

Comparative sensitivity evaluation for 122 CE-marked SARS-CoV-2-antigen rapid tests

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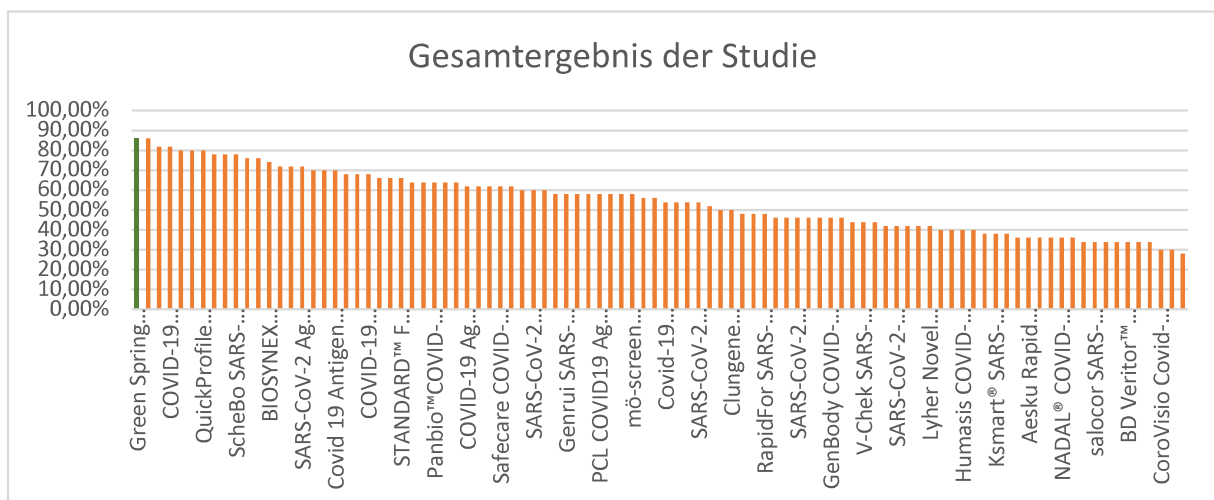
Link zur Studie: <https://www.medrxiv.org/content/10.1101/2021.05.11.21257016v1.full.pdf>

In einer unabhängigen Studie aus dem Mai 2021 hat das Paul-Ehrlich-Institut eine vergleichende Evaluierung von 122 BfArM-gelisteten Antigentests veröffentlicht. Aus dieser Studie geht unser Green Spring Antigentest als bester unter allen 122 Tests hervor.

Die Resultate wurden zusammengefasst in den Bereichen CT <25 (hohe Viruslast), CT 25-30 (geringere Viruslast) und CT >30 (sehr geringe Viruslast).

Green Spring erreicht in der PEI-Studie in allen Kategorien die höchsten Erkennungswerte, während eine Vielzahl von Tests bei sehr hohen Viruslasten (CT <25) noch relativ gut abschneidet, ist die Leistung der meisten Tests im Bereich CT 25-30 unzureichend.

Green Spring detektiert alle Mutanten / Variants of Concern (VOC).



Von den 122 Tests der Stichprobe schnitt Green Spring® SARS-CoV-2-Antigen-Schnelltest-Set (kolloidales Gold) gesamt und bei den jeweiligen CT-Werten mit den höchsten Werten ab.

Übersicht aller Tests und Hersteller, die die Minimalanforderung von 75% Sensitivität bei einem CT-Wert <25 erreicht haben in absteigender Reihenfolge:

