



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



Product description

- The product is used for the qualitative detection of the nucleocapsid antigen of Corona virus (COVID-19) by nasopharyngeal swabs.
- It is used only as a supplementary test for the novel coronavirus nucleic acid test or in combination with the nucleic acid test in suspected cases.
- The COVID-19 Rapid Antigen Test is intended for use by healthcare professionals or trained operators who are familiar with rapid antigen tests.









- OI) 30x Swab
- 30x Extraction liquid
- 30x Test cassettes
- 30x Tube
- 1x Instructions for use



Features





Nasopharyngeal swab

EN ISO 13485:2016 certified

Test location: Point of Care (without device)

Storage temperature : 2-30°C

Fast and reliable test results in 13-15 min

Federal Institute for Drugs and Medical Devices (BfArM)

listed



Sp∈cifity 99%



Sensitivity 96%



Rapid test results In I3 Min

For professional use

Individually packed





Corona Virus (COVID-19)Antigen Rapid Test (Colloidal Gold)

Gebrauchsanweisung (NUR FÜR DIE PROFESSIONELLE VERWENDUNG) Die Ergebnisse sollten innerhalb von 13-15 Minuten abgelesen werden

Verzeichnis:

Gebrauchsanweisung	Deutsch	1-3
Instruction for use	English	3-6
Instruction d'utilisation	Français	6-8
Instrucciones de uso	Espsnol	8-11
Istruzioni per l'uso	Italiaño	11-13

Instruction manual - 5 Languages



[Hauptbestandteile]			
Komponenten	Verpackungsspezififi kationen		Material
Komponenien	1 test/box	30 tests/box	Material
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 ₂ HPO ₄ , NaH ₂ PO ₄ , NaCl, C ₃₁ H ₁₃₄ O ₂₈

[Probensammlung und -handhabung]

cmachtmung wichende Probenentrahme oder unsachgemäße Probenhandhabung kann zu einem falschen Ergebnis führen. «m. Sanneln des Nasenabstrichs sollte der Patient angewiesen werden seine Nase zu putzen. mabstrich:

abstrich:
Sie den gesamten weichen Bereich des Tupfers in ein Nasenloch des Patienten. Der Tupfer sollte bis zu 2,5 cm ingeffähr werden (gemessen vom Rand des Nasenlochs). Sie den Tupfer 7-mal ontlang der Schleinhaut im Nasenloch, um sicherzustellen, dass sowohl Schleim als auch







CoronaVirus (COVID-19)	PCR Ke	enparator	Inspesamt
Antigen	Positiv	Negativ	magestint
Positiv	96	4	100
Negativ	4	396	400
Insgesamt	100	400	500

			PUR Komparator	
ı	Antigen	Positiv	Negativ	Insgesamt
ı	Positiv	120	5	125
ı	Negativ	6	269	275
П	Insgesamt	126	274	400
	Positive Percent Agreement	(PPA)= 120/126(95	24%) (95%CE 89.	92%-98.23%)

odium Cromoglyci Whole Blood

MERS-Coronavirus Florida/USA-2_Saudi Arabia_2014 5 x 10⁴ TCID50/ml

	H1N1 Denver	2 x 105 TCID50/ml
	H1N1 WS/33	1.5 x 10° TCID50/ml
Influenza A	H1N1 Pdm-09	2 x 10° TCID50/ml
	H1N1 New Caledonia	1 x 10° TCID50/ml
	H1N1 New jersey	2 x 105 TCID50/ml
	Nevada/03/2011	2 x 105 TCID50/ml
Influenza B	B/Lee/40	5 x 101 TCID50/ml
	B/Taiwan/2/62	1 x 10° TCID50/ml
	229E	1 x 10° TCID50/ml
Human Coronavirus	OC43	1 x 10° TCID50/ml
	NL63	1 x 105 TCID50/ml
Respiratory syncytial virus	Type A	1 x 105 TCID50/ml
Respiratory syncytial virus	Type B	1 x 105 TCID50/ml
Human	hMPV 3 Type B1 / Peru2-2002	1 x 10 ⁴ TCID50/ml
Metapneumovirus (hMPV)	hMPV 16 Type A1 / IA10-2003	1 x 105 TCID50/ml
	Type I	1 x 10° TCID50/ml
Parainfluenza virus	Type 2	1 x 10° TCID50/ml
	Type 3	1 x 10° TCID50/ml
	Type 4A	1 x 10° TCID50/ml
Rhinovirus	A16	1 x 105 TCID50/ml
Khinovirus	Type B42	1 x 105 TCID50/ml
Enterovirus	Type 68	1 x 105 TCID50/ml
Enterovirus	(09/2014 isolate 4)	1 x 104 TCID50/ml
	K	1 x 104 TCID50/ml
	Erdman	1 x 104 TCID50/ml
fycobacterium tuberculosis	HN878	1 x 104 TCID50/ml
	CDC1551	1 x 104 TCID50/ml
	H37Rv	1 x 10 ⁴ TCID50/ml



mperatur durchgeführt werden, da extreme Temperaturen die Genausigkeit der Ergebenisse

Hoyotek

Hoyotek Liber Tot steller are bit Ramintegerstätt derüglichten versenn, est extress supersonen tot.

Interestitation in Amerikaan der Setzeler gebuis nach 15 Minuten ist ungültig. Wenn der COVID-19-Antigengehalt in der Probe sehr hoch ist, kann die C-Linienzene geschwächt sein, was ein

Hoyotek Biomodical Co., Ltd.
Floor 4, Zone C, Werdshop No. I, Basis für chinesische Zivilluftfahrt der Wissenschaft, Technologie und
Industrialisierun. No. 225, Jimer Road, Tiarrim Wirtschaftbarene am Fluzhafen, 300008 Tiarrim China.

