

Manufacturer	RAT commercial name	CE marking	Clinical performance <i>Data by manufacturer</i>	Clinical performance <i>Data used in MS</i>	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 #) ¹²	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
Hangzhou Clongene Biotech Co., Ltd.	COVID-19 Antigen Rapid Test Kit	Yes	98.5% sensitivity unknown specificity Nasal swab	BE: 91.4% sensitivity, 100% specificity, NP/OP swab DE: 91.4% sensitivity, 99.4% specificity SI: 91.4% sensitivity, 100% specificity, NP/OP swab		AT, BE, DE ^[2] , FR, SI	CH	DE ^[2] CH	HR	Yes (1363)	No
Hangzhou Clongene Biotech Co., Ltd.	COVID-19/Influenza A+B Antigen Combo Rapid Test	Yes	91% sensitivity 100% specificity NP swab	DE: 97.7% sensitivity, 99.8% specificity		DE ^[2]		DE ^[2]		Yes (1365)	Yes
Hangzhou Immuno BiotechCo., Ltd	Immunobio SARS-CoV-2 Antigen ANTERIOR NASAL Rapid Test Kit (minimal invasive)	Yes	94% sensitivity 100% specificity Nasal swab, NP	DE: 94.39% sensitivity 97.67% specificity		DE ^[2]		DE ^[2]		Yes (1844)	
Hangzhou Immuno BiotechCo., Ltd	SARS-CoV2 Antigen Rapid Test	Yes		DE: 95.6% sensitivity, 100% specificity		AT, DE ^[2]		DE ^[2]		No	No
Hangzhou Laihe Biotech Co.	LYHER Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Yes		DE: 96.29% sensitivity, 100% specificity		AT	CH	DE ^[2]		Yes (1215)	No
Hangzhou Lysun Biotechnology Co., Ltd.	COVID-19 antigen Rapid Test Device (Colloidal Gold)	Yes		DE: 96.29% sensitivity, 100% specificity		DE ^[2]	CH	DE ^[2]		Yes (2139)	No
Hangzhou Testsea Biotechnology Co., Ltd.	Testsealabs Covid-19 Antigen Rapid Test Cassette	Yes	92.1% sensitivity 98.1% specificity Nasal swab	DE: 97.6% sensitivity 98.4% specificity		DE ^[2]		DE ^[2]		Yes (1392)	No
Healgen Scientific Limited	Coronavirus Ag Rapid Test Cassette (Swab)	Yes		DE: 97.25% sensitivity, 100% specificity SI: 96.7% sensitivity, 99.2% specificity, NP/Nasal swab		AT, DE ^[2] , NL ^[5] , SE, SI	CH	DE ^[2] , NL ^[5]	SE ^[3]	Yes (1767)	No

Quelle:

https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf