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Table 3

Comparative evaluation results of SARS-CoV-2 antigen rapid diagnostic tests passing the sensitivity criteria (sorted by performance in the subgroups of the evaluation panel), Germany, 2020–2021 (n = 96)

RDT	Manufacturer	Test name	Sensitivity			
			Cq ≤ 25	Cq >25– <30	Cq ≥ 30	Cq 17–36
Subgroup of RDT with detection rates of 100% for Cq ≤ 25 and of >75% for Cq >25– <30						
77	Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	100.0%	95.7%	40.0%	86.0%
84	Toda Pharma	Toda Coronadiag Ag	100.0%	95.7%	40.0%	86.0%
79	Shenzhen Watmind Medical Co.,Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	100.0%	95.7%	20.0%	82.0%
86	ulti med Products (Deutschland) GmbH	COVID-19 Antigen Speicheltest (Immunochromatographie)	100.0%	95.7%	20.0%	82.0%
50	LumiQuick Diagnostics, Inc.	QuickProfile Covid-19 Antigen Test Card	100.0%	91.3%	20.0%	80.0%
72	ScheBo Biotech AG	ScheBo SARS-CoV-2 Quick Antigen	100.0%	91.3%	10.0%	78.0%
7	AmonMed (Xiamen) Biotechnology Co., Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	100.0%	87.0%	30.0%	80.0%
19	Beijing Tigsun Diagnostics Co.,Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	100.0%	87.0%	30.0%	80.0%
60	New Gene (Hangzhou) Bioengineering Co., Ltd.	Covid-19-Antigen-Testkit	100.0%	87.0%	20.0%	78.0%
85	Triplex International Biosciences (China) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	100.0%	87.0%	20.0%	78.0%
96	Zhejiang Orient Gene Biotech Co., Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	100.0%	87.0%	0.0%	76.0%
82	Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Test	100.0%	87.0%	0.0%	76.0%

Cq: quantitative cycle; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2.

Criteria as defined by detection rate of >75% in panel subgroup with Cq ≤ 25.

RDT	Manufacturer	Test name	Sensitivity			
			Cq ≤ 25	Cq >25- <30	Cq ≥ 30	Cq 17-36
33	Getein Biotech, Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	100.0%	82.6%	0.0%	72.0%
53	Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	100.0%	82.6%	0.0%	72.0%
22	BioRepair GmbH	Covid 19 Antigen Schnelltest	100.0%	78.3%	0.0%	70.0%
6	Ameda Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	100.0%	78.3%	0.0%	70.0%
23	BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	100.0%	78.3%	11.1%	74.0%
41	Hangzhou Lysun Biotechnology Co., Ltd.	Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	100.0%	78.3%	0.0%	70.0%
45	Jiangsu Diagnostics Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	100.0%	78.3%	0.0%	68.0%
88	Wantai (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.)	SARS-CoV-2 Ag Rapid Test (FIA)	100.0%	78.3%	0.0%	72.0%
Subgroup of RDT with detection rates of 100% for Cq ≤ 25 and of <75% for Cq >25- <30						
83	Sugentech, Inc.	SGTi-flex COVID-19 Ag	100.0%	73.9%	0.0%	68.0%
89	Wuhan EasyDiagnosis Biomedicine Co., Ltd	COVID-19 (SARS-CoV-2) Antigen Test Kit	100.0%	73.9%	0.0%	68.0%
10	ASAN PHARM.CO.,LTD.	Asan Easy Test COVID-19 Ag	100.0%	69.6%	0.0%	66.0%
49	Lumigenex (Suzhou) Co., Ltd.	PocRoc SARS-CoV-2, Antigen Schnelltest Set (Kolloidales Gold)	100.0%	65.2%	0.0%	64.0%
75	SD BIOSENSOR	STANDARD F COVID-19 Ag FIA	100.0%	65.2%	0.0%	66.0%
21	BIONOTE	NowCheck COVID-19 Ag Test	100.0%	65.2%	0.0%	66.0%
1	Abbott Rapid Diagnostics Jena GmbH	PanbioCOVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	100.0%	60.9%	0.0%	64.0%
11	Atlas Link Technology Co., Ltd.	Nova Test SARS-CoV-2 Antigen Rapid Test Kit	100.0%	60.9%	0.0%	62.0%
25	Chil Tibbi Mal. San. Tic. Ltd. Şti	COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette)	100.0%	60.9%	0.0%	62.0%

Cq: quantitative cycle; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2.

Criteria as defined by detection rate of >75% in panel subgroup with Cq ≤ 25.