EC REP QAdvis EAR AB
Ideon Science Park
Scheelevägen 17, SE-223 70 Lund, Sweder

8	Zum Einmalgebrauch	IVD	Nur zur In-Vitro-Diagnose
1	Bei 2-30°C lagern	Πi	Vor Nutzung Packungsbeilage lesen
	Zu verbrauchen bis	LOT	Chargennummer
®	Bei Verpackungsbeschädigung nicht berutzen	∇	Enthält ausreichend Utensilien für <n> Tests</n>
类	Von Sonnenlicht fernhalten	*	Trocken halten
\sim	Herstellungsdatum	***	Hersteller
EC REP		Benarate Stel	lle



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

Components	Packing Specifications		Material	
2009/10031	1 test box	30 tests/bax		
Corona Virus (COVID-19) Antigen Rapid Test Card	1 bag	30 bags	Colleidal gold labeled means and Corona Virus (COVID-19) nucleocopied protein monoclosal are body; Means anti-Corona Virus (COVID-19) nucleocopied protein monoclosal antibody; Gost anti-monoclosal antibody;	
Sample extraction solution and swab	0.5ml ×1 bottle	0.5ml×30 bottles	Na ₂ HPO ₄ , NaH ₂ PO ₄ , NaCl, C ₁₀ H ₁₁₄ O ₃₆	



aliamization load of the extraction fishe and pair 4 en the workstation.

Another than the contraction the which contains buffer. Rotate the away at least 10 times while pressing the swab struction tube which contains buffer. Rotate the away at least 10 times while pressing the swab struction tube with fingers and fool the evan broad against the inside of the Extraction tube when you remove much liquid as possible. The extracted solution will be used as test specimen.

mptoms.

Only one red quality control line (C) appears in the detection window. It indicates that no COVID-19 antige



or virgo inclusion and culture identification methods by used to verify negative results when in death. Analysis of the (a) Interpret paragraph; transport and trusteent, and insufficient twin despites it samples may lead to fishe negative results, (a) Interpret paragraph; transport and trusteent transport and transport and

should be 10/10(-(-).

Mainman detection limit the miniman detection limit of quality control products \$1.55, \$1 ~ \$4 Corona Virus (COVID-19) Antigen test results should be positive, \$5 Corona Virus (COVID-19) Antigen test results should be

samples were taken by qualified personnel.

500 nanopharyagal swah 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.

Corona Virus (COVID-19)	PCR Comparator		PCR Comparator		Sub total
Antigen	Positive	Negative	1		
Positive	96	4	100		
Negative	4	396	400		
Sub total	100	400	500		

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)	PCR Comparator		Sub total
Antigen	Positive	Negative	
Positive	120	5	125
Negative	6	269	275
Sub total	126	274	400
Positive Percent Agreement Negative Percent Agreement	(PPA)= 120/126(95. (NPA)= 269/274 (9)	24%) (95%CI: 89.5 3.18%) (95%CI:95.	79%-98.23%) 79%-99.41%)

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	



Instruction manual - 5 Languages

Acetyl salicylic acid	10mg/mL	Ibaprofen	3 mM
Acetaminophen	15mg/mL	Flurisolide	120µg/mL
Afrin Nasal Spray (Oxymetazoline)	4% (v/v)	Tobramycin	80µg/mL
Sedium 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

MERS-Coronavirus	Florida/USA-2_Saudi	5 x 10°TCID _{so} /ml	
	Arabia_2014		
	H1N1 Denver	2 x 10 ⁵ TCID ₅₉ /ml	
	HINI WS/33	1.5 x 10 ⁵ TCID ₅₀ /ml	
Influenza A	H1N1 Pdm-09	2 x 10° TCID ₃₀ /ml	
	H1N1 New Caledonia	1 x 10 ⁵ TCID ₅₉ /ml	
	H1N1 New jersey	2 x 10 ³ TCID ₂₀ /ml	
	Nevada/03/2011	2 x 10 ⁴ TCID ₉₉ /ml	
Influenza B	B/Lee/40	5 x 10° TCIDss/ml	
	B/Taiwan/2/62	1 x 10° TCID ₁₀ /ml	
	229E	1 x 10 ⁵ TCID ₂₀ /ml	
Human Coronavirus	OC43	1 x 10° TCID ₂₀ /ml	
	NL63	1 x 10 ⁵ TCID ₅₀ /ml	
Respiratory syncytial virus	Type A	1 x 10 ⁵ TCID ₂₉ /ml	
Respiratory syncytial virus	Type B	1 x 10° TCID ₃₀ /ml	
Human Metapneumovirus (hMPV)	hMPV 3 Type B1 / Peru2-2002	1 x 10° TCID ₃₀ /ml	
numan Metapneumovirus (nMPV)	hMPV 16 Type A1 / IA10-2003	1 x 10 ⁵ TCID ₂₀ /ml	
	Type I	1 x 10° TCID ₁₀ /ml	
Parainflaenza virus	Type 2	1 x 10° TCIDss/ml	
Paramiliuenza virus	Type 3	1 x 10° TCID ₃₀ /ml	
	Type 4A	1 x 10 ¹ TCID ₃₀ /ml	
Rhinovirus	A16	1 v 10 ⁵ TCIDs/ml	
KIIIKÄTRIS	Type B42	1 x 10° TCID ₃₀ /ml	
Enterovirus	Type 68	1 x 10° TCIDss/ml	
Enterovirus	(09/2014 isolate 4)	1 x 10 ⁴ TCID ₂₀ /ml	

	Mycobacterium tuberculosis	K	1 x 10 ⁴ TCID ₅₉ /ml
		Erdman	1 x 10 ⁴ TCID ₅₀ /ml
		HN878	1 x 10 ⁴ TCID ₅₉ /ml
		CDC1551	1 x 10° TCID ₁₀ /ml
		H37Rv	1 x 10 ⁴ TCID ₅₀ /ml

L'aminosi.