Manufacturer	Test name	CT <25	CT 25-30	CT >30	CT 17-36
Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	100,00%	95,70%	40,00%	86,00%
Toda Pharma	Toda Coronadiag Ag	100,00%	95,70%	40,00%	86,00%
Shenzhen Watmind Medical Co.,Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	100,00%	95,70%	20,00%	82,00%
ulti med Products (Deutschland) GmbH	COVID-19 Antigen Speicheltest (Immunochromatographie)	100,00%	95,70%	20,00%	82,00%
AmonMed (Xiamen) Biotechnology Co., Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	100,00%	87,00%	30,00%	80,00%
Beijing Tigsun Diagnostics Co.,Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	100,00%	87,00%	30,00%	80,00%
LumiQuick Diagnostics, Inc.	QuickProfile Covid-19 Antigen Test Card	100,00%	91,30%	20,00%	80,00%
New Gene (Hangzhou) Bioengineering Co., Ltd.	Covid-19-Antigen-Testkit	100,00%	87,00%	20,00%	78,00%
Triplex International Biosciences (China) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	100,00%	87,00%	20,00%	78,00%
ScheBo Biotech AG	ScheBo SARS-CoV-2 Quick Antigen	100,00%	91,30%	10,00%	78,00%
Siemens Healthineers	CLINITEST® Rapid COVID-19 Antigen Test	100,00%	87,00%	0,00%	76,00%
Zhejiang Orient Gene Biotech Co.,Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	100,00%	87,00%	0,00%	76,00%
BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	100,00%	78,30%	11,10%	74,00%
Getein Biotech, Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	100,00%	82,60%	0,00%	72,00%
Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	100,00%	82,60%	0,00%	72,00%
Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)	SARS-CoV-2 Ag Rapid Test (FIA)	100,00%	78,30%	0,00%	72,00%
Ameda Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	100,00%	78,30%	0,00%	70,00%
Hangzhou Lysun Biotechnology Co., Ltd.	Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	100,00%	78,30%	0,00%	70,00%
BioRepair GmbH	Covid 19 Antigen Schnelltest	100,00%	78,30%	0,00%	70,00%
Sugentech, Inc.	SGTi-flex COVID-19 Ag	100,00%	73,90%	0,00%	68,00%
Wuhan EasyDiagnosis Biomedicine Co., Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit	100,00%	73,90%	0,00%	68,00%
Jiangsu Diagnostics Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	100,00%	78,30%	0,00%	68,00%
ASAN PHARM.CO.,LTD.	Asan Easy Test COVID-19 Ag	100,00%	69,60%	0,00%	66,00%

BIONOTE	NowCheck® COVID-19 Ag Test	100,00%	65,20%	0,00%	66,00%
SD BIOSENSOR	STANDARD™ F COVID-19 Ag FIA	100,00%	65,20%	0,00%	66,00%
Lumigenex (Suzhou) Co., Ltd.	PocRoc SARS-CoV-2, Antigen Schnelltest Set (Kolloidales Gold)	100,00%	65,20%	0,00%	64,00%
Abbott Rapid Diagnostics Jena GmbH	Panbio™ COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	100,00%	60,90%	0,00%	64,00%
Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)	COVID-19 Antigen Schnelltest (Colloidal Gold)	100,00%	60,90%	0,00%	64,00%
Precision Biosensor Inc. (Axon Lab AG)	Exdia COVID-19-Ag-Test	100,00%	60,90%	0,00%	64,00%
Guangdong Wesail Biotech Co., Ltd.	COVID-19 Ag Test Kit	100,00%	52,20%	11,10%	62,00%
Atlas Link Technology Co.,Ltd.	Nova Test SARS-CoV-2 Antigen Rapid Test Kit	100,00%	60,90%	0,00%	62,00%
Chil Tibbi Mal. San. Tic. Ltd. Şti	COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette)	100,00%	60,90%	0,00%	62,00%
Safecare Biotech Hangzhou Co., Ltd.	Safecare COVID-19 Ag Rapid Test Kit (Swab)	100,00%	60,90%	0,00%	62,00%
Shenzhen Watmind Medical Co.,Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)	100,00%	60,90%	0,00%	62,00%
Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Saliva Test Kit (Colloidal Gold)	100,00%	56,50%	0,00%	60,00%
Wuhan Life Origin Biotech Joint Stock Co., Ltd.	SARS-CoV-2 Antigen Assay Kit (Immunochromatography)	100,00%	56,50%	0,00%	60,00%
LumiraDX	LumiraDx SARS-CoV-2 Ag Test	100,00%	52,20%	0,00%	60,00%
Shenzhen Microprofit Biotech Co., Ltd	fluorecare COVID-19 SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	100,00%	47,80%	10,00%	58,00%
Anbio (Xiamen) Biotechnology Co., Ltd	Rapid Covid-19 Antigen Test (Colloidal Gold)	100,00%	52,20%	0,00%	58,00%
AXIOM Gesellschaft für Diagnostica und Biochemica mbH	Axiom Diagnostics COVID-19 Ag Schnelltest	100,00%	52,20%	0,00%	58,00%
PCL, Inc.	PCL COVID19 Ag Gold Saliva	100,00%	52,20%	0,00%	58,00%
Affimedix	TestNOW® - COVID-19 Antigen	100,00%	47,80%	0,00%	58,00%
MEDsan GmbH	MEDsan® SARS-CoV-2 Antigen Rapid Test	100,00%	47,80%	0,00%	58,00%
Mölab GmbH	mö-screen Corona Antigen Test	100,00%	47,80%	0,00%	58,00%
Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)	100,00%	47,80%	0,00%	56,00%
Hangzhou Testsea Biotechnology Co., Ltd	Testsealabs® Rapid Test Kit COVID-19 Antigen Test Cassette	100,00%	47,80%	0,00%	56,00%
DNA Diagnostic A/S.	Covid-19 Antigen Detection Kit	100,00%	39,10%	10,00%	54,00%
MP Biomedicals Germany GmbH	Rapid SARS-CoV-2 Antigen Test Card	100,00%	43,50%	0,00%	54,00%

