Novel Coronavirus (SARS-COV-2) Antigen Rapid Test Cassette (Swab)

25 Tests/kit

Features:

Testing Time : 10 Mins
Sensitivity: 96. 17%
Specificity: 99.9%

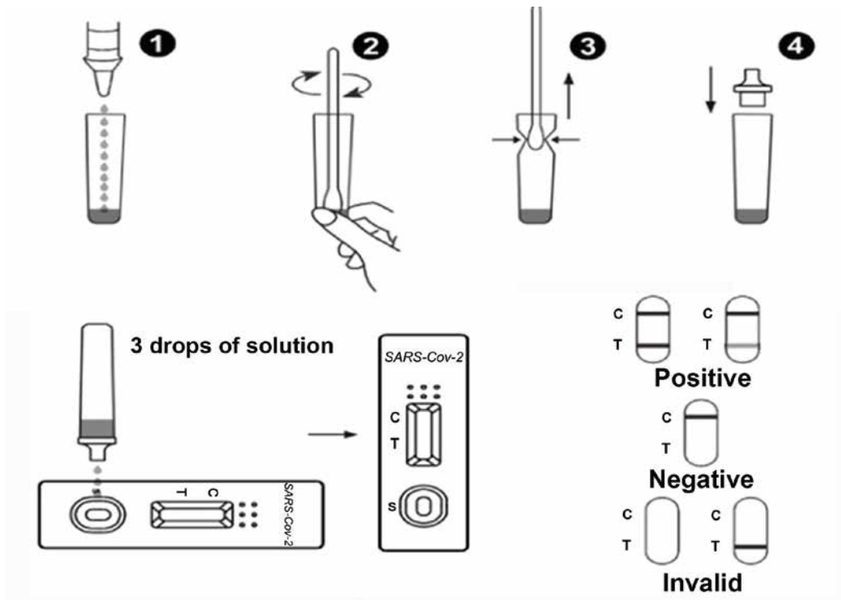
Product name	Ref.	Size	Storage Temp
Novel Coronavirus (SARS-COV-2) Antigen Rapid Test Cassette (Swab)	K511416D	25 Test/kit	2-30℃
Novel Coronavirus (SARS-COV-2) Antigen Rapid Test Cassette (Swab)	K511416D	5 Test/kit	2-30℃

REALY

CE

Realy Novel Coronavirus (SARS-COV-2) Antigen Rapid Test Cassette (Swab) is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx.

DIRECTIONS FOR USE:



Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS IN NASOPHARYNGEAL SWAB.

For professional In Vitro Diagnostic Use Only.

INTENDED USE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an *in vitro* diagnostic test for the qualitative detection of novel coronavirus antigens in Nasopharyngeal swab, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronvirus antigen. It will provide information for clinical doctors to prescribe correct medications.

SUMMARY

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is used for the in vitro qualitative detection of novel coronavirus in the throat swabs, sputum samples of suspected pneumonia patients infected by novel coronavirus, suspected clustering cases and others needing diagnosis or differential diagnosis for novel coronavirus.

The definitions of "suspected cases" and "patients with suspected aggregated cases" and other groups are implemented with reference to the "Diagnosis and Treatment Plan for Pneumonia Infected in novel coronavirus" and "Monitoring Plan for Pneumonia Infected in novel coronavirus" and other documents (current version) issued by CDC.

The product is only used for auxiliary diagnosis of related cases and emergency reserve for in vitro diagnosis of this epidemic during the pneumonia epidemic infected by novel coronavirus (SRAS-Cov-2) since December 2019 and it cannot be used as routine in vitro diagnostic reagents in clinical practice. The kit shall comply with the relevant requirements of the "Diagnosis and Treatment Plan for Pneumonia Infected in novel coronavirus" and "Prevention and Control Plan for Pneumonia Infected in novel coronavirus" and other documents in use.

The detection results of this kit are for clinical reference only and should not be used as the sole criteria for clinical diagnosis. It is recommended to conduct a comprehensive analysis on the condition in combination with the clinical manifestations and other laboratory tests.

PRINCIPLE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to Novel coroinavirus .