The test should only by priferent et noue impression, a sa shown temperature camifiet de accuracy of the results. The test should only by prijette dessalt to selfented by their method.

The regular test should be sended and kept in ally place. The last causels should be tested as soon in possible shift removal from the peckaging, not political politica phenomenon.

6.The results of rapid test are only for clinical reference and should not be the only basis for clinical diagnosis and

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

	Punner or sys	initial and a second		
	8	Do not reuse	IVD	For in vitro diagnostic use only
	1	Store between 2-30°C	(Ii	Consult instructions for use
	Ω	Use by	LOT	Lot number
	®	Do not use if package is damaged	∇	Contains sufficient for <n> tests</n>
	巻	Keep away from sunlight	*	Keep dry
	\sim	Manufacturing date	***	Manufacturer

EC REP

Authorized representative in the European Community



Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold) Instruction d'utilisation (UNIQUEMENT POUR UN USAGE PROFESSIONNEL)

Principe at so 2

The control of the

	Spécifications d'emballage		Matirial
Composants	1Test/boite	30 Tests/ boite	Materiel
Corona Virus (COVID-19) Carte de test rapide d'antigène	1 sac	30 sacs	Anticorps monoclonal de protéine rascléocapside de souris anti-virus Coroca (COVID-19) marqué à l'oc colloidal; Anticorps monoclonal de protéine rascléocapside de virus anti-coroca de souris (COVID-19); Anticorps polyclonal de chève anti-souris;
Solution d'extraction d'échantillon pour	0.5 ml × 1	0.5 ml × 30 boutcille	NacHPOs, NaHrPOs, NaCl, CriHrisOss

[Conditions de stockage et date d'expiration]

Llasière totte l'extrémité souple de l'écouvillon dans la narine, à environ 2,5 cm (1 pouce) du bord de la narine. 2.Faites tourner lentement l'écouvillon 5 fois sur la surface de la narine pour s'assurer que le mocus et les cellules soient recueillis.

10 NA 10

Introduce doccument of interiment recoveries than so a means we passed to the contract of the contract recoveries of the contract recoveries and the contract recoveries of the contract recoveries and the contract recoveries and the contract recoveries are contract as we be manufactured as distinct and definition of the contract recoveries produced 3.5 foils.

Latinat Procession and Tecoveries for each of the contract recoveries produced 3.5 foils.

Latinat Procession of the contract recoveries produced 3.5 foils.

Latinat Procession of the contract recoveries and the contract recoveries and the contract position of the contract process.

Latinat Procession of the contract recoveries and the contract position of the contract position of the contract position.

Circiparation due échantillion.]

Reiner la care de des de sac en alaminism, placer-le sur la toble de travail hocionale plate.

Reiner la care de des de sac en alaminism, placer-le sur la toble de travail hocionale plate.

Reiner la care de des de sac en alaminism, placer-le sur la care de la reiner de la reiner. Le résultat de la reiner de la reiner de la reiner de la reiner. Le résultat de la reiner de la reiner de la reiner de la reiner. Le résultat de la reiner de la reiner. Le résultat de la reiner de

2. Nigorii en encle figu de contrile (en quitie rouge (C) appenit dans la fenire de distrinto, clis nièges qu'anum anjuge (CVDP3-1) en distribution dus franches (La baise de Gournille x 1) agre de partie en simple (en qu'anum anjuge (CVD3-1) en de contrile rà part de louis de grande (en qu'anum anjuge (ex CVD3-1) en de partie de partie de la familie La baise de Gournille x 2) en de partie en grande (en qu'anum anjuge (ex CVD3-1) en qu'anum anjuge (ex 1) en sur des parties (en partie en qu'anum anjuge (ex 1) en qu'an



[Indicateur de performance du produit]

1. Aspect lisse, fixation du matérius solide, contenu complet, embullage complet aucun dommage, signes clairement

Fig. — By Visic Comm (CVVD-19) Landgine duit tre positif, he tau de cenfirmet de centre on quara resonabilità direct de 3-15 - "shimit de centre direct des inspirit, sergicine di active de 3-15 - "shimit de centre de se consideration production de centre d

La performance da lei a de teste sus des chancilhon de patients suspects de COVID-19 pélevés entre mars 2020 et junivier 2021 hers de la punique chiajene quotidiente un CDC de librance et un Sisiolium hépital populaire de Elbouyang 2009 chancillises d'accourtiloungus mospharpages cort éléprofessis pour le diagnostim molécitaire utilisate la RT-CR, pour les test repide d'antigine. Il a dé démontré que le test avait une sensibilité diagnostique de 96 % et une spécificité diagnostique de 90 % par report aux residents de la RT-CR.