Qingdao Hightop Biotech Co., Ltd.	Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	100,00%	43,50%	0,00%	54,00%
Xiamen Boson Biotech Co., Ltd	SARS-CoV-2 Antigen Schnelltest	100,00%	43,50%	0,00%	54,00%
Anhui Deepblue Medical Technology Co., Ltd.	COVID-19 (SARS CoV-2) Antigen Test Kit (Colloidal Gold)	100,00%	39,10%	0,00%	52,00%
Edinburgh Genetics Limited	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	100,00%	34,80%	0,00%	50,00%
BIOMERICA Inc.	COVID-19-Antigen-Schnelltest (Nasopharyngeal-Abstrich)	100,00%	30,40%	0,00%	48,00%
Vitrosens Biyoteknoloji Ltd. Sti	RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	100,00%	30,40%	0,00%	48,00%
Beijing Lepu Medical Technology Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	100,00%	26,10%	0,00%	46,00%
Fujirebio Inc. (Mast Diagnostica GmbH)	ESPLINE® SARS-CoV-2	100,00%	21,70%	0,00%	46,00%
R-Biopharm AG	RIDA®QUICK SARS-CoV-2 Antigen	100,00%	17,40%	0,00%	44,00%
PerGrande BioTech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	100,00%	17,40%	0,00%	42,00%
Hangzhou Clongene Biotech Co., Ltd.	Clongene COVID-19 Antigen Rapid Test	94,40%	34,80%	0,00%	50,00%
IVC Pragen Healthcare	GenBody COVID-19 Ag	94,40%	26,10%	0,00%	46,00%
Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)	Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	94,40%	17,40%	0,00%	42,00%
ProGnosis Biotech	Rapid Test Ag 2019-nCoV	94,10%	65,20%	10,00%	64,00%
Genrui Biotech Inc.	Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	94,10%	56,50%	0,00%	58,00%
Eurobio Scientific	EBS SARS-CoV-2 Ag Rapid Test	94,10%	34,80%	0,00%	48,00%
Oncosem Onkolojik Sistemler San. Ve Tic. A.S.	CAT Antigen Covid Rapid Test	94,10%	30,40%	0,00%	46,00%
Zhejiang Anji Saianfu Biotech Co.,Ltd.	reOpenTest COVID-19 Antigen Rapid Test (Colloidal Gold)	94,10%	30,40%	0,00%	46,00%
Nanjing Norman Biological Technology Co.,Ltd	Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)	94,10%	26,10%	0,00%	44,00%
SGA Mühendislik DAN. EG. Içve DIS,Ltd,STI	V-Chek SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)	94,10%	26,10%	0,00%	44,00%
Jiangsu Medomics Medical Technology Co., Ltd	SARS-CoV-2-Antigen-Testkit (LFIA)	94,10%	21,70%	0,00%	42,00%
Novatech Tibbi Cihaz Ürünleri San. Ve Tic.A.S.	novacheck®-Ag SARS-CoV-2 Covid-19 Antigen Rapid Test	94,10%	21,70%	0,00%	42,00%
BTNX, Inc. (Biotrend Chemikalien GmbH)	Rapid Response COVID-19 Rapid Test Device	94,10%	13,00%	10,00%	40,00%
Labnovation Technologies, Inc.	Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	94,10%	17,40%	0,00%	40,00%
Avalun	Ksmart® SARS-COV2 Antigen Rapid Test	94,10%	13,00%	0,00%	38,00%