The test device is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus;the reaction membrane contains the secondary antibodies for Novel coroinavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

When the sample is added into the sample window,conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coroinavirus is present in the sample, a complex formed between the anti- Novel coroinavirus conjugate and the virus will be caught by the specific anti- Novel coroinavirus monoclonal coated on the T region.

Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

REAGENTS

The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus; the reaction membrane contains the secondary antibodies for Novel coroinavirus,and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform test at room temperature 15 to 30°C.
- Wear gloves when hanging the samples, avoid touching the reagent membrane and sample window.
- All samples and used accessories should be treated as infectious and discarded according to local regulations.
- Avoid using bloody samples.

STORAGE AND STABILITY

Store the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) at room temperature or refrigerated (2-30°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

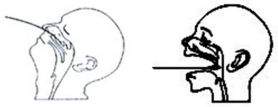
SPECIMEN COLLECTION AND PREPARATION

1. Specimen collection:

It is applicable to the diagnosis of the Novel coroinavirus from the samples of Nasopharyngeal swab.Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

Nasopharyngeal Swab

For nasal swab completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.



For throat swab completely insert the sterilized swab supplied in this kit into the posterior pharynx,tonsils and other inflamed areas.Avoid touching the tongue,cheeks and teeth with the swab.

It is recommended to collect sample from Nasopharyngeal for more accurate results.

2. Specimen preparation:

1) Add **10 drops (about 0.3 ml)** of the sample extraction buffer into the extraction tube supplied in this kit, and put it on the tube stand.

2) **Nasopharyngeal Swabbing**

Insert the swab into the extraction tube which contains **10 drops (about 0.3 ml)** of the sample extraction buffer. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that liquid is expressed and reabsorbed from the swab.Remove the swab. The extracted solution will be used as test sample.

MATERIALS

Materials provided

- Test Device
- Sterilized Swab
- Extraction Tube
- Tube Stand
- Package Insert
- Nozzle With Filter
- Sample Extraction Buffer

Materials required but not provided

- Timer

DIRECTIONS FOR USE

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

1.Remove the test device from the sealed foil pouch and use it as soon as possible. Place the test device on a clean and level surface . Best results will be obtained if the assay is performed immediately after opening the foil pouch.

2. Unscrew the whole cap of the specimen collection tube,

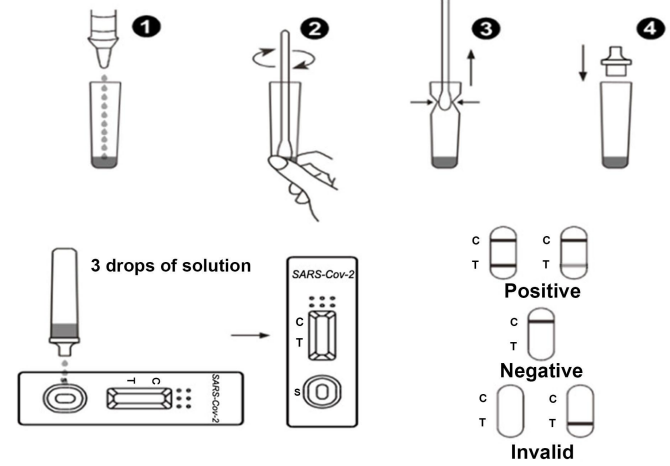
3. Add **10 drops (about 0.3 ml)** of the sample extraction buffer into the extraction tube.

4.Place the sterilized swab specimen in the sample extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.

5.Remove the sterilized swab while squeezing the sterilized swab head against the inside of Buffer as you remove it to expel as much liquid as possible from the swab. Discard the sterilized swab in accordance with your biohazard waste disposal protocol.

6. Screw on and tighten the cap onto the specimen collection tube,then **shake the specimen collection tube vigorously** to mix the specimen and the sample extraction buffer.. See illustration 4.

7.Add 3 drops of the solution (approx.80ul) to the sample well and then start the timer. Read the result at 10~20 minutes.Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two red lines appear. One red line appears in the control region(C), and one red line in the test region(T). The shade of color may vary，but it should be considered positive whenever there is even a faint line.

