

PEI Laborbewertung

Green Spring: Testsieger !

Empfindlichkeit-Leistung Nr. 1 in insgesamt 122 bewerteten Tests

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

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This study has been submitted as tandem manuscript together with the study of Puyskens A et al. "Establishment of an evaluation panel for the decentralized technical evaluation of the sensitivity of 31 rapid detection tests for SARS-CoV-2 diagnostics"

Table 1

Comparative evaluation results of SARS-CoV-2 antigen RDT passing the sensitivity criteria



No.	Manufacturer	Test name	Sensitivity			
			CT <25	CT 25-30	CT >30	CT 17-36
1	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	Toda Pharma	Toda Coronadiag Ag	100.0%	95.7%	40.0%	86.0%
3	Shenzhen Watmind Medical Co..Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	100.0%	95.7%	20.0%	82.0%
4	ulti med Products (Deutschland) GmbH	COVID-19 Antigen Speicheltest (Immunochromatographie)	100.0%	95.7%	20.0%	82.0%
5	AmonMed (Xiamen) Biotechnology Co.. Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	100.0%	87.0%	30.0%	80.0%
6	Beijing Tigsun Diagnostics Co.,Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	100.0%	87.0%	30.0%	80.0%
7	LumiQuick Diagnostics. Inc.	QuickProfile Covid-19 Antigen Test Card	100.0%	91.3%	20.0%	80.0%
8	New Gene (Hangzhou) Bioengineering Co.. Ltd.	Covid-19-Antigen-Testkit	100.0%	87.0%	20.0%	78.0%
9	Triplex International Biosciences (China) Co.. Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	100.0%	87.0%	20.0%	78.0%
10	ScheBo Biotech AG	ScheBo SARS-CoV-2 Quick Antigen	100.0%	91.3%	10.0%	78.0%
11	Siemens Healthineers	CLINITEST® Rapid COVID-19 Antigen Test	100.0%	87.0%	0.0%	76.0%
12	Zhejiang Orient Gene Biotech Co..Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	100.0%	87.0%	0.0%	76.0%
13	BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	100.0%	78.3%	11.1%	74.0%
14	Getein Biotech. Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	100.0%	82.6%	0.0%	72.0%
15	Merlin Biomedical (Xiamen) Co.. Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	100.0%	82.6%	0.0%	72.0%
16	Wantai (Beijing Wantai Biological Pharmacy Enterprise Co.. Ltd.)	SARS-CoV-2 Ag Rapid Test (FIA)	100.0%	78.3%	0.0%	72.0%
17	Ameda Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	100.0%	78.3%	0.0%	70.0%
18	BioRepair GmbH	Covid 19 Antigen Schnelltest	100.0%	78.3%	0.0%	70.0%
19	Hangzhou Lysun Biotechnology Co.. Ltd.	Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	100.0%	78.3%	0.0%	70.0%
20	Jiangsu Diagnostics Biotechnology Co.. Ltd	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	100.0%	78.3%	0.0%	68.0%
21	Sugentech. Inc.	SGTi-flex COVID-19 Ag	100.0%	73.9%	0.0%	68.0%
22	Wuhan EasyDiagnosis Biomedicine Co.. Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit	100.0%	73.9%	0.0%	68.0%
23	ASAN PHARM.CO..LTD.	Asan Easy Test COVID-19 Ag	100.0%	69.6%	0.0%	66.0%
24	BIONOTE	NowCheck® COVID-19 Ag Test	100.0%	65.2%	0.0%	66.0%
25	SD BIOSENSOR	STANDARD™ F COVID-19 Ag FIA	100.0%	65.2%	0.0%	66.0%
26	ProGnosis Biotech	Rapid Test Ag 2019-nCoV	94.1%	65.2%	10.0%	64.0%
27	Lumigenex (Suzhou) Co.. Ltd.	PocRoc SARS-CoV-2. Antigen Schnelltest Set (Kolloidales Gold)	100.0%	65.2%	0.0%	64.0%
28	Abbott Rapid Diagnostics Jena GmbH	Panbio™COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	100.0%	60.9%	0.0%	64.0%
29	Joinstar Biomedical Technology Co.. Ltd (CIV care impuls Vertrieb)	COVID-19 Antigen Schnelltest (Colloidal Gold)	100.0%	60.9%	0.0%	64.0%
30	Precision Biosensor Inc. (Axon Lab AG)	Exdia COVID-19-Ag-Test	100.0%	60.9%	0.0%	64.0%
31	Guangdong Wesail Biotech Co.. Ltd.	COVID-19 Ag Test Kit	100.0%	52.2%	11.1%	62.0%
32	Atlas Link Technology Co..Ltd.	Nova Test SARS-CoV-2 Antigen Rapid Test Kit	100.0%	60.9%	0.0%	62.0%
33	Chil Tibbi Mal. San. Tic. Ltd. Şti	COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kasette)	100.0%	60.9%	0.0%	62.0%
34	Safecare Biotech Hangzhou Co.. Ltd.	Safecare COVID-19 Ag Rapid Test Kit (Swab)	100.0%	60.9%	0.0%	62.0%
35	Shenzhen Watmind Medical Co..Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)	100.0%	60.9%	0.0%	62.0%
36	Nantong Diagnos Biotechnology Co.. Ltd.	COVID-19 Antigen Saliva Test Kit (Colloidal Gold)	100.0%	56.5%	0.0%	60.0%
37	Wuhan Life Origin Biotech Joint Stock Co.. Ltd.	SARS-CoV-2 Antigen Assay Kit (Immunochromatography)	100.0%	56.5%	0.0%	60.0%
38	LumiraDX	LumiraDx SARS-CoV-2 Ag Test	100.0%	52.2%	0.0%	60.0%
39	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%
40	Genrui Biotech Inc.	Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	94.1%	56.5%	0.0%	58.0%
41	Anbio (Xiamen) Biotechnology Co.. Ltd	Rapid Covid-19 Antigen Test (Colloidal Gold)	100.0%	52.2%	0.0%	58.0%
42	AXIOM Gesellschaft für Diagnostica und Biochemica mbH	Axiom Diagnostics COVID-19 Ag Schnelltest	100.0%	52.2%	0.0%	58.0%
43	PCL. Inc.	PCL COVID19 Ag Gold Saliva	100.0%	52.2%	0.0%	58.0%
44	Affimedix	TestNOW® - COVID-19 Antigen	100.0%	47.8%	0.0%	58.0%
45	MEDsan GmbH	MEDsan® SARS-CoV-2 Antigen Rapid Test	100.0%	47.8%	0.0%	58.0%
46	Mölab GmbH	mö-screen Corona Antigen Test	100.0%	47.8%	0.0%	58.0%
47	Beijing Hotgen Biotech Co.. Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)	100.0%	47.8%	0.0%	56.0%
48	Hangzhou Testsea Biotechnology Co.. Ltd	Testsealabs® Rapid Test Kit COVID-19 Antigen Test Cassette	100.0%	47.8%	0.0%	56.0%