Antigêne du virus Corona	PCR Comparateur		sous-total
(COVID-19)	Positif	Negatif	1
Positif	96	4	100
Negatif	4	396	400
sous-total	100	400	500

(COVID-19)	Positif	Negative	
Positif	120	5	125
Négatif	6	209	275
sous-total	126	274	400
Accord de pourcentage positi Accord de pourcentage négati	f (PPA)= 120/126(9: f (NPA)= 269/274 (5	5.24%) (95%CE: 89 (8.18%) (95%CE:95	1.92%-98.23%) 5.79%-99.41%)

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	l mg/mL
Anetyl solicylic acid	10mg/mI	Desperation	1 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

MERS-Coronavirus	Florida/USA-2_Saudi Arabia_2014	5 x 10° TCID ₅₀ /ml			
	H1N1 Denver	2 x 10 ⁴ TCID ₅₀ /ml			
	H1N1 WS/33	1.5 x 10 ⁵ TCID ₅₉ /ml			
Influenza A	H1N1 Pdm-09	2 x 10 ⁶ TCID ₅₀ /ml			
	H1N1 New Caledonia	1 x 10 ⁴ TCIDss/ml			
	H1N1 New jersey	2 x 10 ⁵ TCID ₁₀ /ml			
	Nevada/03/2011	2 x 10 ⁵ TCID ₂₀ /ml			
Influenza B	B/Lee/40	5 x 10° TCID-v/ml			
	B/Taiwan/2/62	1 x 10 ^s TCID ₅₀ /ml			
	229E	1 x 10° TCID ₁₀ /ml			
Human Coronavirus	OC43	1 x 10° TCID ₂₀ /ml			
	NL63	1 x 10 ^s TCIDss/ml			
Respiratory syncytial virus	Type A	1 x 10 ⁴ TCID ₅₀ /ml			

	Type B	1 x 10 ⁵ TCID ₅₀ /ml	22 00
ovirus (hMPV)	hMPV 3 Type B1 / Peru2-2002	1 x 10* TCID ₅₀ /ml	
iovirus (nMPV)	hMPV 16 Type A1 / IA10-2003	1 x 10 ⁵ TCID ₃₉ /ml	No.
	Type I	1 x 10 ⁵ TCID ₃₀ /ml	(A)
za virus	Type 2	1 x 10° TCIDss/ml	>\<
Za virus	Type 3	1 x 10 ⁵ TCID ₃₀ /ml	ZIT In
	Type 4A	1 x 10 ⁵ TCIDss/ml	п
irus	A16	1 x 10 ⁵ TCID ₃₉ /ml	
irus	Type B42	1 x 10 ⁵ TCID ₅₉ /ml	
irus	Type 68	1 x 10 ^t TCID _{ro} /ml	EC REP Re
irus	(09/2014 isolate 4)	1 x 10 ⁴ TCID ₁₀ /ml	
	K	1 x 10 ⁴ TCID ₅₉ /ml	
	Erdman	1 x 10 ⁴ TCID ₅₉ /ml	
tuberculosis	HN878	1 x 10 ⁴ TCID ₅₀ /ml	
	CDC1551	1 x 10 ^s TCIDss/ml	May

pocel anticorps muscolonal contre le cocenarions est une protinte qui reconnult la protétine de meléocapside et peut ter des variantes génétiques de succles.

(crations)

(crations)

gnostie chiaque et le trakement.

se chantillome et les titu de tot de déclets doivent être traités comme des agents infectieux potentiels.
heure d'apparation de la ligne de contrôle ne doit pas être prise comme base de temps pour juger les résultats de la
set éte tet. Les résultats du retude des contrôle ne doit pas être prise comme base de temps pour juger les résultats de la
set tet. Les résultats du retude des contrôles noivent être desverées et jugis dams un déside de la 3 à 15 minutes.

te test rapids riest stalisé que pour désignancie in vitre.

Et produit doit étre utiliée par le personnel formé professionnellement, tel que le personnel médical ayant des

Index du symbole					
Ne pas réutiliser	IVD	Pour usage diagnostique in vitro uniquement			
Conserver entre 2 et 30 °C	[]i	Consulter les instructions d'utilisation			

(COVID-19)	Positif	Negative	
Positif	120	5	125
Négatif	6	209	275
sous-total	126	274	400
Accord de pourcentage posit Accord de pourcentage négat	if (PPA)= 120/126(9) if (NPA)= 269/274 (5.24%) (95%CE 89 (8.18%) (95%CE95	.92%-98.23%) 5.79%-99.41%)

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	l mg/mL
Acetyl solicylic acid	10mg/mI	Desperation	1 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
naleate Dexamethason	1 mg/mL	Peramivir	1.0mmol/L
Doxycycline hyclate	50µM	Quinine	150µM

Réactivité croisée
 Il n'y a pas eu de réaction croisée et d'interférence avec les micro-organismes potentiels à réaction croisée énumérés

Σ	Utiliser avant	LOT	Numéro de lot de production		
	Ne pas utiliser si l'emballage est endommagé	∇	Contient suffisamment pour <n> tests</n>		
类	Tenir à l'écart de la lumière du soleil	^	Garder au sec		
~~	Date de fabrication	•••	Fabricant		
EC REP Représentant autorisé dans la Communauté européenne					



Corona Virus (COVID-19) Antigen Rapid Test

[Principie de procha]

Il producto e un immensorare de flago lateral baseda en el principio de la tecnología de sindució de dade articural y la producto e un immensorare de flago lateral baseda en el principio de la tecnología de sindució de dade articural y entre destructo en entre entre entre el proche a entre entre entre el proche a entre entr

[Componente principal]

