BETTER AG

Top quality at manufacturer prices

COVID-19 Rapid test for professional use

With an integrated buffer solution

Paul-Ehrlich-Institut

Überprüft und dem derzeitigen Stand der Technik entsprechend

3 in 1
Nasopharyngeal | Oropharyngeal | Nasal Swab

Bundesinstitut für Arzneimittel und Medizinprodukte

Erstattungsfähig dank BfarM Listung AT 731/21

05 21

Listed for EU-wide recognition in the "EU common list"
of the European Commission - Directorate General for Health and Food Safety
Common list of COVID-19 rapid antigen tests
Test winner in the accuracy list of the Paul-Ehrlich Institute

15 min

Visible result in 15-20 Minutes

Sensitivity	95,51%
Specifity	99,72%
Result in	15-20 Minutes
Packaging	25 pieces per box

LONGSEE

English

2019-nCoV Ag Rapid Detection Kit(Immuno-Chromatography)

Instructions for Use

REF LS-C-T-009

【Intended Use】

The kit is an immunochromatographic test for rapid, qualitative detection of the SARS-CoV-2 nucleocapsid antigen extracted from the nasopharyngeal swab or oropharyngeal swab specimens from persons suspected of COVID-19 . The kit is intended to support the rapid diagnosis of SARS-CoV-2 infections.

For in vitro diagnostic use only. For professional use only.

【Summary】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

【Test Principle】

This kit applies immunochromatography technology to detect the presence or absence of 2019-nCoV nucleocapsid proteins in swab specimens from patients with signs and symptoms of infection suspected of having 2019-nCoV by the double antibody sandwich method. While the concentration of the 2019-nCoV antigens in samples is higher than or equal to the minimum detection limit, these antigens react separately with corresponding antibodies to form complexes, and the 2019-nCoV antibodies are coated in the detection area (T). These antigens are captured and a red line of reaction is formed. The result is rated as positive. Otherwise the result formed in T without a red line is assessed as negative. Under normal test conditions, the quality control area (C) should be colored to indicate that the test is valid.

【Components】

	Component	1 T/kit	5 T/kit	25 T/kit	50 T/kit
1	Test Cartridge	1 pc	5 pcs	25 pcs	50 pcs
2	One-off Swab	1 pc	5 pcs	25 pcs	50 pcs
3	Extraction Tube	1 pc	5 pcs	25 pcs	50 pcs

【Storage and Stability】

1) Store at 4-35 °C up to the expiration date printed on the package.

2) Do not freeze the kit or its components.

【Specimen Collection and Preparation】

The test can be performed with oropharyngeal swab or nasopharyngeal swab specimen.

1.Oropharyngeal swab specimen collection: Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.Place swab, tip first, into the extraction tube provided.

2.Nasopharyngeal swab specimen collection: Tilt patient's head back 70 degrees.Gently and slowly insert a minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) 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.Gently rub and roll the swab.Leave swab in place for several seconds to absorb secretions.Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection.If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.Place swab, tip first, into the extraction tube provided.

3.It is recommended that specimens be treated with the sample extraction buffer provided with the kit as soon as possible after collection. If immediate processing is not possible, the specimen can be stored in a dry, sterilized and tightly sealed plastic tube at 2°C ~8°C for up to 8 hours.

【Test Procedure】

Test Preparation

1. Allow all kit components to equilibrate to room temperature (15-30°C) prior to testing for 30 minutes,if previously stored in a cool place.

Extraction

1.Open the drip cap of the extraction tube and immerse the sampled swab tip into the extraction tube and rotate the swab tip 10 times in the buffer liquid while applying pressure with your fingers. Then let it sit at room temperature for 5 min.

2.Remove the swab while squeezing the sides of the tube to extract the liquid with the sample from the swab.

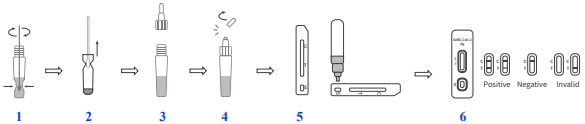
3.Screw the drip cap tightly onto the extraction tube.

4.Screw off the tip of the drip cap of the extraction tube.

