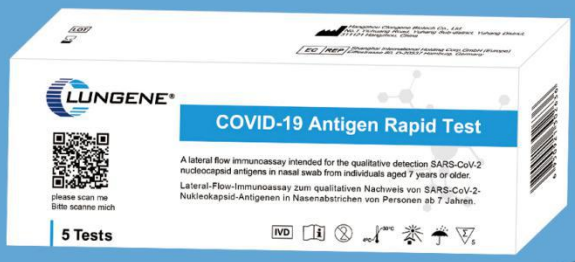
LUNGENE®

COVID-19 Antigen Rapid Test (Self-Testing)



Kit Contents

Product	Extraction Reagent	Test Cassette	Tube	Swab
 1 Test	 X 1	 X 1	 X 1	X 1
 5 Tests	 X 5	 X 5	 X 5	X 5

Product Features

- Detection of SARS-Cov-2 antigen
- Easy to collect samples
- No equipment required
- Results are clearly visible
- Instant result at 15-20 minutes
- Suitable for preventing the infection

- **Overview of COVID-19 Antigen Rapid Test (*For Self-Testing*)**

The self-testing product is transformed from the professional-testing product (COVID-19 Antigen Rapid Test) developed 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.

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	

- **National List of COVID-19 Antigen Rapid Test (*For professional use*)**

1) Listed by BfArM (*Liste der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2*);

2) Listed in the EU common list of COVID-19 rapid antigen tests on 17 February 2021 (*EU health preparedness: A common list of COVID-19 rapid antigen tests, including those of which their test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates, agreed by the Health Secu*);

3) Validated by Paul-Ehrlich-Institut (PEI) in Germany (*Übersicht SARS-CoV-2 Antigenschnelltests, die als „dem derzeitigen Stand der Technik entsprechend" bewertet wurden*);

4) Validated by Nationalen Referenzzentrum für neu auftretende Virusinfektionen (NAVI) in Switzerland (*Validierte SARS-CoV-2-Schnelltests*), with comments as "*Diese Ergebnisse liegen deutlich über den Empfehlungen der WHO für Ag-Schnelltests*" by BAG.

- **Related Products**

Catglog No.	Product Name	Specimen	Remark
ICOV4212	COVID-19 IgG/IgM Rapid Test	Whole Blood/Serum/Plasma	Professional-testing/CE
ICOV5002	COVID-19 Antigen Rapid Test Cassette (Nasal Swab)	Nasal Swab	Professional-testing/CE
ICOV5002	COVID-19 Antigen Rapid Test	Nasal Swab/Nasopharyngeal Swab/ Oropharyngeal Swab	Professional-testing/CE
ICOV7002	COVID-19 Antigen Rapid Test Cassette (Saliva)	Saliva	Professional-testing/CE
IrID5325	COVID-19/Influenza A+B Antigen Combo Rapid Test	Nasopharyngeal Swab	Professional-testing/CE