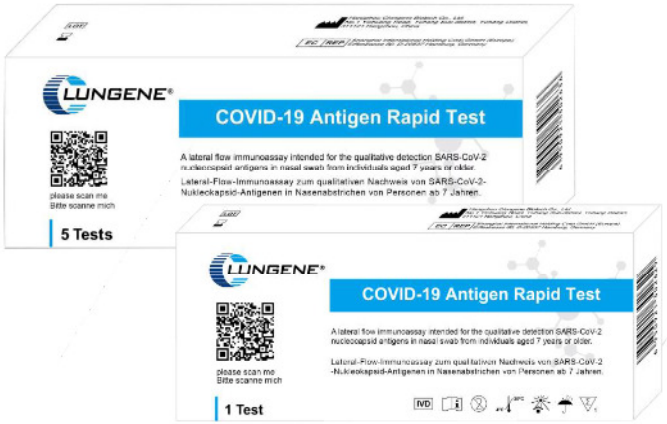
CLUNGENE® COVID-19 Antigen Rapid Test

SUMMARY



01

For Self-Testing

CLUNGENE® COVID-19 Antigen Rapid Test

Product	Specifications	MEAS/BOX
	1 Test/Box	165*68*20mm

Extraction Reagent x1	Test Cassette x1	Tube x1	Swab x1
			

Packing Carton Information	MEAS/CTN	TESTS/CTN	Estimated G.W./CTN
	52*35*57cm	400tests	14.2kg

Product	Specifications	MEAS/BOX
	5 Tests/Box	190*70*38mm

Extraction Reagent x5	Test Cassette x5	Tube x5	Swab x5
			

Packing Carton Information	MEAS/CTN	TESTS/CTN	Estimated G.W./CTN
	59*40*58cm	1200tests	20.3kg

Tests zur Eigenanwendung durch Laien

Das BfArM hat die ersten Sonderzulassungen nach §11 Absatz 1 Medizinproduktegesetz (MPG) von Antigen-Tests zur Eigenanwendung durch Laien (Selbsttests) zum Nachweis von SARS-CoV-2 erteilt. Weitere Informationen zur rechtlichen Grundlage und den dabei geprüften Anforderungen finden Sie weiter unten auf dieser Seite unter dem Menüpunkt „Hinweise zur Sonderzulassung von Antigen-Tests durch das BfArM".

Es handelt sich um folgende Tests, die Liste wird kontinuierlich aktualisiert:

Aktenzeichen der Sonderzulassung des BfArM	Hersteller	Antragsteller	Testname	BfArM-AT-Nummer*
5640-S-168/21	Hangzhou Clongene Biotech Co., Ltd.	Hangzhou Clongene Biotech Co., Ltd.	COVID-19 Antigen Rapid Test	

The self-testing product is transformed from the professional-testing product ***(CLUNGENE® COVID-19 Antigen Rapid Test)*** manufactured by Clongene. The BfArM has granted the first special approvals according to §11 paragraph 1 of the German Medical Devices Act (MPG) of antigen tests for self-administration by laypersons (self-tests) for the detection of SARS-CoV-2. Our self-testing product can be sold and used in Germany.

Test Procedure

CLUNGENE® COVID-19 Antigen Rapid Test (For Self-Testing)

Take one-test kit as an example.

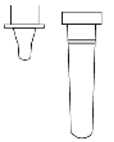
■ Test Preparation

[What is included in the test kit]

Swab (1X)

Test Cassette (1X)

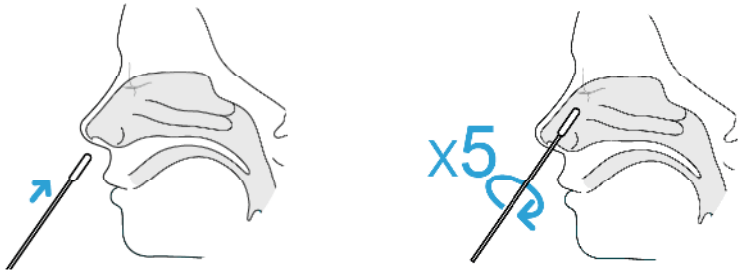
Extraction Reagent (1X)



Tube (1X)

Instructions for Use is also included.