Reaction with Test Cartridge

5.Remove a test cartridge from the sealed pouch by tearing at the notch and place it on a level surface.Drip 3~4 drops (about 100 μL) of extracted specimens vertically into the specimen well (S) on the test cartridge by squeezing the tube. The formation of air bubbles in the specimen well (S) must be avoided.Do not handle or move the test cartridge until the test is complete and ready for reading.

6.Start timer. Read result within 15 ~20 minutes of adding the sample. The test result is invalid after 20 minutes.



【Interpretation of the Result】

To read the test results, all you have to do is look at the results window.

1. Positive

If two color bands respectively appear at the position of the quality control line (C line) and the detection line (T line) in the observation window, the test result is positive. The test result indicates that the sample contains 2019-nCoV antigens.

2.Negative

If one color band appear at the position of the quality control line (C line) and no one color band at the detection line (T line) in the observation window, the test result is negative.The test result indicates that the 2019-nCoV antigens in the sample are negative or the concentration is below the detection limit of the set.

3.Invalid

If no color band appear at the position of the quality control line (Line C) or only one color band at the detection line (T line) in the observation window , the test is invalid. The sample should be taken again and the test repeated.

【Limitations】

1. The contents of this kit are for professional use and qualitative detection of 2019-nCoV antigen from swab specimen. Other specimen types may lead to incorrect results and must not be used.

2. Failure to follow the instructions for test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

3. Due to the limitations of the methodology, experimenters should pay more attention to negative results.A negative test result may occur if the specimen was collected, extracted or transported improperly. A negative test result does not eliminate the possibility of 2019-nCoV infection and should be confirmed by viral culture or a molecular assay.

4. Positive test results do not rule out co-infections with other pathogens. Positive results may occur in cases of infection with SARS-CoV.

5. Test results must be evaluated in conjunction with other clinical data available to the physician.

6. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.

【Performance Characteristics】

1. LIMIT OF DETECTION

The limit of detection has been evaluated at 6.0×10^2 $TCID_{50}$/mL.

2. CROSS-REACTIVITY

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

Potential Cross-Reactant		Test Concentration
Virus	Adenovirus	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus HKU1	1.0×10^5 $TCID_{50}$/mL
	MERS-coronavirus	1.0×10^5 $TCID_{50}$/mL
	SARS-coronavirus	1.0×10^5 $TCID_{50}$/mL
	Human Metapneumovirus (hMPV)	1.0×10^5 $TCID_{50}$/mL
	Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL
	Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL
	Parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL
	Parainfluenza virus 4	1.0×10^5 $TCID_{50}$/mL
	Influenza A	1.0×10^5 $TCID_{50}$/mL
	Influenza B	1.0×10^5 $TCID_{50}$/mL
	Enterovirus	1.0×10^5 $TCID_{50}$/mL
	Respiratory syncytial virus	1.0×10^5 PFU/mL
	Rhinovirus	1.0×10^5 PFU/mL
Bacteria	Bordetella pertussis	1.0×10^6 cells/mL
	Chlamydia pneumoniae	1.0×10^6 IFU/mL
	Haemophilus influenzae	1.0×10^6 cells/mL
	Legionella pneumophila	1.0×10^6 cells/mL
	Mycoplasma pneumoniae	1.0×10^6 U/mL
	Streptococcus pyogenes	1.0×10^6 cells/mL
	Streptococcus pneumoniae	1.0×10^6 cells/mL
	Mycobacterium tuberculosis	1.0×10^6 cells/mL
	Staphylococcus aureus	1.0×10^6 org/mL
	Staphylococcus epidermidis	1.0×10^6 org/mL
Yeast	Candida albicans	1.0×10^6 cells/mL

3. INTERFERING SUBSTANCES

There was no interference for potential interfering substances listed below:

Substance	Concentration
Whole Blood	4%
Mucin	0.5%
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Naso GEL (NeilMed)	5% v/v
CVS Nasal Drops (Phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Homeopathic (Alkalol)	1:10 dilution
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 μg/mL
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v
Tamiflu (Oseltamivir Phosphate)	5 mg/mL

4. HOOK EFFECT

There is no hook effect at $1.5\times10^6$$TCID_{50}$/mL of SARS-CoV-2 which was isolated from a COVID-19 confirmed patient in China.