NEGATIVE: Only one red line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no Novel coroinavirus particles in the sample or the number of viral particles is below the detectable range.

INVALID: No red line appears in the control region(C). The test is invalid even if there is a line on test region(T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus
- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present.Therefore,the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
- A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained
- Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other coronavirus infection except the SARS-Cov-1
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children List.
- :A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-Cov-2 infection, and should be confirmed by viral culture or an molecular assay or ELISA

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) and PCR. The results were summarized below:

Table: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) vs. PCR

		SARS-Cov-2 Ag Rapid Test		Total Result
		+	-	
PCR	+	27	5	32
	-	0	200	200
Total Results		27	205	232

Relative sensitivity: 84.4% Relative specificity: >99%

Overall agreement: 97.8%

Cross Reaction

No cross reaction has been confirmed of the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) with the following pathogens:

①Bacteria

Acinetobacter baumannii, Bordetella pertussis,Branhamella catarrhalis,Candida albicans, Candida glabrata,Cardiobacterium hominis,Eikenella corrodens,Enterococcus faecalis, Enterococcus gallinarum.Escherichia coil,Group C streptococcus,Group G streptococcus, Haemophilus aphrophilus,Haemophilus influenzae, Haemophilus paraphrophilus, Klebsiella pneumoniae,Neisseria gonorrhoeae Peptococcus asaccharolyticus,Peptostreptococcus anaerobius, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis,Streptococcus agalactiae(group B),Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes(group A), Veillonella parvula

②Virus

Influenza A,Influenza B,Adenovirus Type 1 ～ 8,11,19,37,Coxsackie virus Type A16,B1 ～ 5, Cytomegalovirus,Echovirus Type 3,6,9,11,14,18,30,Enterovirus Type 71,HSV-1,Mumps virus, Tyep I simple herpes virus Parainfluenza virus Type 1～3, Poliovirus Type 1～3,Respiratory syncytial virus,Rhinovirus Type 1A,13,14, Type I simple herpes virus, MERS.

③Mycoplasma etc.

No cross reaction with Chlamydia pneumoniae,Chlamydia psittaci,Chlamydia trachomatis, Mycoplasma pneumoniae.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction foe use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

HANGZHOU REALY TECH CO., LTD.
4th Floor, #12 Building, Eastern Medicine Town,
Xiasha Economic &Technology Development,
310018 Hangzhou, Zhejiang, P. R. China

EC REP **Luxus Lebenswelt GmbH**
Kochstr.1,47877, Willich, Germany

Number:1101381601
Version:1.5
Effective Date:2020-09-15

EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer:

Name: *HANGZHOU REALY TECH CO., LTD.*
Address:4th Floor,#12 Building,Eastern Medicine Town,Xiasha Economic&Technology Development,310018 Hangzhou,Zhejiang,P.R.China

Product/s	*Catalogue number*
Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	K511416D

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III,except Point 6,of Directive

Applicable Standards:EN ISO 13485:2016;EN ISO 15223-1:2016; EN ISO 14971:2012 ;EN ISO 13612:2002;EN ISO 17511:2003; EN ISO 18113-1:2011;EN ISO 18113-2:2011,EN ISO 23640:2015.

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Luxus Lebenswelt GmbH,located at Kochstr.1,47877, Willich,Germany to act as our European Authorised Representative as defined in the aforementioned Directive.

Hangzhou 2020.8.17

(Place and date of issue)

Dean

(Signature and position)