No.	Manufacturer	Test name	Sensitivity			
			CT <25	CT 25-30	CT >30	CT 17-36
49	DNA Diagnostic A/S.	Covid-19 Antigen Detection Kit	100.0%	39.1%	10.0%	54.0%
50	MP Biomedicals Germany GmbH	Rapid SARS-CoV-2 Antigen Test Card	100.0%	43.5%	0.0%	54.0%
51	Qingdao Hightop Biotech Co.. Ltd.	Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	100.0%	43.5%	0.0%	54.0%
52	Xiamen Boson Biotech Co.. Ltd	SARS-CoV-2 Antigen Schnelltest	100.0%	43.5%	0.0%	54.0%
53	Anhui Deepblue Medical Technology Co. . Ltd.	COVID-19 (SARS CoV-2) Antigen Test Kit (Colloidal Gold)	100.0%	39.1%	0.0%	52.0%
54	Edinburgh Genetics Limited	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	100.0%	34.8%	0.0%	50.0%
55	Hangzhou Clongene Biotech Co.. Ltd.	Clungene COVID-19 Antigen Rapid Test	94.4%	34.8%	0.0%	50.0%
56	Eurobio Scientific	EBS SARS-CoV-2 Ag Rapid Test	94.1%	34.8%	0.0%	48.0%
57	BIOMERICA Inc.	COVID-19-Antigen-Schnelltest (Nasopharyngeal-Abstrich)	100.0%	30.4%	0.0%	48.0%
58	Vitrosens Biyoteknoloji Ltd. Sti	RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	100.0%	30.4%	0.0%	48.0%
59	Oncosem Onkolojik Sistemler San. Ve Tic. A.S.	CAT Antigen Covid Rapid Test	94.1%	30.4%	0.0%	46.0%
60	Zhejiang Anji Saianfu Biotech Co..Ltd.	reOpenTest COVID-19 Antigen Rapid Test (Colloidal Gold)	94.1%	30.4%	0.0%	46.0%
61	SD BIOSENSOR (Roche Diagnostics GmbH)	SARS-CoV-2 Rapid Antigen Test	88.9%	30.4%	0.0%	46.0%
62	SD BIOSENSOR	STANDARD™ Q COVID-19 Ag Test	88.9%	30.4%	0.0%	46.0%
63	Beijing Lepu Medical Technology Co.. Ltd	SARS-CoV-2 Antigen Rapid Test Kit	100.0%	26.1%	0.0%	46.0%
64	IVC Pragen Healthcare	GenBody COVID-19 Ag	94.4%	26.1%	0.0%	46.0%
65	Fujirebio Inc. (Mast Diagnostica GmbH)	ESPLINE® SARS-CoV-2	100.0%	21.7%	0.0%	46.0%
66	Nanjing Norman Biological Technology Co..Ltd	Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)	94.1%	26.1%	0.0%	44.0%
67	SGA Mühendislik DAN. EG. Içve DIS.Ltd.STI	V-Chek SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)	94.1%	26.1%	0.0%	44.0%
68	R-Biopharm AG	RIDA®QUICK SARS-CoV-2 Antigen	100.0%	17.4%	0.0%	44.0%
69	Core Technology Co.. Ltd.	Canea COVID-19 Antigen Schnelltest	88.2%	26.1%	0.0%	42.0%
70	Jiangsu Medomics Medical Technology Co.. Ltd	SARS-CoV-2-Antigen-Testkit (LFIA)	94.1%	21.7%	0.0%	42.0%
71	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	PerGrande BioTech Development Co.. Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	100.0%	17.4%	0.0%	42.0%