5. CLINICAL EVALUATION

Clinical evaluation was performed to compare the results obtained by The SARS-CoV-2 Antigen Rapid Test Kit and RT-PCR. The results were summarized below:

5.1 Nasopharyngeal swabs

Table 1. 2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)
Performance within 7 days of symptom onset against the RT-PCR test method

Nasopharyngeal Swabs	Reference Extracted SARS-CoV-2 RT-PCR assay						95% CI	
		POS	NEG	Total			LCI	UCI
2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	POS	340	1	341	PPA	95.51%	92.66%	97.32%
	NEG	16*	362	378	NPA	99.72%	98.23%	99.99%
	Total	356	363	719	PPV	99.71%	98.12%	99.98%
					NPV	95.77%	93.08%	97.48%
					Prevalence	49.51%	45.80%	53.23%
					OPA	97.64%	96.25%	98.52%
					Kappa	95.27%	93.43%	97.11%

*3 of the discrepant samples had high Ct values (>30) when tested by the comparative method

5.2 Oropharyngeal swabs

Table 2. 2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)
Performance within 7 days of symptom onset against the RT-PCR test Method

Oropharyngeal Swabs	Reference Extracted SARS-CoV-2 RT-PCR assay						95% CI	
		POS	NEG	Total			LCI	UCI
2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	POS	339	1	340	PPA	95.22%	92.32%	97.11%
	NEG	17*	362	379	NPA	99.72%	98.23%	99.99%
	Total	356	363	719	PPV	99.71%	98.11%	99.98%
					NPV	95.51%	92.78%	97.28%
					Prevalence	49.51%	45.80%	53.23%
					OPA	97.50%	96.08%	98.41%
					Kappa	94.99%	93.10%	96.88%

*4 of the discrepant samples had high Ct values (>30) when tested by the comparative method

Marknote:

PPA - Positive Percent Agreement (Sensitivity)
NPA - Negative Percent Agreement (Specificity)
PPV - Positive Predictive Value
NPV - Negative Predictive Value
OPA - Overall Percent Agreement
CI - Confidence Interval
LCI - Lower Confidence Interval
UCI - Upper Confidence Interval

【Symbol Explanation】

Symbols	Title of symbol	Symbols	Title of symbol	Symbols	Title of symbol
IVD	In vitro diagnostic medical device	LOT	Batch code	4°C 35°C	Store between 4~35ºC
	Do not re-use		Date of manufacture	EC REP	Authorized representative in the European Community
	Keep away from sunlight		Use-by date	CE	CE mark
	Keep dry		Do not use if package is damaged		Manufacturer
	Contains sufficient for <n> tests		Consult instructions for use		

【Warnings and Precautions】

1. Take the appropriate precautions for infected material if necessary.
2. There is a desiccant in the package and it is not allowed to be taken orally.
3. Please read the instructions carefully before use and strictly follow the instructions. The reagents cannot be used when expired or the packaging bag is damaged or the seal fails. There should be no coloured lines on the test card before use.
4. When opening the foil pouch, pay attention that the test cartridge should not fall out. After the foil pouch is opened, test cartridge should be used within 30 minutes .
5. The test kit should be sealed and stored at 4-35 °C, keeping away from moisture and sunlight, the test kit stored at low temperature should be restored to room temperature before use.
6. For samples containing or suspected of containing the source of infection, there should be appropriate bio-safety guarantee safe operation procedures. The following are relevant precautions:
   1) The gloves or reagents used in processing samples should be disinfected,
   2) Use disinfectant to disinfect the spilled samples or reagents.
7. It is a disposable in vitro diagnostic product. For experimental wastes such as test cards, gloves, pipette tips, unused samples or reagents, etc., which have potential biological hazards, should be in accordance with biological safety regulations, environmental protection regulations or medical waste regulations for disinfection and disposal.
8. Avoid skin or eyes touching the sample extraction buffer. If accidentally touch sample extraction buffer, immediately use plenty water to wash the skin or eyes. Forbid drinking the sample extraction buffer. If carelessly intake,please gargle thoroughly. Go to hospital if you feel not well.

