

Summary of Comparative sensitivity evaluation for 122 CE-marked SARS-CoV-2 antigen rapid tests on the European market (May 2021).¹

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Objective

Independent evaluation of the sensitivity of CE-marked SARS-CoV-2 antigen rapid diagnostic tests (Ag RDT) carried out by the The Paul Ehrlich Institute, Federal Reference Centre (Langen, Germany) and commissioned by the German Ministry of Health.

Methods

The sensitivity of 122 Ag RDT was addressed using a common evaluation panel. Minimum sensitivity of 75% for panel members with CT<25 was used for differentiation of devices eligible for reimbursement in the German healthcare system.

Results

The sensitivity of different SARS-CoV-2 Ag RDT varied over a wide range. The sensitivity limit of 75% for panel members with CT <25 was met by 96 of the 122 tests evaluated; 26 tests exhibited lower sensitivity, few of which were completely failing. Some devices exhibited high sensitivity, e.g. 100% for CT<30.

Conclusion

This comparative evaluation succeeded to distinguish less sensitive from better performing Ag RDT. Most of the Ag RDT evaluated appear to be suitable for fast identification of acute infections associated with high viral loads. Market access of SARS-CoV-2 Ag RDT should be based on minimal requirements for sensitivity and specificity.

Comparison of the performance of the main suppliers of antigen tests on the French market.

Manufacturer	Test name	Sensitivity				Ranking
		CT <25	CT 25-30	CT >30	CT 17-36	
Toda Pharma	Toda Coronadiag Ag	100,0%	95,7%	40,0%	86,0%	1/96
Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	100,0%	95,7%	40,0%	86,0%	2/96
Shenzhen Watmind Medical Co.,Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	100,0%	95,7%	20,0%	82,0%	3/96
ulti med Products (Deutschland) GmbH	COVID-19 Antigen Speicheltest (Immunochemographie)	100,0%	95,7%	20,0%	82,0%	4/96
AmonMed (Xiamen) Biotechnology Co., Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	100,0%	87,0%	30,0%	80,0%	5/96
Beijing Tigsun Diagnostics Co.,Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	100,0%	87,0%	30,0%	80,0%	6/96
LumiQuick Diagnostics, Inc.	QuickProfile Covid-19 Antigen Test Card	100,0%	91,3%	20,0%	80,0%	7/96
New Gene (Hangzhou) Bioengineering Co., Ltd.	Covid-19-Antigen-Testkit	100,0%	87,0%	20,0%	78,0%	8/96
ScheBo Biotech AG	ScheBo SARS-CoV-2 Quick Antigen	100,0%	91,3%	10,0%	78,0%	9/96
Triplex International Biosciences (China) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	100,0%	87,0%	20,0%	78,0%	10/96
Siemens Healthineers	CLINITEST® Rapid COVID-19 Antigen Test	100,0%	87,0%	0,0%	76,0%	11/96
Zhejiang Orient Gene Biotech Co.,Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	100,0%	87,0%	0,0%	76,0%	12/96
BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	100,0%	78,3%	11,1%	74,0%	13/96
Getein Biotech, Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	100,0%	82,6%	0,0%	72,0%	14/96
Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	100,0%	82,6%	0,0%	72,0%	15/96
Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)	SARS-CoV-2 Ag Rapid Test (FIA)	100,0%	78,3%	0,0%	72,0%	16/96
Ameda Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	100,0%	78,3%	0,0%	70,0%	17/96
BioRepair GmbH	Covid 19 Antigen Schnelltest	100,0%	78,3%	0,0%	70,0%	18/96
Hangzhou Lysun Biotechnology Co., Ltd.	Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	100,0%	78,3%	0,0%	70,0%	19/96
Jiangsu Diagnostics Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	100,0%	78,3%	0,0%	68,0%	20/96
Sugentech, Inc.	SGTI-flex COVID-19 Ag	100,0%	73,9%	0,0%	68,0%	21/96
Wuhan EasyDiagnosis Biomedicine Co., Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit	100,0%	73,9%	0,0%	68,0%	22/96
ASAN PHARM.CO.,LTD.	Asan Easy Test COVID-19 Ag	100,0%	69,6%	0,0%	66,0%	23/96