Material	1. 2. el 3.
mal de proteina de sucleocápsido de irus (COVID-19) marcado com ono corpo monocional de proteina de ión anti-Cerona Virus (COVID-19); de cabra anti-ratón;	en 4. 5. re

I bolsa 30 bolsas

[Recedección y manipulación de muestras]
Recedección de muestras
- La recedección insdecuada de especimenes o la manipulación inadecuada de especimenes puede producir un resultas

el mismo hisopo, repita este proceso para la otra fosa nasal para asegurar que se recoge una muestra adecuada de













(1) El Biolótico, el Tistolpolót y es unassenses massensantes, y un guana se veno sense nueva memor puede condicir arestinado histo negativos.
(a) El Biolótico a resultado histo negativos, que en insi probable que ocurren con reactivos de atricurapes mescelandos.
(a) Para u masser vene corona emergente, es pomble que no escentrare el troje derino de mentra que se ven a sanitar y licerpo de mentros opismo desporte de la infección (titulo vial máximo), per los que el muestros orientes de la infección (titulo vial máximo), per los que el muestros orientes de la contra de cont

Flack cited for repatients of a production of the production of th negativos, N1 \sim N10 Corena virus (COVILI-19) se requiere que es antigeno nea negativo, no nomo un compromissoro una control de calidad interno negativo debe ser 1010 (-/-). 5.Limite minimo de detección: El limite minimo de detección de los productos de control de calidad S1-S5, S1 \sim S4

Corona Virus (COVID-19) Los resultados de la prueba del antigeno deben ser positivos, S5 Corona Virus (COVID-19)

Cerona Veria (C.V.P.II.-17) LOS Terumanos ne un puncous sus manages sessione de la precisa del migrar debra ser regulivos.

Los resultados de la precisa del migrar debra ser regulivos.

Los resultados de la precisa del migrar de cuitado de reguliva de percisidad interna, cada prueba 10 veces, los resultados de la precisa debra ser positivos. No lay reacción con el virsa de la gripe A y el virsa de la gripe B.

Resultados del estadio clinico con hisopo nasal | Augustion der Versi corena | (COVID-19) | Positive | Negative | Positive | 96 | 4 | 100 | Negative | 4 | 396 | 440 | Sab total | 100 | 400 | 500 | Accupted de percentaje positivo (PSA) - 967 (105(095)) (3954) (100 | 760-95) |

Se tomaron 400 muestras de hisopos nasales para diagnóstico molecular mediante RT-PCR para la pruebarápida de antigenos, se demostró que la prueba tenia una sensibilidad diagnóstica del 95.24 % y una especificidad diagnóstica del

paración con los resultados de la	RT-PCR.			
Antigeno del virus corona	PCR Co	mparator	Sub total	7
(COVID-19)	Positivo	Negativo		
Positivo	120	5	125	
Negativo	6	269	275	
Sub total	126	274	400	7

Acuerdo de porcentaje nega L Experimento de interferencia Las siguientes sustancias se prueban a la con		59/274 (98.18%) (95%CL95. se muestra a continuación y re	
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	4% (v/v)	Tobramycin	80µg/mL
(Oxymetazoline)			
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
Dogwooding boolete	50uM	Onleine	150-M

Reactividad cruzada
 No procedo cruzada ni interferencia con los microorganismos potenciales de reacción cruzada que se enumeran a continuación.

MERS-Coronavirus	Florida/USA-2_Saudi Arabia_2014	5 x 10 ⁴ TCID ₅₀ /ml
	H1N1 Denver	2 x 10 ⁵ TCID ₅₀ /ml
	H1N1 WS/33	1.5 x 10° TCID ₃₀ /ml
Influenza A	H1N1 Pdm-09	2 x 10 ¹ TCID ₅₀ /ml
	H1N1 New Caledonia	1 x 10 ⁵ TCID ₅₉ /ml
	H1N1 New jersey	2 x 10 ⁵ TCID ₅₀ /ml
	Nevada/03/2011	2 x 10° TCID ₁₀ /ml
Influenza B	B/Lee/40	5 x 10 ⁶ TCID ₅₉ /ml
	B/Taiwan/2/62	1 x 10 ⁵ TCID ₅₀ /ml
	229E	1 x 10° TCID ₅₀ /ml
Coronavirus humano	OC43	1 x 10 ^s TCIDss/ml
	NL63	1 x 10° TCID ₅₀ /ml
	Type A	1 x 10 ⁵ TCID ₃₀ /ml
Virus sincitial respiratorio	Type B	1 x 10° TCIDss/ml
	hMPV 3 Type B1 / Peru2-2002	1 x 10 ⁵ TCID ₅₉ /ml
Metaneumovirus humano (hMPV)	hMPV 16 Type A1 / IA10-2003	1 x 10 ⁵ TCID ₅₉ /ml
	Type I	1 x 10 ⁵ TCID ₁₀ /ml
Virus de la parainfluenza	Type 2	1 x 10° TCID ₁₀ /ml
Virus de la paraintiuenza	Type 3	1 x 10 ⁶ TCID ₅₀ /ml
	Type 4A	1 x 10 ⁵ TCIDss/ml
	A16	1 x 10° TCID ₃₀ /ml
Rinovirus	Type B42	1 x 10 ⁵ TCID ₅₉ /ml
Entenwinus	Type 68	1 x 10 ⁵ TCID ₅₀ /ml
Enterovirus	(09/2014 isolate 4)	1 x 10 ⁴ TCID ₁₀ /ml
	K	1 x 10 ⁴ TCID ₃₉ /ml
	Erdman	1 x 10 ⁴ TCID ₅₉ /ml
Tuberculosis micobacteriana	HN878	1 x 10 ⁴ TCID ₃₉ /ml
	CDC1551	1 x 10 ⁴ TCID ₃₉ /ml
	H379 v	Ly 105 TCIDecircl

