

ALLTEST COVID-19 Antigen Rapid Tests (Swab)

We are now on the
EU Recommendation List !



EU Common List & EU Recommendation List(Health Security Committee)


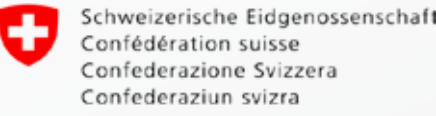
Ct No.	RAT commercial name	CE marking	Clinical performance Data by manufacturer	Clinical performance Data used in MS	FIND evaluation studies	EU Member States using in practice	Other countries using in practice	Countries that have completed practical validation studies	MS currently validating	In JRC database (Device ID #)10	In FIND database
Hangzhou AllTest Biotech Co., Ltd	COVID-19 Antigen Rapid Test	YES	/	DE:93,40% sensitivity, 99,90% specificity	/	AT, BE, BG, FR, SI, RO	CH	DE	AT	Yes (1257)	Yes

White Listed in:

- 1 **BFARM: AT766/21
AT1151/21
Germany**
- 2 **Switzerland**
- 3 **Belgium**
- 4 **France**
- 5 **Slovenia**
- 6 **Portugal**
- 7 **Italy**
- 8 **Austria**
- 9 **Croatia**
- 10 **U.K.**
- 11 **Brazil**
- 12 **Singapore**
- 13 **Philippines**
- 14 **Malaysia**
- 15 **Myanmar**
- 16 **Japan** :
- 17 **India**
- 18 **Turkey**
- 19 **Chile**

In addition, we have registered in more than 20 other countries, including, Hungary, Spain, Ukraine, Argentina, Indonesia, Serbia, Peru, Russia, Ecuador, Bulgaria, Guatemala, etc.

Self Test Listing

CE1434		BFARM: AT1172/21 Germany	
Czech Republic		Austria	
France		Sweden	
Switzerland		U.K.	
Malaysia			

Validated In:

Germany:

1 The test has been evaluated and approved by a reputable laboratory from Germany: **Clinical Study Results** (>100 positive samples; > 100 negative samples):

1. Analytical Results with correlation to Ct-values of the positive samples:

Ct value	No. of Samples	No. of true positive Rapid Test Samples	No. of false negative Rapid Test Samples	Sensitivity of SARS-CoV-2 Antigen Rapid Test (CI)
≤30	82	81	1	98.8% (93-100)
≤32	106	101	5	95.3% (89-98)

2. Analytical Results with correlation to Ct-values of the negative samples:

No. of Samples	No. of true neg. Rapid Test Samples	No. of false positive Rapid Test Samples	Specificity of SARS-CoV-2 Antigen Rapid Test (CI)
100	100	0	100% (96-100), Wilson 95% CI: 96-100%

2 France : SPIRAL Evaluation with good results: Sensitivity 97.1%, Specificity 100%

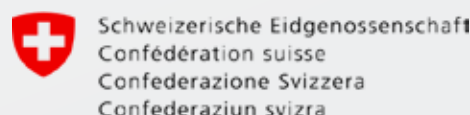
3 Malaysia : IMR(Institute for Medical Research) Evaluation with good results: Sensitivity 96.0%, Specificity 100%



4 Japan : PMDA Evaluation with good results: Sensitivity 100%, Specificity 100%





5 Switzerland: BAG Evaluation with good results: Sensitivity 95.1%, Specificity 100%



WHO

SARS-CoV Rapid Antigen Tests: progress of the applications in the emergency use listing assessment pipeline



Manufacturer name	Product name	Product code(s)	Dossier review	QMS Desk Assessment	EUL application number
Hangzhou AllTest Biotech Co	SARS-CoV-2 Antigen Rapid Test	INCP-502-N			0631-111-00

Web links: https://extranet.who.int/pqweb/sites/default/files/documents/210504_EUL_SARS-CoV-2_product_list.pdf

Published Articles in Health Science Journal



Web links: <https://www.hsj.gr/medicine/different-methods-of-covid19-detection.pdf>

Web links: <https://www.hsj.gr/medicine/a-reallife-approach-for-evaluation-of-rapid-ag-testing-in-sarscov2-infection.pdf>