73	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%
74	Zet Medikal Tekstil Dis Ticaret Ltd. STI.	softec SARS COV-2 (Covid-19) Antigen Test Kit	82.4%	21.7%	10.0%	40.0%
75	BTNX. Inc. (Biotrend Chemikalien GmbH)	Rapid Response COVID-19 Rapid Test Device	94.1%	13.0%	10.0%	40.0%
76	Humasis Co.. Ltd.	Humasis COVID-19 Ag Test	88.2%	21.7%	0.0%	40.0%
77	Labnovation Technologies. Inc.	Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	94.1%	17.4%	0.0%	40.0%
78	Wuhan UNscience Biotechnology Co.. Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	88.2%	17.4%	0.0%	38.0%
79	Avalun	Ksmart® SARS-COV2 Antigen Rapid Test	94.1%	13.0%	0.0%	38.0%
80	GenSure Biotech Inc.	DIA-COVID® COVID-19 Ag Rapid Test Kit	94.1%	13.0%	0.0%	38.0%
81	Azure Biotech Inc.	Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	76.5%	13.0%	20.0%	36.0%
82	Aesku Diagnostics GmbH	Aesku Rapid SARS-CoV-2 Rapid Test	82.4%	17.4%	0.0%	36.0%
83	Hangzhou Immuno Biotech Co..Ltd.	IMMUNOBIO SARS-CoV-2 Antigen-Schnelltest (COVID-19 Ag)	88.2%	13.0%	0.0%	36.0%
84	Xiamen WIZ Biotech Co.. Ltd.	Wizbiotech SARS-CoV-2 Antigen Rapid Test	88.2%	13.0%	0.0%	36.0%
85	nal von minden gmbh	NADAL® COVID-19 Ag Schnelltest	83.3%	13.0%	0.0%	36.0%
86	Quidel Corporation	Sofia SARS Antigen FIA	88.9%	8.7%	0.0%	36.0%
87	Guangdong Hecin Scientific.Inc.	2019-nCoV Antigen Test Kit(colloidal gold method)	82.4%	13.0%	0.0%	34.0%
88	Salofa OY	salocor SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal swab)	82.4%	13.0%	0.0%	34.0%
89	Shenzhen Zhenrui Biotech co.Ltd.	Zhenrui COVID-19 (SARS-COV-2) Antigen Test Kits	82.4%	13.0%	0.0%	34.0%
90	NanoEntek Inc	FREND™ COVID-19 Ag	88.2%	8.7%	0.0%	34.0%
91	Becton Dickinson	BD Veritor™ System for Rapid Detection of SARS-CoV-2	83.3%	8.7%	0.0%	34.0%
92	Green Cross Medical Science Corp. (Weko Pharma GmbH)	Genedia W Covid-19 Ag	83.3%	8.7%	0.0%	34.0%
93	ACON Biotech (Hangzhou) Co.. Ltd	Flowflex SARS-CoV-2-Antigenschnelltest (Nasopharynx tupfer)	94.1%	4.3%	0.0%	34.0%
94	Amazing Biotech (Shanghai) Co.. Ltd	CoroVisio Covid-19 Ag Versieglungsröhrchen Teststreifen (Kolloidales Gold)	76.5%	8.7%	0.0%	30.0%
95	Guangzhou Wondfo Biotech Co. Ltd	Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	88.2%	0.0%	0.0%	30.0%
96	Beijing Beier Bioengineering Co.. Ltd.	Covid-19 Antigen Schnelltest	77.8%	0.0%	0.0%	28.0%