H37Rv 1 x 10⁴ TCIDss/ml
El muevo anticuerpo monoclonal de coronavirus es una proteina que reconoce la proteina de nucleocápside y puede



Instruction manual - 5 Languages



La prueba ripida debe sellarse y mantenerse en un lagar seco. La barra de proeba debe probarse lo antes posible después es acerta del rapante para evitar la humendal causada per colocarla en el arre darante demaniado tempo. La profinadidad del raporte para evitar la humenda causada per colocarla en el arre darante demaniado tempo. La profinadidad del raporte del la linea de presento ao está necesariamente associada con el tilino del antigeno en la muestra y los resultados después de l'Emission no son visidos.

n fenómeno normal. Los resultados de la prueba rápida son solo para referencia clinica y no deben considerarse como la única base para el

aggnòtico y tratamiento clinicos. Las muestras de descolos y las pruebas deben tratarse como posibles agentes infecciosos. El tiempo de aparición del color de la linea de control no debe tomane como base de tiempo para jurgar los resultados le a linea de penden. Los resultados de la repoedución cromítica deben observane y evaluarse dentro de un limite de

Floor 4, Zone C, Workshop No.1, China civil Aviation science and technology industrialization Base No. 225, Jinger Road, Tunjin Airport Economic Zone

[Índice de símbolo]

8	No reutilizar	IVD	Sólo para uso diagnóstico in vitro	
1	Almacenar entre 2-30 °C	[]i	Consultar instrucciones de uso	
Ω	fecha de cadacidad	LOT	Numero de lote	
®	No lo use si el paquete está dañado	\sum	Contiene suficiente para <n> pruebas</n>	
类	Mantener alejado de la luz solar.	7	Mantener seco	
\sim	Fecha de fabricación	***	Fabricante	
EC REP	Representante autorizado en la Comunidad Europea			



Virus della Corona(COVID-19) Test Rapido di Antigene (Oro Colloidale) Instruzioni per l'uso (Solo per l'uso professionale)

Nome del prodotto
Virus della Corona (COVID-19)Test Rapido di Antigene (Oro Colloidale)
Codice modello

The first policy of the policy

Componenti del prod	otto		
Componenti	Specifiche di confezionamento		materiale
	1Test/Scatola	30Test/Scatola	
Virus della Corona (COVID-19) Carta di prova rapida antigene	l pacco	30 pacchi	Virus anticoagularite del topo marcato con oro colloidale (COVID-19) anticorpo monoclonale proteico nucleocapso proteico; Virus anti-Corena del topo (COVID-19) anticorpo monoclorale proteico nucleocapso proteico; anticorpo polsicolnale anti-mouse di caprino;
Soluzione per estrazione del campione e tampone	0.5ml×1 bottiglia	0.5ml ×30 bottiglie	Na ₂ HPO ₄ , NaH ₂ PO ₄ , NaCl, C ₅₈ H ₁₁₄ O ₂₈

(Condizioni di canservazione e data di scalenza)

1. Comercure tra 2 e 30 °C, tenne tontan dalla loce, valida per 12 mani.

1. Comercure tra 2 e 30 °C, tenne tontan dalla loce, valida per 12 mani.

Locale della considerazione di 18-20 °C, militario della considerazione di 18-20 °C, de tenne della considerazione di 18-20 °C, militario alla considerazione di 18-20 °C, militario alla considerazione di 18-20 °C, della considerazione di 18-20 °C, de

Svabbiamento nasale :

1. Inserire l'intera estremità morbida del tampone nella narice, a circa 2,5 cm (1 pollice) dal bordo della narice.

2. Ruotare lentamente il tampone 5 volte sulla superficie della narice per assicurarsi che sia il muco che le cellule.





(15-30°C) in in committee pass.

Persparations experience del table de cintratione e motterlo nil genio di lavono.

1 regluer al fugini di allumini del labori de cintratione e motterlo nil genio di lavono.

10 vello del tampone primere il tampone controli fundo e il labo del table di cintratione.

3 Prazzarei labori di cittazione con la diaz primere il latori del tampone controli l'induce del tampone.

3 Prazzarei labori di cittazione con la diaz primere il latori del tampone controli l'induce del tampone.

3 Prazzarei labori di cittazione con la diazione con la diazione controli l'anticoni del tampone.

5 Aggiungori quatto proce della soluzione (circa 100 d.) celli cannota di prova e pei inizione il constanti. Il rindutati









clinici.

vivo Nella finestrella di individuzione appure solo una linea di controllo della qualità rossa (C). Indica che non è raviso alcun antiquese COVID-19 nel campione.

si nel regione di linimizzazione con la linimizzazione con la regione co



Elimitazione dei meteolo de preva 2

1. Quede cimilate del miesco del preva del produte si dei di riferimente cimico e son deve servire come tancia base per la minima resultate del miesco del produte del produte del mismo resultate del mismo resultate qual del henciterio, alla risposta di trattamente e alle informazione sprincedegolosi, come la similate comitario del produce del produce

Etadicatore di prestazione dei prodotti).

1. Parcer mobilos, leggera di materiale solido, contenuto completo, confezionamento completo, segni chiaramente softmifiabili, imperere vissibili nous sono state invoite nell'estratto del campione.