Guangdong Longsee Biomedical Co.,Ltd.
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510000, Guangzhou, China

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Email: info@OdemShop.com
Shop: www.OdemShop.com

DECLARATION OF CONFORMITY

Manufacturer	Guangdong Longsee Biomedical Co.,Ltd.
Address	5/F Building A, No.83, Ruihe Road, Huangpu District, 510000, Guangzhou, China
European Representative	MedPath GmbH
Address	Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
Product Information	2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)
Model code	LS-C-T-009
Classification	Other IVD Device
Registration Number in German DIMDI Database	DE/CA61/1M50/294
Conformity Assessment Route: Annex lll	
General Applicable Directives:	In vitro diagnostic medical devices Directive: 98/79/EC

Standards Applied	EN13612:2002/AC: 2002	EN ISO13485:2016
	EN ISO 23640:2015	EN ISO14971:2012
	EN 13641:2002	EN ISO18113-1:2011
	EN 15223-1:2016	EN ISO18113-2:2011

We,the manufacturer, hereby declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. The products meet prospective uses and all supporting documentations are retained under the premises of the manufacturer.

Place, date of issued: Guangzhou, P. R. China, May 10, 2021

Signature of Vice President:

Marco

(Marco Zhang)

CE

LONGSEE 南芯医疗
Guangdong Longsee Biomedical Co.,Ltd.
5/F, Building A, No. 83 Ruihe Road, Huangpu District, Guangzhou, China 510000

Statement

Guangdong Longsee Biomedical Co., Ltd. ,based on the mutation site nucleic acid sequence of Omicron (B.1.1.529) published by GISAID database.

A detailed comparison with the specific N protein sequence used in our 2019-nCoV Ag Rapid Detection Kit(Immuno-Chromatography), and bioinformatics analysis of the monitoring area with the mutation site of the above mutant strain showed that the nuclear shell mutation point of the new variant Omicron (B.1.1529) was located in DEL31/33. PI3I, R203K and G204R, all mutation points are outside the epitope region identified by one of our antibodies.
Our 2019-nCoV Ag Rapid Detection Kit will not appear off-target or missed detection, which can guarantee the sensitivity and specificity of the detection kit. The LONGSEE 2019-nCoV Ag Rapid Detection Kit can effectively cover the Omicron (B.1.1529), with no effect on performance.

We will continue to monitor the ever-changing situation, also strive to comply with high-quality management standards to ensure high-quality products that meet customer expectations and market needs.

Guangdong Longsee Biomedical Co., Ltd.