RDT	Manufacturer	Test name	Sensitivity			
			Cq ≤ 25	Cq >25- <30	Cq ≥ 30	Cq 17-36
47	Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)	COVID-19 Antigen Schnelltest (Colloidal Gold)	100.0%	60.9%	0.0%	64.0%
65	Precision Biosensor Inc. (Axon Laboratory AG)	Exdia COVID-19-Ag-Test	100.0%	60.9%	0.0%	64.0%
70	Safecare Biotech Hangzhou Co., Ltd.	Safecare COVID-19 Ag Rapid Test Kit (Swab)	100.0%	60.9%	0.0%	62.0%
80	Shenzhen Watmind Medical Co.,Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)	100.0%	60.9%	0.0%	62.0%
59	Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Saliva Test Kit (Colloidal Gold)	100.0%	56.5%	0.0%	60.0%
90	Wuhan Life Origin Biotech Joint Stock Co., Ltd.	SARS-CoV-2 Antigen Assay Kit (Immunochromatography)	100.0%	56.5%	0.0%	60.0%
36	Guangdong Wesail Biotech Co., Ltd.	COVID-19 Ag Test Kit	100.0%	52.2%	11.1%	62.0%
8	Anbio (Xiamen) Biotechnology Co., Ltd	Rapid Covid-19 Antigen Test (Colloidal Gold)	100.0%	52.2%	0.0%	58.0%
13	AXIOM Gesellschaft für Diagnostica und Biochemica mbH	Axiom Diagnostics COVID-19 Ag Schnelltest	100.0%	52.2%	0.0%	58.0%
51	LumiraDX	LumiraDx SARS-CoV-2 Ag Test	100.0%	52.2%	0.0%	60.0%
63	PCL, Inc.	PCL COVID19 Ag Gold Saliva	100.0%	52.2%	0.0%	58.0%
78	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%
17	Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)	100.0%	47.8%	0.0%	56.0%
42	Hangzhou Testsea Biotechnology Co., Ltd	Testsealabs Rapid Test Kit COVID-19 Antigen Test Cassette	100.0%	47.8%	0.0%	56.0%
52	MEDsan GmbH	MEDsan SARS-CoV-2 Antigen Rapid Test	100.0%	47.8%	0.0%	58.0%
54	Mölaboratory GmbH	mö-screen Corona Antigen Test	100.0%	47.8%	0.0%	58.0%

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Criteria as defined by detection rate of >75% in panel subgroup with Cq ≤ 25.

RDT	Manufacturer	Test name	Sensitivity			
			Cq ≤ 25	Cq >25- <30	Cq ≥ 30	Cq 17-36
4	Affimedix	TestNOW - COVID-19 Antigen	100.0%	47.8%	0.0%	58.0%
55	MP Biomedicals Germany GmbH	Rapid SARS-CoV-2 Antigen Test Card	100.0%	43.5%	0.0%	54.0%
68	Qingdao Hightop Biotech Co., Ltd.	Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	100.0%	43.5%	0.0%	54.0%
92	Xiamen Boson Biotech Co., Ltd	SARS-CoV-2 Antigen Schnelltest	100.0%	43.5%	0.0%	54.0%
27	DNA Diagnostic A/S.	Covid-19 Antigen Detection Kit	100.0%	39.1%	10.0%	54.0%
9	Anhui Deepblue Medical Technology Co., Ltd.	COVID-19 (SARS CoV-2) Antigen Test Kit (Colloidal Gold)	100.0%	39.1%	0.0%	52.0%
28	Edinburgh Genetics Limited	Edinburgh Genetics ActivXpress + COVID-19 Antigen Complete Testing Kit	100.0%	34.8%	0.0%	50.0%
20	BIOMERICA Inc.	COVID-19-Antigen-Schnelltest (Nasopharyngeal-Abstrich)	100.0%	30.4%	0.0%	48.0%
87	Vitrosens Biyoteknoloji Ltd. Sti	RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	100.0%	30.4%	0.0%	48.0%
18	Beijing Lepu Medical Technology Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	100.0%	26.1%	0.0%	46.0%
30	Fujirebio Inc. (Mast Diagnostica GmbH)	ESPLINE SARS-CoV-2	100.0%	21.7%	0.0%	46.0%
69	R-Biopharm AG	RIDAQUICK SARS-CoV-2 Antigen	100.0%	17.4%	0.0%	44.0%
64	PerGrande BioTech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	100.0%	17.4%	0.0%	42.0%
Subgroup of RDT with detection rates of <100% for Cq ≤ 25						
66	ProGnosis Biotech	Rapid Test Ag 2019-nCoV	94.1%	65.2%	10.0%	64.0%
31	Genrui Biotech Inc.	Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	94.1%	56.5%	0.0%	58.0%
38	Hangzhou Clongene Biotech Co., Ltd.	Clongene COVID-19 Antigen Rapid Test	94.4%	34.8%	0.0%	50.0%
29	Eurobio Scientific	EBS SARS-CoV-2 Ag Rapid Test	94.1%	34.8%	0.0%	48.0%

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Criteria as defined by detection rate of >75% in panel subgroup with Cq ≤ 25.