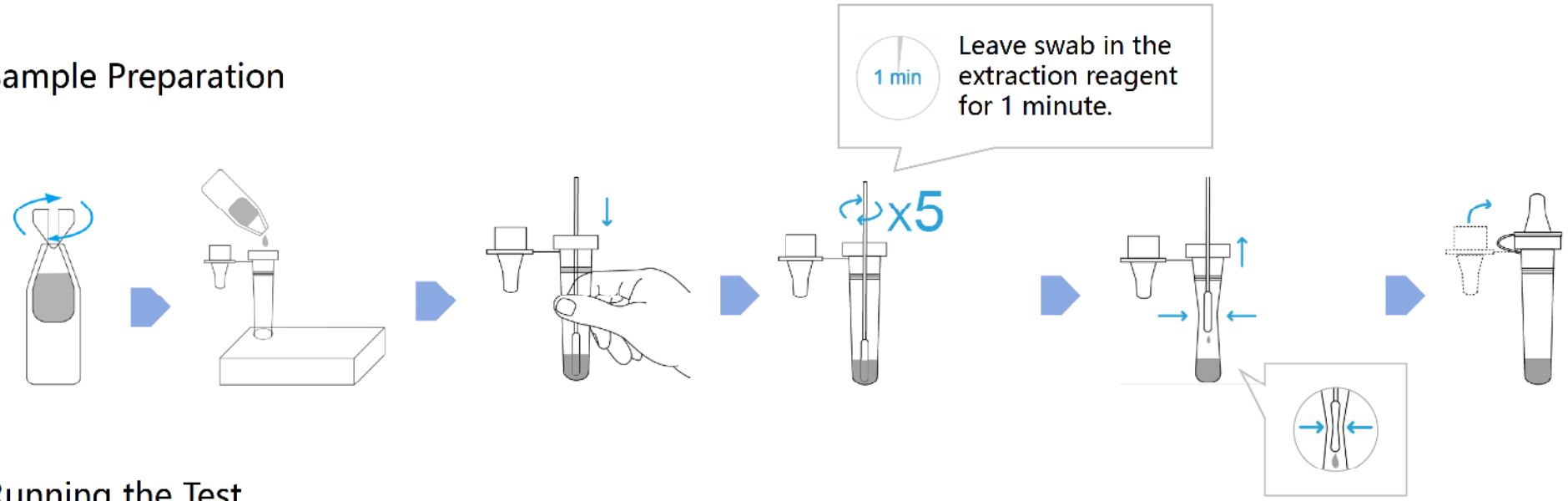
■ Sample Collection



Swab Left Nostril

Swab Right Nostril

■ Sample Preparation



■ Running the Test

BACK

02

For Professional

CLUNGENE® COVID-19 Antigen Rapid Test

National List

BfArM

Listed by BfArM.

PEI

Validated by Paul-Ehrlich-Institut (PEI) in Germany.

EU

Listed in the EU common list of COVID-19 rapid antigen tests on 17 February 2021.

NAVI

Validated by Nationalen Referenzzentrum für neu auftretende Virusinfektionen (NAVI) in Switzerland, with comments as "Diese Ergebnisse liegen deutlich über den Empfehlungen der WHO für Ag-Schnelltests" by BAG.

Performance Characteristics

The self-testing product is transformed from the professional-testing product (***CLUNGENE® COVID-19 Antigen Rapid Test***) manufactured by Clongene.

■ Clinical Performance

617 nasal swabs were collected from individual symptomatic patients (within 7 days of onset) and asymptomatic patients who were suspected of COVID-19. The swabs were detected by COVID-19 Antigen Rapid Test of Clongene and the RT-PCR. Summary data as below:

COVID-19 Antigen		RT-PCR (Ct value≤33)		Total
		Positive	Negative	
CLUNGENE®	Positive	132	3	135
	Negative	4	462	466
Total		136	465	601

PPA (Ct≤33):97.1% (132/136), (95%CI: 92.7%～98.9%)
NPA: 99.4% (462/465), (95%CI: 98.1%～99.8%)

COVID-19 Antigen		RT-PCR (Ct value≤37)		Total
		Positive	Negative	
CLUNGENE®	Positive	139	3	142
	Negative	13	462	475
Total		152	465	617

PPA (Ct≤37):91.4% (139/152), (95%CI: 85.9%～94.9%)
NPA: 99.4% (462/465), (95%CI: 98.1%～99.8%)

PPA - Positive Percent Agreement (Sensitivity)
NPA - Negative Percent Agreement(Specificity)