December 2, 2021

Paul-Ehrlich-Institut

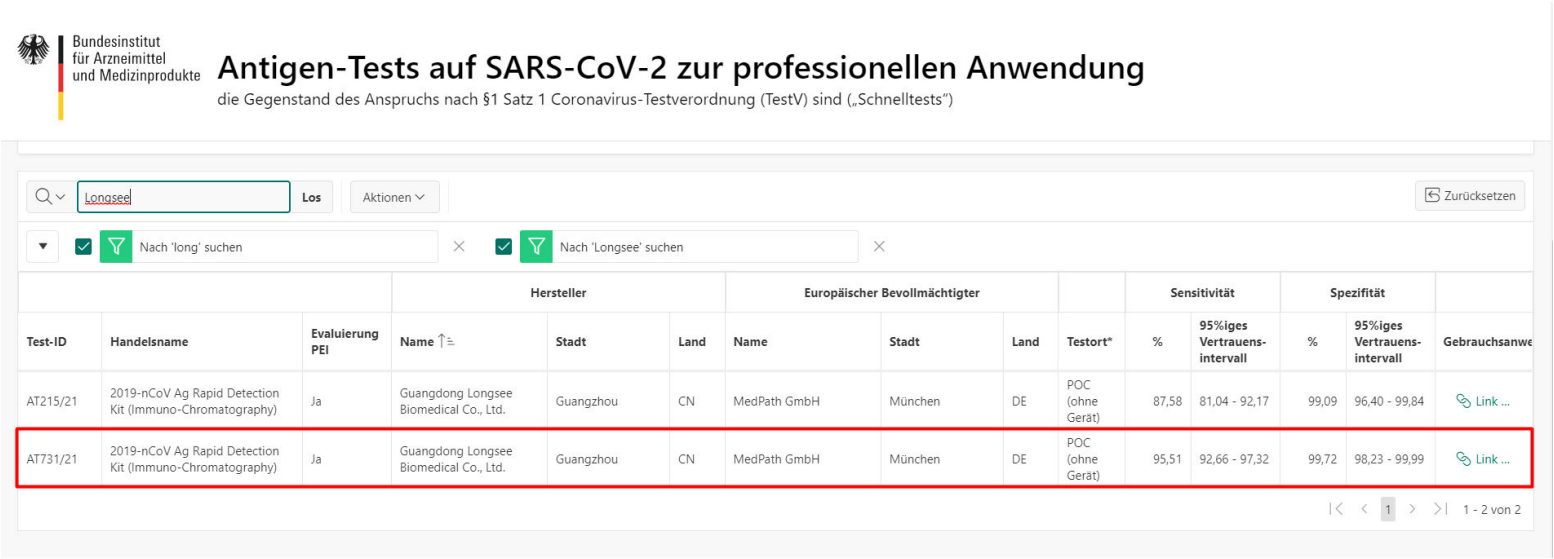
AT-Nr. / AT-No.	AT-Nr. Selbsttest # / AT-No. self-test #	Ref-Nr. * / ID-No. *	Hersteller / Manufacturer	Testname / Test name	Zielantigen / target antigen	Sensitivität / Sensitivity: Cq ≤25	Cq 25-30	Cq ≥30	Gesamt-Sensitvität / total sensitivity	Omikron Erkennung entsprechend der Bridging Prüfung / Omicron detection by bridging
AT587/21		16696722	FUJIFILM Corporation	FUJIFILM COVID-19 Ag Test	N	85,0%	10,0%	0,0%	38,0%	
AT029/20		231906	Fujirebio Inc. (Mast Diagnostica GmbH)	ESPLINE® SARS-CoV-2	N	100,0%	21,7%	0,0%	46,0%	
AT019/20		COVAG025	GenBody Inc.	GenBody COVID-19 Ag	N	94,4%	26,1%	0,0%	46,0%	
AT1100/21		CoVSLFA-20	Genobio Pharmaceutical Co., Ltd.	Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Saliva/Swab)	N	100,0%	95,0%	40,0%	86,0%	
AT111/20	AT1200/21	52026075	Genrui Biotech Inc.	Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	N	94,1%	56,5%	0,0%	58,0%	
AT161/20		P2004	GenSure Biotech Inc.	DIA-COVID® COVID-19 Ag Rapid Test Kit	N	94,1%	13,0%	0,0%	38,0%	
AT166/20	AT1257/21	CG2061	Getein Biotech, Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	N	100,0%	82,6%	0,0%	72,0%	
AT755/21		600008	Giallergen CO., LTD.	Novel Corona Virus (2019-nCoV) Ag Rapid Test Kit	N	100,0%	100,0%	60,0%	92,0%	
AT533/21	AT1295/21	CG123005	Goldsite Diagnostics Inc.	Goldsite COVID-19 SARS-CoV-2 Antigen Kit (Colloidal Gold)	N	100,0%	35,0%	0,0%	54,0%	
AT018/20		n.a.	Green Cross Medical Science Corp. (Weko Pharma GmbH)	Genedia W Covid-19 Ag	N	83,3%	8,7%	0,0%	34,0%	
AT542/20		n.a.	Guangdong Hecin Scientific,Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	N	82,4%	13,0%	0,0%	34,0%	
AT731/21		LS-C-T-009	Guangdong Longsee Biomedical Co.,Inc.	Longsee 2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	N	100,0%	100,0%	100,0%	100,0%	Ja
AT086/20	AT1158/21	BE0040	Guangdong Wesail Biotech Co., Ltd.	COVID-19 Ag Test Kit	N	100,0%	52,2%	11,1%	62,0%	Ja
AT582/21		n.a.	Guangzhou Tebsun Bio-Tech Development Co., Ltd.	Tebsun 2019-nCoV Antigen Test Kit	N	95,0%	65,0%	0,0%	64,0%	
AT125/20		W196	Guangzhou Wondfo Biotech Co. Ltd	Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	N	88,2%	0,0%	0,0%	30,0%	Ja
AT276/21	AT1117/21	ICOV-802	Hangzhou AllTest Biotech Co., Ltd.	Covid-19 Antigen Rapid Test (Oral fluid)	N	100,0%	55,0%	0,0%	62,0%	
AT766/21	AT1172/21	INCP-502-N	Hangzhou AllTest Biotech Co.,Ltd.	AllTest SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	N	90,0%	20,0%	0,0%	44,0%	Ja
AT568/21	AT1331/21	302281	Hangzhou Biotest Biotech Co., Ltd	Sienna COVID-19 Antigen-Schnelltestkassette (Nasenabstrich)	N	100,0%	95,0%	60,0%	90,0%	Ja
AT825/21		n.a.	Hangzhou Careomedic Tech Co., Ltd.	SARS-CoV-2-Antigen-Schnelltest	N	75,0%	0,0%	0,0%	30,0%	Ja
AT079/20		n.a.	Hangzhou Clongene Biotech Co., Ltd.	Clungene COVID-19 Antigen Rapid Test	N	94,4%	34,8%	0,0%	50,0%	Ja
AT816/21		n.a.	Hangzhou DIAN Biotechnology Co., Ltd.	GENEDIAN COVID-19 Antigen Test Cassette	N	90,0%	5,0%	0,0%	38,0%	Ja