Signed for and on behalf of the manufacturer

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00157558

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA20**		
	Bezeichnung / Name **Bezirksregierung Düsseldorf, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Düsseldorf**		Postleitzahl / Postal code **40474**
	Straße, Haus-Nr. / Street, house no. **Cecilienallee 2**		
	Telefon / Phone **+49-211-4750**		Telefax / Fax **+49-211-4752671**
	E-Mail / E-mail **dez24.mpg@brd.nrw.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **09.09.2020**		Registriernummer / Registration number **DE/CA20/01-IVD-Luxuslebenswelt-210/20**
	Typ der Anzeige / Notification type S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change £ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG £ Hersteller / Manufacturer S Bevollmächtigter / Authorised Representative £ Einführer / Importer £ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG £ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV £ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)			
	Code **DE/0000047791**		
	Bezeichnung / Name **Luxus Lebenswelt GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Hangzhou Realy Tech Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Hangzhou**		Postleitzahl / Postal code **310018**
	Straße, Haus-Nr. / Street, house no. **4th Floor, #12 Building, Eastern Medicine Town, Xiasha Economic &Technology Development**		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Lin Sun**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Willich**		Postleitzahl / Postal code **47877**
	Straße, Haus-Nr. / Street, house no. **Kochstr. 1**		
	Telefon / Phone **0049-1715605732**		Telefax / Fax
	E-Mail / E-mail **info.m@luxuslw.de**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device	
	Klassifizierung / Classification £ Produkt der Liste A, Anhang II / Device of List A, Annex II £ Produkt der Liste B, Anhang II / Device of List B, Annex II £ Produkt zur Eigenanwendung / Device for self-testing S Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
	App (Software auf mobilen Endgeräten) £ ja / yes S nein / no
	Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG £ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
	Handelsname des Produktes / Trade name of the device **Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)**
	Produktbezeichnung / Name of device **Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)**
	Angabe der benutzten Nomenklatur / Nomenclature used S EDMS-Klassifikation / EDMS Classification £ GMDN
	Nomenklaturcode / Nomenclature code **15-70-90-90-00**
	Nomenklaturbezeichnung / Nomenclature term **OTHER OTHER VIROLOGY RAPID TESTS**
	Kurzbeschreibung / Short description In Deutsch / In German **Das COVID-19 Ag-Schnelltestgerät ist ein diagnostischer In-vitro-Test zum qualitativen Nachweis neuartiger Coronavirus-Antigene in Nasentupfer- und Nasenaspiratproben unter Verwendung der schnellen immunochromatographischen Methode. Die Identifizierung basiert auf den monoklonalen Antikörpern, die für das neue Coronvirus-Antigen spezifisch sind. Es wird Informationen für klinische Ärzte bereitstellen, um korrekte Medikamente zu verschreiben.**
	In Englisch / In English **The COVID-19 Ag Rapid Test Device is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigens in Nasal Swab and nasal aspirate samples, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronvirus antigen. It will provide information for clinical doctors to prescribe correct medications.**

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices	
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	£ In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Willich**

Datum
Date **2020-08-13**

Name **Lin Sun**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Nadine Schlingmeier**		Telefon / Phone **0211-475-3853**

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante: **HANGZHOU REALY TECH CO., LTD.**
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: **1990347**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:06/09/2020

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	1990347	S	K511416D	NOVEL CORONAVIRUS (SARS-COV-2) AGTEST RAPIDO CARD	W0105040619 - CORONAVIRUS	IVD - Altro tipo di IVD	04/09/2020		FABBRICANTE	HANGZHOU REALY TECH CO., LTD.			CN
									MANDATARIO	LUXUS LEBENSWELT GMBH		DE305829099	DE

<< < Pagina:1 > >> Num. Pagine:1 Num. Dispositivi:1

海 运
By Sea

NO.2020088765

中国认可
检验
INSPECTION
CNAS IB0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 新型冠状病毒抗原检测试剂盒

Sample Name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)

委托单位： 杭州睿丽科技有限公司

生产单位： 杭州睿丽科技有限公司

上海化工院检测有限公司
检验检测专用章

上化院 上海化工院检测有限公司
Shanghai Research Institute of Chemical Industry Testing Co., Ltd