Table 2**Comparative evaluation results of SARS-CoV-2 antigen RDT missing the sensitivity criteria**

(in alphabetical order of manufacturers)

No.	Manufacturer	Test name	Sensitivity			
			CT <25	CT 25-30	CT >30	CT 17-36
1	Acro Biotech Inc	Acro COVID-19 Antigen Rapid Test	16,7%	0,0%	0,0%	6,0%
2	Aikang Diagnostics Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Immunochromatography)	11,8%	0,0%	0,0%	4,0%
3	Beijing Savant Biotechnology Co., Ltd	New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunchromatography)	0,0%	0,0%	0,0%	0,0%
4	Certest Biotec S. L.	CerTest SARS-CoV-2	29,4%	0,0%	0,0%	10,0%
5	Coris Bioconcept	COVID-19 Ag Respi-Strip	33,3%	0,0%	0,0%	12,0%
6	Hangzhou AllTest Biotech Co. Ltd.	COVID-19 AG AllTest	16,7%	0,0%	0,0%	6,0%
7	Hangzhou Biotest Biotech Co., Ltd.	Lumiratek SARS-CoV-2 Antigen Rapid Test Cassette	29,4%	0,0%	0,0%	10,0%
8	Hangzhou Genesis Biocontrol Co., Ltd	KaiBiLi COVID-19 Antigen Rapid Test Device	52,9%	0,0%	0,0%	18,0%
9	Hangzhou Realy Tech Co., Ltd.	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	58,8%	0,0%	0,0%	20,0%
10	Inzek International Trading	Biozek medical COVID-19 Antigen Rapid Test Cassette	52,9%	0,0%	0,0%	18,0%
11	Joinstar Biomedical Technology Co., Ltd	COVID-19 Antigen Rapid Test (Latex)	0,0%	0,0%	0,0%	0,0%
12	Joysbio (Tianjin) Biotechnology Co., Ltd.	Joysbio SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	47,1%	4,3%	0,0%	18,0%
13	Lionex GmbH	Lionex COVID-19 Ag Rapid Test	0,0%	0,0%	0,0%	0,0%
14	Medicon Co., Ltd.	Trueline COVID-19 Ag Rapid Test	58,8%	4,3%	0,0%	22,0%
15	Mexacare GmbH Heidelberg	QuickTestCorona COVID-19 Antigen Schnelltest	52,9%	4,3%	0,0%	20,0%
16	nal von minden GmbH	dedicio Medical Test COVID-19 Ag plus Test	35,3%	0,0%	0,0%	12,0%
17	Rapigen	Biocredit COVID-19 Ag	16,7%	0,0%	0,0%	6,0%
18	Servoprax	Cleartest Coronaantigen	66,7%	0,0%	0,0%	24,0%
19	Spring Healthcare Services SP zoo	SARS-Cov-2 Antigen Rapid Test Cassette (swab)	29,4%	0,0%	0,0%	10,0%
20	SureScreen Diagnostics Ltd	COVID-19 Antigen Rapid Test Cassette	52,9%	0,0%	0,0%	18,0%
21	TaiDoc TechnologyCorp.	FORA COVID-19 ANTIGEN RAPID TEST	27,8%	0,0%	0,0%	10,0%
22	Unioninvest	Unibioscience COVID-19 Rapid Antigen Test	0,0%	0,0%	0,0%	0,0%
23	VivaChek Biotech (Hangzhou) Co,Ltd.	VivaDiag SARS-CoV-2 Ag Rapid Test	50,0%	0,0%	0,0%	18,0%
24	VivaChek Biotech (Hangzhou) Co,Ltd.	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	64,7%	0,0%	0,0%	22,0%
25	W.H.P.M, Inc	First SIGN SARS-CoV-2 Antigen Test	47,1%	0,0%	0,0%	16,0%
26	Xiamen Zhongsheng Langjie Biotechnology Co., Ltd	Covid-19 Antigen Test Cassette	11,8%	0,0%	0,0%	4,0%