BIONOTE	NowCheck® COVID-19 Ag Test	100,0%	65,2%	0,0%	66,0%	24/96
SD BIOSENSOR	STANDARD™ F COVID-19 Ag FIA	100,0%	65,2%	0,0%	66,0%	25/96
Abbott Rapid Diagnostics Jena GmbH	Panbio™ COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	100,0%	60,9%	0,0%	64,0%	26/96
Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)	COVID-19 Antigen Schnelltest (Colloidal Gold)	100,0%	60,9%	0,0%	64,0%	27/96
Lumigenex (Suzhou) Co., Ltd.	PocRoc SARS-CoV-2, Antigen Schnelltest Set (Kolloidales Gold)	100,0%	65,2%	0,0%	64,0%	28/96
Precision Biosensor Inc. (Axon Lab AG)	Exdia COVID-19-Ag-Test	100,0%	60,9%	0,0%	64,0%	29/96
ProGnosis Biotech	Rapid Test Ag 2019-nCoV	94,1%	65,2%	10,0%	64,0%	30/96
Atlas Link Technology Co.,Ltd.	Nova Test SARS-CoV-2 Antigen Rapid Test Kit	100,0%	60,9%	0,0%	62,0%	31/96
Chil Tibbi Mal. San. Tic. Ltd. Şti	COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette)	100,0%	60,9%	0,0%	62,0%	32/96
Guangdong Wesail Biotech Co., Ltd.	COVID-19 Ag Test Kit	100,0%	52,2%	11,1%	62,0%	33/96
Safecare Biotech Hangzhou Co., Ltd.	Safecare COVID-19 Ag Rapid Test Kit (Swab)	100,0%	60,9%	0,0%	62,0%	34/96
Shenzhen Watmind Medical Co.,Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)	100,0%	60,9%	0,0%	62,0%	35/96
LumiraDX	LumiraDx SARS-CoV-2 Ag Test	100,0%	52,2%	0,0%	60,0%	36/96
Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Saliva Test Kit (Colloidal Gold)	100,0%	56,5%	0,0%	60,0%	37/97
Wuhan Life Origin Biotech Joint Stock Co., Ltd.	SARS-CoV-2 Antigen Assay Kit (Immunochromatography)	100,0%	56,5%	0,0%	60,0%	38/97
Affimedix	TestNOW® - COVID-19 Antigen	100,0%	47,8%	0,0%	58,0%	39/97
Anbio (Xiamen) Biotechnology Co., Ltd	Rapid Covid-19 Antigen Test (Colloidal Gold)	100,0%	52,2%	0,0%	58,0%	40/97
AXIOM Gesellschaft für Diagnostica und Biochemica mbH	Axiom Diagnostics COVID-19 Ag Schnelltest	100,0%	52,2%	0,0%	58,0%	41/97
Genrui Biotech Inc.	Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	94,1%	56,5%	0,0%	58,0%	42/97
MEDsan GmbH	MEDsan® SARS-CoV-2 Antigen Rapid Test	100,0%	47,8%	0,0%	58,0%	43/97
Mölab GmbH	mö-screen Corona Antigen Test	100,0%	47,8%	0,0%	58,0%	44/98
PCL, Inc.	PCL COVID19 Ag Gold Saliva	100,0%	52,2%	0,0%	58,0%	45/98
Shenzhen Microprofit Biotech Co., Ltd	fluorecare COVID-19 SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	100,0%	47,8%	10,0%	58,0%	46/98
Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)	100,0%	47,8%	0,0%	56,0%	47/98
Hangzhou Testsea Biotechnology Co., Ltd	Testsealabs® Rapid Test Kit COVID-19 Antigen Test Cassette	100,0%	47,8%	0,0%	56,0%	48/98
DNA Diagnostic A/S.	Covid-19 Antigen Detection Kit	100,0%	39,1%	10,0%	54,0%	49/98
MP Biomedicals Germany GmbH	Rapid SARS-CoV-2 Antigen Test Card	100,0%	43,5%	0,0%	54,0%	50/98