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [16]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [17]	Included in EU common list since:
				Nasopharyngeal: Clinical sensitivity: 97.14% (95% CI: 91.88 – 99.41%); Clinical specificity: 99.60% (95% CI: 98.58 – 99.95%)				
Green Cross Medical Science Corp.	GENEDIA W COVID-19 Ag	1144	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 100%	100% sensitivity 90.1% sensitivity 100% specificity NP swab, Anterior nasal swab	DE[2]	Nucleo-protein	Anterior nasal swab, Nasopharyngeal swab	10 May 2021
Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	1747	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 82% at Ct ≤ 25; Manufacturer specificity: 99.07%	96.83% sensitivity 99.39% specificity Nasal swab	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	10 May 2021
Guangdong Longsee Biomedical Co., Ltd.	2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	1216	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%	OP swab: sensitivity 95.22%, specificity 99.72% Nasal swab: sensitivity 94.15%, specificity 99.68% NP swab: sensitivity 95.51%, specificity 99.72%	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab, Oropharyngeal swab, Nasal swab	14 July 2021
Guangdong Wesail Biotech Co. Ltd	COVID-19 Ag Test Kit	1360	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 98%	90% sensitivity 98% specificity Nasal swab	DE[2]	Nucleo-protein	Nasal swab, Nasopharyngeal swab	17 February 2021
Guangzhou Decheng Biotechnology CO., Ltd	V-CHEK, 2019-nCoV Ag Rapid Test Kit (Immuno-chromatography)	1324	*Retrospective in vitro study* **DE**: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 94,1% at Ct < 25; Manufacturer specificity: 99,5%	Clinical Sensitivity: 95.83% Specificity 99.57% Nasal swab	DE[2]	Nucleo-protein	Nasal swab	7 July 2021

Bundesinstitut
für Arzneimittel
und Medizinprodukte

Antigen-Tests auf SARS-CoV-2 zur professionellen Anwendung

die Gegenstand des Anspruchs nach §1 Satz 1 Coronavirus-Testverordnung (TestV) sind („Schnelltests")



			Hersteller			Europäischer Bevollmächtigter				Sensitivität		Spezifität		
Test-ID	Handelsname	Evaluierung PEI	Name	Stadt	Land	Name	Stadt	Land	Testort*	%	95%iges Vertrauens-intervall	%	95%iges Vertrauens-intervall	Gebrauchsanwe
AT215/21	2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	Ja	Guangdong Longsee Biomedical Co., Ltd.	Guangzhou	CN	MedPath GmbH	München	DE	POC (ohne Gerät)	87,58	81,04 - 92,17	99,09	96,40 - 99,84	Link ...
AT731/21	2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	Ja	Guangdong Longsee Biomedical Co., Ltd.	Guangzhou	CN	MedPath GmbH	München	DE	POC (ohne Gerät)	95,51	92,66 - 97,32	99,72	98,23 - 99,99	Link ...

1 - 2 von 2