海 运
By Sea

海 运
By Sea

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020088765

样品名称 Sample Name	中文 Chinese	新型冠状病毒抗原检测试剂盒
	英文 English	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)
委托单位 Consignor		杭州睿丽科技有限公司
生产单位 Manufacturer		杭州睿丽科技有限公司
检验方法、程序 Inspection Methods and Procedures		国际海事组织《国际海运危险货物规则》(2018版) IMO International Maritime Dangerous Goods Code (2018 Edition)
样品外观与气味 Appearance & Odor		多种颜色纸盒(内含白色塑料测试板及无色透明液体)，稍有气味 Multicolor Paper box(containing white plastic test board and colorless transparent liquid), Weak odor
IDENTIFICATION CONCLUSION 鉴定结论		1. 危险性识别(Hazards identification) 无。 None. 2. 海运按照IMO IMDG Code办理的类项(Suggestion according to IMO IMDG Code) 根据特殊规定286，可按非限制性货物条件办理。 The substance is not subject to IMO IMDG Code according to special provision 286. 3. 包装要求(Packaging requirements) 无。 None. 检验日期: Inspection Date: 2020-08-31 签发日期: Issue Date: 2020-08-31 生效日期: Effective Date: 2020-08-31
备注 Comment		无。 None.

批准 Approver: 审核 Checker: 主检 Appraiser:

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020088765

鉴定项目 Identification Items	鉴 定 结 果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	该货物不属易燃危险品。 The product is not classified in flammable substance.
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:752693-

报告结束

空 运
By Air

NO.2020088764

中国认可
检验
INSPECTION
CNAS IB0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 新型冠状病毒抗原检测试剂盒

Sample Name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)

委托单位： 杭州睿丽科技有限公司

生产单位： 杭州睿丽科技有限公司

上海化工院检测有限公司 检验检测专用章

上化院 上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd

空 运
By Air

空 运
By Air

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods　　NO. 2020088764

样品名称 Sample Name	中文 Chinese	新型冠状病毒抗原检测试剂盒
	英文 English	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)
委托单位 Consignor		杭州睿丽科技有限公司
生产单位 Manufacturer		杭州睿丽科技有限公司
检验方法、程序 Inspection Methods and Procedures		国际航空运输协会《危险品规则》61版 IATA Dangerous Goods Regulations (DGR) 61st Edition
样品外观与气味 Appearance & Odor		多种颜色纸盒(内含白色塑料测试板及无色透明液体)，稍有气味 Multicolor Paper box(containing white plastic test board and colorless transparent liquid),Weak odor

IDENTIFICATION CONCLUSION 鉴定结论

1. 危险性识别(Hazards identification)

无。
None.

2. 空运按照IATA DGR办理的类项(Suggestion according to IATA DGR)

根据特殊规定A122，可按非限制性货物条件办理。
The substance is not subject to IATA DGR according to special provision A122.

3. 包装要求(Packaging requirements)

无。
None.

检验日期: Inspection Date: 2020-08-31　　签发日期: Issue Date: 2020-08-31　　生效日期: Effective Date: 2020-08-31

备注 Comment	无。 None.

批准 Approver:　　审核 Checker:　　主检 Appraiser:

货物运输条件鉴定书

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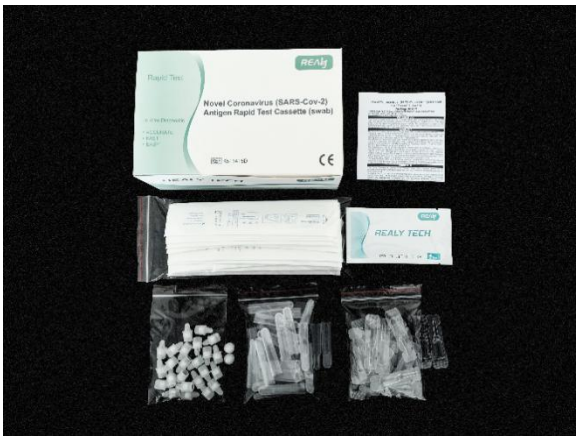
鉴定项目 Identification Items	鉴 定 结 果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	该货物不属易燃危险品。 The product is not classified in flammable substance.
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:220172-

报告结束



25 tests/kit

500 tests/carton

Carton size: 45*44*28cm

Volume: 0.056CBM

Gross weight per carton: 7.5KG

Volume weight per carton via air cargo:9.5KG

Volume weight per carton via express:11.5KG

5 tests/kit

1075 tests/carton

Carton size: 65*55*45cm

Volume: 0.16CBM

Gross weight per carton: 20KG

Volume weight per carton via air cargo: 27KG

Volume weight per carton via express: 32KG