Qingdao Hightop Biotech Co., Ltd.	Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	100,0%	43,5%	0,0%	54,0%	51/99
Xiamen Boson Biotech Co., Ltd	SARS-CoV-2 Antigen Schnelltest	100,0%	43,5%	0,0%	54,0%	52/96
Anhui Deepblue Medical Technology Co. , Ltd.	COVID-19 (SARS CoV-2) Antigen Test Kit (Colloidal Gold)	100,0%	39,1%	0,0%	52,0%	53/96
Edinburgh Genetics Limited	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	100,0%	34,8%	0,0%	50,0%	54/96
Hangzhou Clongene Biotech Co., Ltd.	Clungene COVID-19 Antigen Rapid Test	94,4%	34,8%	0,0%	50,0%	55/96
BIOMERICA Inc.	COVID-19-Antigen-Schnelltest (Nasopharyngeal-Abstrich)	100,0%	30,4%	0,0%	48,0%	56/96
Eurobio Scientific	EBS SARS-CoV-2 Ag Rapid Test	94,1%	34,8%	0,0%	48,0%	57/96
Vitrosens Biyoteknoloji Ltd. Sti	RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	100,0%	30,4%	0,0%	48,0%	58/96
Beijing Lepu Medical Technology Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	100,0%	26,1%	0,0%	46,0%	59/96
Fujirebio Inc. (Mast Diagnostica GmbH)	ESPLINE® SARS-CoV-2	100,0%	21,7%	0,0%	46,0%	60/96
IVC Pragen Healthcare	GenBody COVID-19 Ag	94,4%	26,1%	0,0%	46,0%	61/96
Oncosem Onkolojik Sistemler San. Ve Tic. A.S.	CAT Antigen Covid Rapid Test	94,1%	30,4%	0,0%	46,0%	62/96
SD BIOSENSOR (Roche Diagnostics GmbH)	SARS-CoV-2 Rapid Antigen Test	88,9%	30,4%	0,0%	46,0%	63/96
SD BIOSENSOR	STANDARD™ Q COVID-19 Ag Test	88,9%	30,4%	0,0%	46,0%	64/96
Zhejiang Anji Saianfu Biotech Co.,Ltd.	reOpenTest COVID-19 Antigen Rapid Test (Colloidal Gold)	94,1%	30,4%	0,0%	46,0%	65/96
Nanjing Norman Biological Technology Co.,Ltd	Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)	94,1%	26,1%	0,0%	44,0%	66/96
R-Biopharm AG	RIDA®QUICK SARS-CoV-2 Antigen	100,0%	17,4%	0,0%	44,0%	67/96
SGA Mühendislik DAN. EG. İcve DIS.Ltd.STI	V-Chek SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)	94,1%	26,1%	0,0%	44,0%	68/96
Core Technology Co., Ltd.	Canea COVID-19 Antigen Schnelltest	88,2%	26,1%	0,0%	42,0%	69/96
Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)	Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	94,4%	17,4%	0,0%	42,0%	70/96
Jiangsu Medomics Medical Technology Co., Ltd	SARS-CoV-2-Antigen-Testkit (LFIA)	94,1%	21,7%	0,0%	42,0%	71/96
Novatech Tibbi Cihaz Ürünleri San. Ve Tic.A.S.	novacheck®-Ag SARS-CoV-2 Covid-19 Antigen Rapid Test	94,1%	21,7%	0,0%	42,0%	72/96
PerGrande BioTech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	100,0%	17,4%	0,0%	42,0%	73/96
BTNX, Inc. (Biotrend Chemikalien GmbH)	Rapid Response COVID-19 Rapid Test Device	94,1%	13,0%	10,0%	40,0%	74/96
Humasis Co., Ltd.	Humasis COVID-19 Ag Test	88,2%	21,7%	0,0%	40,0%	75/96
Labnovation Technologies, Inc.	Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	94,1%	17,4%	0,0%	40,0%	76/96
Zet Medikal Tekstil Dis Ticaret Ltd. STI.	softec SARS COV-2 (Covid-19) Antigen Test Kit	82,4%	21,7%	10,0%	40,0%	77/96

Avalun	Ksmart® SARS-COV2 Antigen Rapid Test	94,1%	13,0%	0,0%	38,0%	78/96
GenSure Biotech Inc.	DIA-COVID® COVID-19 Ag Rapid Test Kit	94,1%	13,0%	0,0%	38,0%	79/96
Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	88,2%	17,4%	0,0%	38,0%	80/96
Aesku Diagnostics GmbH	Aesku Rapid SARS-CoV-2 Rapid Test	82,4%	17,4%	0,0%	36,0%	81/96
Azure Biotech Inc.	Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	76,5%	13,0%	20,0%	36,0%	82/96
Hangzhou Immuno Biotech Co.,Ltd.	IMMUNOBIO SARS-CoV-2 Antigen-Schnelltest (COVID-19 Ag)	88,2%	13,0%	0,0%	36,0%	83/96
nal von minden gmbh	NADAL® COVID-19 Ag Schnelltest	83,3%	13,0%	0,0%	36,0%	84/96
Quidel Corporation	Sofia SARS Antigen FIA	88,9%	8,7%	0,0%	36,0%	85/96
Xiamen WIZ Biotech Co., Ltd.	Wizbiotech SARS-CoV-2 Antigen Rapid Test	88,2%	13,0%	0,0%	36,0%	86/96
ACON Biotech (Hangzhou) Co., Ltd	Flowflex SARS-CoV-2-Antigenschnelltest (Nasopharynxtpuffer)	94,1%	4,3%	0,0%	34,0%	87/96
Becton Dickinson	BD Veritor™ System for Rapid Detection of SARS-CoV-2	83,3%	8,7%	0,0%	34,0%	88/96
Green Cross Medical Science Corp. (Weko Pharma GmbH)	Genedia W Covid-19 Ag	83,3%	8,7%	0,0%	34,0%	89/96
Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit(colloidal gold method)	82,4%	13,0%	0,0%	34,0%	90/96
NanoEntek Inc	FREND™ COVID-19 Ag	88,2%	8,7%	0,0%	34,0%	91/96
Salofa OY	salocor SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal swab)	82,4%	13,0%	0,0%	34,0%	92/96
Shenzhen Zhenrui Biotech co.Ltd.	Zhenrui COVID-19 (SARS-COV-2) Antigen Test Kits	82,4%	13,0%	0,0%	34,0%	93/96
Amazing Biotech (Shanghai) Co., Ltd	CoroVisio Covid-19 Ag Versieglungsrohrchen Teststreifen (Kolloidales Gold)	76,5%	8,7%	0,0%	30,0%	94/96
Guangzhou Wondfo Biotech Co. Ltd	Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	88,2%	0,0%	0,0%	30,0%	95/96
Beijing Beier Bioengineering Co., Ltd.	Covid-19 Antigen Schnelltest	77,8%	0,0%	0,0%	28,0%	96/96

*ranking based on the performance of the TC17-36 from the different suppliers.