GenSure Biotech Inc.	DIA-COVID® COVID-19 Ag Rapid Test Kit	94,10%	13,00%	0,00%	38,00%
ACON Biotech (Hangzhou) Co., Ltd	Flowflex SARS-CoV-2-Antigenschnelltest (Nasopharynx tupfer)	94,10%	4,30%	0,00%	34,00%
SD BIOSENSOR (Roche Diagnostics GmbH)	SARS-CoV-2 Rapid Antigen Test	88,90%	30,40%	0,00%	46,00%
SD BIOSENSOR	STANDARD™ Q COVID-19 Ag Test	88,90%	30,40%	0,00%	46,00%
Quidel Corporation	Sofia SARS Antigen FIA	88,90%	8,70%	0,00%	36,00%
Core Technology Co., Ltd.	Canea COVID-19 Antigen Schnelltest	88,20%	26,10%	0,00%	42,00%
Humasis Co., Ltd.	Humasis COVID-19 Ag Test	88,20%	21,70%	0,00%	40,00%
Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	88,20%	17,40%	0,00%	38,00%
Hangzhou Immuno Biotech Co., Ltd.	IMMUNOBIO SARS-CoV-2 Antigen-Schnelltest (COVID-19 Ag)	88,20%	13,00%	0,00%	36,00%
Xiamen WIZ Biotech Co., Ltd.	Wizbiotech SARS-CoV-2 Antigen Rapid Test	88,20%	13,00%	0,00%	36,00%
NanoEntek Inc	FREND™ COVID-19 Ag	88,20%	8,70%	0,00%	34,00%
Guangzhou Wondfo Biotech Co. Ltd	Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	88,20%	0,00%	0,00%	30,00%
nal von minden gmbh	NADAL® COVID-19 Ag Schnelltest	83,30%	13,00%	0,00%	36,00%
Becton Dickinson	BD Veritor™ System for Rapid Detection of SARS-CoV-2	83,30%	8,70%	0,00%	34,00%
Green Cross Medical Science Corp. (Weko Pharma GmbH)	Genedia W Covid-19 Ag	83,30%	8,70%	0,00%	34,00%
Zet Medikal Tekstil Dis Ticaret Ltd. STI.	softec SARS COV-2 (Covid-19) Antigen Test Kit	82,40%	21,70%	10,00%	40,00%
Aesku Diagnostics GmbH	Aesku Rapid SARS-CoV-2 Rapid Test	82,40%	17,40%	0,00%	36,00%
Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	82,40%	13,00%	0,00%	34,00%
Salofa OY	salocor SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal swab)	82,40%	13,00%	0,00%	34,00%
Shenzhen Zhenrui Biotech co., Ltd.	Zhenrui COVID-19 (SARS-COV-2) Antigen Test Kits	82,40%	13,00%	0,00%	34,00%
Beijing Beier Bioengineering Co., Ltd.	Covid-19 Antigen Schnelltest	77,80%	0,00%	0,00%	28,00%
Azure Biotech Inc.	Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	76,50%	13,00%	20,00%	36,00%
Amazing Biotech (Shanghai) Co., Ltd	CoroVisio Covid-19 Ag Versieglungsröhrchen Teststreifen (Kolloidales Gold)	76,50%	8,70%	0,00%	30,00%

