.25	29.72	slight
88	27	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	27.75	31.96	25.28	slight
89	76	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	33.36	34.45	29.02	Serious
90	71	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	20.49	31.05	29.85	slight
91	35	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	20.06	30.28	27.85	slight
92	50	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	36.14	31.59	27.12	slight
93	24	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	34.77	30.46	28.85	slight
94	47	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	34.84	36.37	26.13	medium
95	60	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	20.69	35.48	28.94	medium
96	46	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	40.00	35.11	25.26	slight
97	33	Man	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	29.97	31.15	29.93	slight
98	31	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	37.78	35.38	27.53	medium
99	53	Woman	Nasopharyngeal swabs/Oropharyngeal /saliva	2020/3/23	29.20	38.22	26.89	slight
100	30	Woman	Oropharyngeal swabs	2020/3/23	26.96	35.66	27.90	slight