

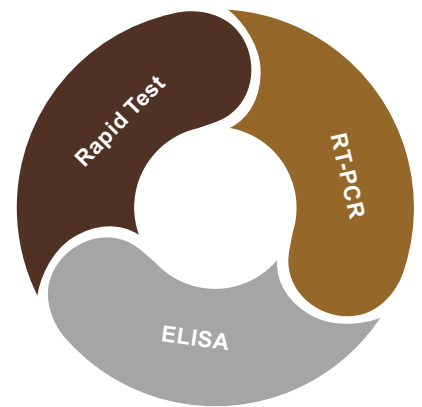
LifecoscM Biotech Limited is a GMP standard manufacturer dedicated in infectious disease diagnosis for human and animals. Right now, LifecoscM provides our customer with over 180 kinds of test kit and instrument, covers rapid test, ELISA test kit and PCR test kit. In the past 20 years, LifecoscM team has experienced in antigen design, prokaryotic expression, eukaryotic expression, mAb production, ELISA/Immunochromatography system optimization.



Professional And Experienced Technical Competancy

Continuous R&d Progress

Production Capability For Superior Quality



No.1 Sensitivity in 245 Antigen Test Kits

In a recent evaluation study of sensitivity against 245 test kits by Paul Ehrlich Institute, the top authority in Germany, LifecoscM COVID-19 ANTIGEN TEST CASSETTE won the No.1 sensitivity result (100% sensitivity with comparator Ct≤25, 100% sensitivity with comparator Ct 25~30, 100% sensitivity with comparator Ct≥30).

Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests /
Comparative evaluation of the sensitivities of SARSCoV-2 antigen rapid tests

Paul-Ehrlich-Institut

AT-Nr. / AT-No.	Ref-Nr. / ID-No. *	Hersteller / Manufacturer	Testname / Test name	Sensitivität / Sensitivity			Gesamt-Sensitivität / total sensitivity
				Zielantigen / target antigen	Cq ≤ 25	Cq 25-30	
AT105421	n.a.	LifecoscM Biotech Limited	COVID-19 Rapid Test Cassette Antigen Test Kit	N	100.0%	100.0%	100.0%

https://covid-19.sante.gouv.fr/tests

PLATEFORME COVID-19

NOM	FABRICANT	DISTRIBUTEUR	CE	UE	CNR	SOUS-TYPE DE TEST	CIBLES	TYPE DE PRÉLEVEMENT
LifecoscM COVID-19 Antigen Test Cassette	LifecoscM Biotech Limited		✓	✓	✓	Antigénique non automatisé (dont TROD)	N	Nasopharyngé

NOTIS

Notify medical devices and IVDs

General data

NOTIS number: 20212039
Date of receipt: 4/10/2021
Status: Finalised
Date finalised: 5/4/2021

Client details

Name: SUNGO Europe B.V.
Contact person concerning this notification: Luc, dir. R.

Manufacturer details

Authorized representative of manufacturer: LifecoscM Biotech Limited
Address: 28, Fuzen Building, 689 Shuangping Avenue, Guangming District, Zhenjiang
City: Zhenjiang
Country: CHINA

Products

Serial	Model	Article number(s)	Model(s)	Class	Status
C	LifecoscM COVID-19 A...			IVD	REV

Documents

Date	File	Title
9/4/2021	20211029-2001.pdf	20211029
9/4/2021	20211029-2001.pdf	20211029-2001_1 product
4/19/2021	20210201-2001.pdf	Declaration of Conformity
4/19/2021	20210201-2002.docx	Product Information

Antigen Tests avec résultat Empirisme des Coronavirus SARS-CoV-2

AT-Nr.	Modèle	Prélèvement	Marque	Statut	Classe	Statut	Statut	Statut	Statut
AT105421	COVID-19 Antigen Test Cassette	Nasopharyngé	LifecoscM	Finalisé	IVD	REV	REV	REV	REV

Lifecosc COVID-19 Antigen Test

Product Code	Product Name	Packing	Sample Type	Components
RC-HM01	Lifecosc™ COVID-19 Antigen Test Cassette	25T/Box	Nasopharyngeal swab; Anterior nasal swab; Oropharyngeal swab; Saliva	Test cassette*25 Buffer tube*25 Dropper*25 Flocked swab*25
RC-HM02	Lifecosc™ COVID-19 Antigen Test Cassette (Nasal Swab)	1T/Pack 24Packs/Box	Anterior nasal swab;	Test cassette*24 Buffer tube*24 Dropper*24 Flocked swab*24



DESCRIPTION

- Type: professional use, test type: qualitative
- CE certified, class IVD others
- **Sample type:** refer to above table
- **Time consumption:** 15 minutes
- BFARM listing: AT1054/21, AT1055/21
- Evaluated by the Paul Ehrlich Institute: Yes
- **Ct value:** ≤ 25 **sensitivity:** 100% **specificity:** 99.2%,
- **Ct value:** 25~30 **sensitivity:** 100% **specificity:** 99.2%,
- **Ct value:** ≥ 30 **sensitivity:** 100% **specificity:** 99.2%,

WARNINGS AND PRECAUTIONS

- For healthcare professionals and individuals trained in point of care settings.
- Do not use this product as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status of COVID-19.
- The used test cassette should be discarded according to federal, state and local regulations

SPECIAL STORAGE REQUIREMENT

- First in - First out
- Store dry
- Not in direct heat (above 30°C) for a long time or cold (below 4°C).
- Avoid direct sunlight
- Avoid storage next to radiators and/or next to storage gates and doors

Elongation approx. (in %):	N/A
Sterilisation:	N/A
Washable up to:	N/A
CE marking:	Yes
Customs tariff number:	3822.0000
Shelf life:	24 Month
Classification:	IVD
Language:	Germany/English

Lifecosc COVID-19 Neutralizing Antibody Test

Product Code	Product Name	Packing	Sample Type	Components
RC-HM03	Lifecosc™ COVID-19 Neutralizing Antibody Test Cassette	25T/Box	Whole blood; Plasma; Serum	Test cassette * 25 Transfer pipette * 25 5 ml Sample Diluent * 1 Lancet * 25 Alcohol pad * 25

Neutralizing Antibody Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of neutralizing Antibody after vaccination. It is used for evaluating the neutralizing antibodies level in serum, plasma and whole blood after vaccination of COVID-19.

Lifecosc Biotech Limited

3B Fusen Building, 669 Shuangming Avenue, Guangming District, Shenzhen, China
T: +86 755 2342 0845 E: info@lifecosc.com