2. La velociti di movimento dei dibiarte dei campione "O them al mismio." 3. Tasso di conformità dei prodotti di controllo di qualità positivi, projetime 5 prodetti di controllo di qualità positivi, vinus

Corona P1-P5 (COVID-19) Antigene deve essere positivo; il tasso di conformità del controllo interno positivo deve essere 55 (r/s).

Al Taso di confemiti dei prodotti di controllo della qualtià negativi: ispezione di 10 prodotti di controllo della qualtià negativi; vina della Corona NI-NIO (COVID-19) Antigme deve essere negativo; il tasso di confemnia del controllo difficiame negativo dei controllo della qualtià inferime negativo deve essere (1910(-4)).

3. Limite minimo di ribevamento: il inimi minimo di ribevamento del prodocti di controllo della qualtà 51-53, 51-54 (corona Vivas (COVID-19) risultati dei toti di antignue deveno essere positivi, il 35 Corona Vivas (COVID-19) risultati

Corena Virus (COVID-19) i risultati dei test di antigene oeveno essere ponant, necessione dei dei test di antigene devono essere negativi.

6. Repetibiliti: test 2 prodotti di controllo della qualità di ripetibilità interna, ogni test per 10 volte, i risultati dei test devono essere positivi.

7. La reazione crociata dell'agente patogeno: non c'è reazione con il virus dell'influenza A e il virus dell'influenza B.

[Promised Experience]
Literatures of Sea in Section on comprised department on supports COVID-18 profession to marco 2000 e genuino 2021 durante la pretica clinica quicidissan presso IC-DC di Human el Secto espedale proplare di Sheoyang (Cma) I compression sonsistà princiva di personale, qualificarity con la Section product propolare di support de dispossion del profession di susposta di susposta moderature sondi prefeste con la finale del productiva del productiva del productiva del productiva del productiva del productiva del profession del profession del productiva del productiva del profession del productiva del profession del productiva del profession d

	Risultati degli stud	li clinici	
Virus della Corona	PCR Co	mparatore	
(COVID-19) Antigene	Positivo	Negative	Totale
Positivo	96	4	100
Negative	4	396	400
Totale	100	400	500

Sono stati prelevati 400 campioni di tampone nasale per la diagnosi molecolare utilizzando RT-PCR per il test rapido di antigene, il test ha dimostrato una sensibilità diagnostica del 95,24 % e una specificità diagnostica del 98,18 % rispetto ai

Virus della Corona	PCR Comparatore		Totale
(COVID-19) Antigene	Positivo	Negative	
Positivo	120	5	125
Negative	6	269	275
Totale	126	274	400

OTC Gola drop (Halls)	15%	Budesonide	2 mg/mL
OTC Gola drop (Ricola)	15%	Menthol	10 mg/mL
OTC Spray nasale (Afrin)	15%	Mucin	10µg/mL
OTC Spray nasale (VicksSinex)	15%	Mometasone	1 mg/mL
Acetyl salicylic acid	10mg/mL	Ibuprofene	3 mM
Acetaminophen	15mg/mL	Flunisolide	120µg/mL
Spray nasale Afrin (Ossimetazolina)	4% (v/v)	Tobramicina	80µg/mL
Cromoglicato di sodio	12 mg/mL	Fluticasone	0.4ng/mL
Sangue intera	5% (v/v)	Ritonavir	8.0mg/mL
Chloropheniramines	5 mg/mL	Abidor	420mg/mL

Dexamethasone malate	1 mg/mL	Peramivir	- 1	1.0mmol/L
Hyelated daxyeyelines	50µM	Quinine		150µM
Reattività incrociata m sono state osservate reazioni crociate	e interferenze con	i potenziali microrganismi	crocia	iti elencati di seguito:
MERS-Coronavirus	Florida/USA	-2_Arabia Saudita_2014		5 x 10 ⁴ TCIDss/ml
	H	IINI Denver		2 x 10 ⁵ TCID ₅₀ /ml
	F	IINI WS/33		1.5 x 10 ⁵ TCID ₅₀ /ml
Influenza A	Н	1N1 Pdm-09		2 x 10 ⁵ TCIDso/ml
	HIN	New Caledonia		1 x 105 TCID ₅₀ /ml
	HI	N1 New jersey		2 x 105 TCID ₅₀ /ml
	Ne	wada/03/2011		2 x 10 ⁵ TCID ₅₉ /ml
Influenza B		B/Lee/40		5 x 10 ⁸ TCID ₅₀ /ml
	В	/Taiwan/2/62		1 x 10 ⁵ TCID ₅₀ /ml
		229E		1 x 10 ⁵ TCID ₅₀ /ml
Coronavirus umano		OC43		1 x 10 ⁵ TCID _{so} /ml
		NL63		1 x 10 ⁵ TCID ₁₀ /ml
		Type A		1 x 10 ⁵ TCID ₅₀ /ml
Virus sinciziale respiratorio		Type B		1 x 10 ⁵ TCID ₅₉ /ml
Metappeumovirus umano (hMPV)	hMPV 3 T	Type B1 / Peru2-2002		1 x 10 ⁵ TCID ₃₉ /ml
Metapneumovirus umano (hMPV)	hMPV 16	Type A1 / IA10-2003		1 x 10 ⁵ TCID ₅₉ /ml
		Type I		1 x 10 ⁵ TCID ₃₀ /ml
		Type 2		1 x 10 ⁵ TCID ₅₀ /ml
Virus parainfluenza		Type 3		1 x 10 ⁵ TCID ₅₉ /ml
		Type 4A		1 x 10 ⁵ TCIDss/ml
Rinovirus		A16		1 x 10 ⁵ TCID ₅₉ /ml
Kinovirus		Type B42		1 x 10 ⁵ TCID ₅₉ /ml
Enterovirus		Type 68		1 x 10 ⁸ TCID ₅₀ /ml
Emerovirus	(09)	2014 isolate 4)		1 x 10 ⁴ TCID ₅₀ /ml