RDT	Manufacturer	Test name	Sensitivity			
			Cq ≤ 25	Cq >25- <30	Cq ≥ 30	Cq 17-36
62	Oncosem Onkolojik Sistemler San. Ve Tic. A.S.	CAT Antigen Covid Rapid Test	94.1%	30.4%	0.0%	46.0%
95	Zhejiang Anji Saianfu Biotech Co., Ltd.	reOpenTest COVID-19 Antigen Rapid Test (Colloidal Gold)	94.1%	30.4%	0.0%	46.0%
44	IVC Pragen Healthcare	GenBody COVID-19 Ag	94.4%	26.1%	0.0%	46.0%
57	Nanjing Norman Biological Technology Co.,Ltd	Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)	94.1%	26.1%	0.0%	44.0%
76	SGA Mühendislik DAN. EG. Icve DIS.Ltd.STI	V-Chek SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)	94.1%	26.1%	0.0%	44.0%
46	Jiangsu Medomics Medical Technology Co., Ltd	SARS-CoV-2-Antigen-Testkit (LFIA)	94.1%	21.7%	0.0%	42.0%
61	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%
40	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%
48	Labnovation Technologies, Inc.	Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	94.1%	17.4%	0.0%	40.0%
24	BTNX, Inc. (Biotrend Chemikalien GmbH)	Rapid Response COVID-19 Rapid Test Device	94.1%	13.0%	10.0%	40.0%
12	Avalun	Ksmart SARS-COV2 Antigen Rapid Test	94.1%	13.0%	0.0%	38.0%
32	GenSure Biotech Inc.	DIA-COVID COVID-19 Ag Rapid Test Kit	94.1%	13.0%	0.0%	38.0%
2	ACON Biotech (Hangzhou) Co., Ltd	Flowflex SARS-CoV-2-Antigenschnelltest (Nasopharynxtpfer)	94.1%	4.3%	0.0%	34.0%
Subgroup of RDT with detection rates of <90% for Cq ≤ 25						
73	SD BIOSENSOR (Roche Diagnostics GmbH)	SARS-CoV-2 Rapid Antigen Test	88.9%	30.4%	0.0%	46.0%
74	SD BIOSENSOR	STANDARD Q COVID-19 Ag Test	88.9%	30.4%	0.0%	46.0%

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Criteria as defined by detection rate of >75% in panel subgroup with Cq ≤ 25.

RDT	Manufacturer	Test name	Sensitivity			
			Cq ≤ 25	Cq >25- <30	Cq ≥ 30	Cq 17-36
67	Quidel Corporation	Sofia SARS Antigen FIA	88.9%	8.7%	0.0%	36.0%
26	Core Technology Co., Ltd.	Canea COVID-19 Antigen Schnelltest	88.2%	26.1%	0.0%	42.0%
43	Humasis Co., Ltd.	Humasis COVID-19 Ag Test	88.2%	21.7%	0.0%	40.0%
91	Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	88.2%	17.4%	0.0%	38.0%
39	Hangzhou Immuno Biotech Co., Ltd.	IMMUNOBIO SARS-CoV-2 Antigen-Schnelltest (COVID-19 Ag)	88.2%	13.0%	0.0%	36.0%
93	Xiamen WIZ Biotech Co., Ltd.	Wizbiotech SARS-CoV-2 Antigen Rapid Test	88.2%	13.0%	0.0%	36.0%
58	NanoEntek Inc	FRENDTM COVID-19 Ag	88.2%	8.7%	0.0%	34.0%
37	Guangzhou Wondfo Biotech Co. Ltd	Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	88.2%	0.0%	0.0%	30.0%
56	nal von minden gmbh	NADAL COVID-19 Ag Schnelltest	83.3%	13.0%	0.0%	36.0%
15	Becton Dickinson	BD Veritor System for Rapid Detection of SARS-CoV-2	83.3%	8.7%	0.0%	34.0%
34	Green Cross Medical Science Corp. (Weko Pharma GmbH)	Genedia W Covid-19 Ag	83.3%	8.7%	0.0%	34.0%
94	Zet Medikal Tekstil Dis Ticaret Ltd. STI.	softec SARS COV-2 (Covid-19) Antigen Test Kit	82.4%	21.7%	10.0%	40.0%
3	Aesku Diagnostics GmbH	Aesku Rapid SARS-CoV-2 Rapid Test	82.4%	17.4%	0.0%	36.0%
35	Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit(colloidal gold method)	82.4%	13.0%	0.0%	34.0%
71	Salofa OY	salocor SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal swab)	82.4%	13.0%	0.0%	34.0%
81	Shenzhen Zhenrui Biotech co. Ltd.	Zhenrui COVID-19 (SARS-COV-2) Antigen Test Kits	82.4%	13.0%	0.0%	34.0%
16	Beijing Beier Bioengineering Co., Ltd.	Covid-19 Antigen Schnelltest	77.8%	0.0%	0.0%	28.0%

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Criteria as defined by detection rate of >75% in panel subgroup with Cq ≤ 25.

RDT	Manufacturer	Test name	Sensitivity			
			Cq ≤ 25	Cq >25- <30	Cq ≥ 30	Cq 17-36
14	Azure Biotech Inc.	Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	76.5%	13.0%	20.0%	36.0%
5	Amazing Biotech (Shanghai) Co., Ltd	CoroVisio Covid-19 Ag Versieglungsröhrchen Teststreifen (Kolloidales Gold)	76.5%	8.7%	0.0%	30.0%

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Criteria as defined by detection rate of >75% in panel subgroup with Cq ≤ 25.