Übersicht aller Tests und Hersteller, die die Minimalanforderung von 75% Sensitivität bei einem CT-Wert <25 nicht erreicht haben und somit durchgefallen sind:

Manufacturer	Test name	CT <25	CT 25-30	CT >30	CT 17-36
Servoprax	ClearTest Coronaantigen	66,70%	0,00%	0,00%	24,00%
VivaChek Biotech (Hangzhou) Co.,Ltd.	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	64,70%	0,00%	0,00%	22,00%
Medicon Co., Ltd.	Trueline COVID-19 Ag Rapid Test	58,80%	4,30%	0,00%	22,00%
Hangzhou Realy Tech Co., Ltd.	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	58,80%	0,00%	0,00%	20,00%
Mexacare GmbH Heidelberg	QuickTestCorona COVID-19 Antigen Schnelltest	52,90%	4,30%	0,00%	20,00%
Hangzhou Genesis Biocontrol Co., Ltd	KaiBiLi COVID-19 Antigen Rapid Test Device	52,90%	0,00%	0,00%	18,00%
Inzek International Trading	Biozek medical COVID-19 Antigen Rapid Test Cassette	52,90%	0,00%	0,00%	18,00%
SureScreen Diagnostics Ltd	COVID-19 Antigen Rapid Test Cassette	52,90%	0,00%	0,00%	18,00%
VivaChek Biotech (Hangzhou) Co.,Ltd.	VivaDiag SARS-CoV-2 Ag Rapid Test	50,00%	0,00%	0,00%	18,00%
Joysbio (Tianjin) Biotechnology Co., Ltd.	Joysbio SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	47,10%	4,30%	0,00%	18,00%
W.H.P.M, Inc	First SIGN SARS-CoV-2 Antigen Test	47,10%	0,00%	0,00%	16,00%
nal von minden GmbH	dedicio Medical Test COVID-19 Ag plus Test	35,30%	0,00%	0,00%	12,00%
Coris Bioconcept	COVID-19 Ag Respi-Strip	33,30%	0,00%	0,00%	12,00%
Certest Biotec S. L.	CerTest SARS-CoV-2	29,40%	0,00%	0,00%	10,00%
Hangzhou Biotest Biotech Co., Ltd.	Lumiratek SARS-CoV-2 Antigen Rapid Test Cassette	29,40%	0,00%	0,00%	10,00%
Spring Healthcare Services SP zoo	SARS-Cov-2 Antigen Rapid Test Cassette (swab)	29,40%	0,00%	0,00%	10,00%
TaiDoc TechnologyCorp.	FORA COVID-19 ANTIGEN RAPID TEST	27,80%	0,00%	0,00%	10,00%
Acro Biotech Inc	Acro COVID-19 Antigen Rapid Test	16,70%	0,00%	0,00%	6,00%
Hangzhou AllTest Biotech Co. Ltd.	COVID-19 AG AllTest	16,70%	0,00%	0,00%	6,00%
Rapigen	Biocredit COVID-19 Ag	16,70%	0,00%	0,00%	6,00%
Aikang Diagnostics Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Immunochromatography)	11,80%	0,00%	0,00%	4,00%
Xiamen Zhongsheng Langjie Biotechnology Co., Ltd	Covid-19 Antigen Test Cassette	11,80%	0,00%	0,00%	4,00%
Beijing Savant Biotechnology Co., Ltd	New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunchromatography)	0,00%	0,00%	0,00%	0,00%
Joinstar Biomedical Technology Co., Ltd	COVID-19 Antigen Rapid Test (Latex)	0,00%	0,00%	0,00%	0,00%
Lionex GmbH	Lionex COVID-19 Ag Rapid Test	0,00%	0,00%	0,00%	0,00%
Unioninvest	Unibioscience COVID-19 Rapid Antigen Test	0,00%	0,00%	0,00%	0,00%



Green Spring® SARS-CoV-2-Antigen-Schnelltest-Set (kolloidales Gold)