H37Rv 1 x 10⁴ TCID₃₀/ml

Novel Coronavirus Monoclonale Anticorpodi è una proteina che riconosce le proteine nucleocapside e può individuare

Erdman

[Precauzioni]

1. Il ted deve cuere eseguito solo a temperatura ambiente, possible temperature netwente possono influire sull'accuratezza.
2. I campunis postivi estimati con il test rapido deveno accese confirmati con abit messi.
3. Il test rapido deveno cuere sigliato e tamba posto secue. La campuni di pressa devene tostati il prima possibile deveno accese confirmati con abit messi.
3. Il test rapido deveno regilizato i tamba posto secue. La campuni di prima devene tostati il prima possibile del la considerazione della considerazione della

minuti. 9. Il test rapido è utilizzato solo per la diagnosi in vitro. 10. Questo prodotto deve essere gestito da personale qualificato, come il personale medico con esperienza clinica.

Piano 4, Zona C, Fabbrica No. I, Base di industrializzazione scientifica e tecnologica dell'aviazione civile della Cina No. 225, Via Jing'er, l'area economica dell'aeroporto di Tiantin 300308 Tiantin

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

dice dei simb	ooli]		
2	Non riutilizzare	IVD	Solo per uso diagnostico in vitro
X	Conservare tra 2 e 30 °C	[]i	Consulti le istruzioni per l¹ uso
Ω	Uso da	LOT	Numero di lotto
®	Non usare se la confezione è danneggiata	Σ	Contiene abbastanza per i <n> test</n>
类	Tenere lontano dalla luce solare	†	Mantenere l'aridità
w	Data di produzione	***	Produttore

Numero della versione: 04 Data efficiente: 3 dicembre 2021

EC REP

1 x 10⁴ TCID₅₉/ml

1 x 10⁴ TCID₅₉/ml

1 x 10° TCID₅₉/ml



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

QAdvis EAR AB

Ideon Science Park

Scheelevägen 17 SE-223 70 Lund, Sweden

Product Name:

Representative:

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, <u>Hovotek Biomedical Co., Ltd</u> 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

lame

Function

Transin Who 2000.11.

Signature

Place and Date of issue

Certificate of CE registration

European Authorized Representative

OAD 105

HYT-G03

Manufacturer nam and address:

Manufacturer name 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 HYT-G01
(colloidal gold)
Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test HYT-G02

(colloidal gold)

Corona Virus (COVID-19)

Combined (IgM/IgG/Neutralizing antibody) Rapid Test

olloidal gold)

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 is a higher of the sound of the sound

QAdvis EAR AB

SS: Ideon Science Park, Scheelevägen 17, SE-223 70 Lund, Sweden Tel office: +46 8 621 01 05. Email: ear@gadvis.com. Web: www.gadvis.com Clinical evaluation report

Documentation

Doc No. HYT-G01-009

Rev.: 00

Page: 1-11

Company Name: Hovotek Biomedical Co., Ltd.

Hovotek 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

Hoyotek Biomedical Co., Ltd.

EU-Konformitätserklärung

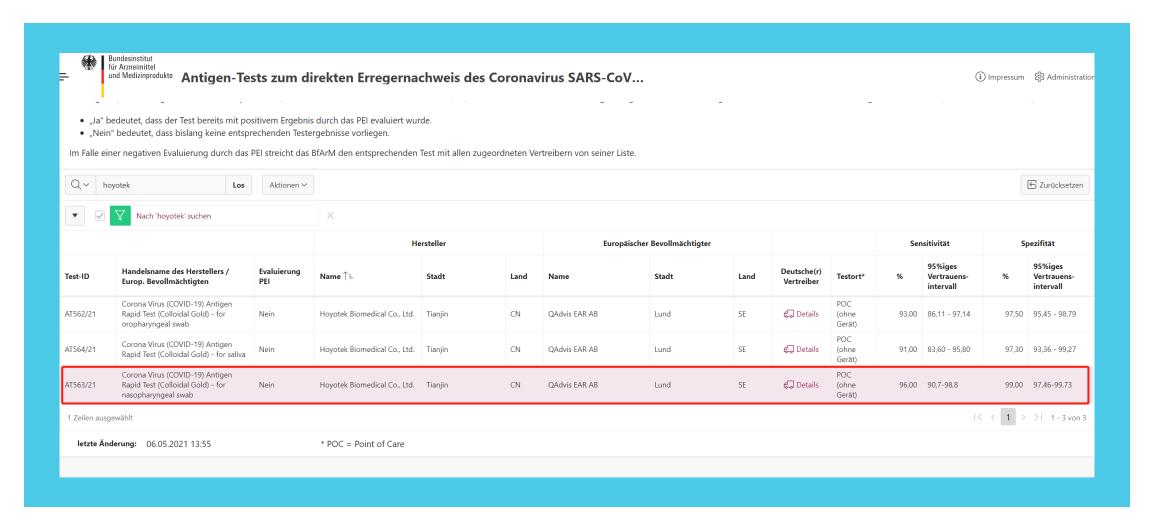
Zertifikat

klinischer Bericht



Certification





Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)