

Anlage 2 - Auszug aus der Liste 1 des Bundesinstitutes für Arzneimittel und Medizinprodukte (BfArM) über geeignete Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2 vom MSGIV, die für Kinder unter sechs Jahren geeignet sind

Test-ID	Name des Tests	Evaluierung PEI	MSGIV	Hersteller Name	Hersteller Lanc EU	Bevollmächtig EU	Bevollmäc	Probennahme	Sensitivität %	Sensitivitaet Ver	Spezifität %	Spezifitaet Ver	Gebrauchsanweisung
AT1217/21	SARS-CoV-2 Antigen Rapid Test(Self-testing)	Ja	anderer Name, ACON	ACON Biotech(Hangzhou) Co., Ltd	CN	MedNet GmbH	DE	nasal	97,1	93,1 - 98,9	99,5	98,2 - 99,9	https://www.aconbio.com/download/BfArM-CE0123.pdf
AT1332/21	Rapid COVID-19 Antigen Test(Colloidal Gold)/Nasal swab	Ja	ja	Anbio (Xiamen) Biotechnology.,Ltd.	CN	Lotus NL B.V.	NL	nasal	99	97,11 - 99,79	100	99,47 - 100,00	https://www.anbio.com/file-74338-70431.html
AT1333/21	Rapid COVID-19 Antigen Test(Colloidal Gold)/saliva	Ja	ja	Anbio (Xiamen)Biotechnology Co.,Ltd.	CN	Lotus NL B.V.	NL	nasal	98,33	96,15 - 99,46	100	98,47 - 100,00	https://www.anbio.com/page-73803.html
AT1288/21	COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold) - Speichel	Ja	ja	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	CN	Luxus Lebenswelt Gmb DE	DE	Speichel	98,7	92,33 - 99,07	99,9	98,17 - 100	https://waimao-us-west.oss-us-west-1.aliyuncs.com/customerFiles/dbluemedical/2021/11/23/fb28da6ac97307bcdcc291c0ef9e5708a73b2831.pdf
AT1190/21	COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold)	Ja	ja	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	CN	Luxus Lebenswelt Gmb DE	DE	nasal	96,4	90,8 - 98,2	99,8	94,4 - 99,9	https://waimao-us-west.oss-us-west-1.aliyuncs.com/customerFiles/dbluemedical/2021/07/30/d7d0baccb26c3c60c9a9cb02edb217bb66800d71.pdf
AT1353/21	Artron COVID-19 Antigen Home Test	Nein	nein	Artron Laboratories Inc.	CA	MedNet EC-REP GmbH	DE	nasal	91,26	84,06 - 95,93	99,56	97,57 - 99,99	https://artronselftest.com/ifu
AT1322/21	SARS-CoV-2 Antigen Rapid Test Cassette	Nein	nein	Beijing Applied Biological Technologies Co., Ltd.	CN	Luxus Lebenswelt Gmb DE	DE	nasal	95,83	92,47 - 97,98	99,99	99,22 - 100,00	https://www.x-abt.com/uploadfile/2021/1201/3-1instructionforuse-DE.pdf
AT1236/21	Coronavirus (2019-nCoV)-Antigentest-	Ja	ja	Beijing Hotgen Biotech Co., Ltd.	CN	MedNet GmbH	DE	nasal	96,95	92,4 - 99,2	98,88	96,8 - 99,8	https://mailing.com/free/?e=dwlp8LUGUSer6
AT1265/21	WANTAI SARS-CoV-2 Ag Schnelltest (Kolloidales Gold)	Ja	ja	Beijing WANTAI Biological Pharmacy Enterprise Co.,	CN	Qarad BV	BE	Speichel / nasal	89,76	85,42 - 92,92	99,61	98,58 - 99,89	https://www.medrhein.de/wp-content/uploads/wantai/ifu_ce2854_medRhein_wantai.pdf
AT1189/21	Dräger COVID-19 Home Test	Ja	ja	Dräger Safety AG & Co KGaA	DE		DE	nasal	87,5	81,3 - 91,9	99,3	97,6 - 99,8	https://ffgshop.imgbolt.de/media/pdf/4d/7c/0b/Gebrauchsanweisung-Dr-ger-Covid-19-Home-Test.pdf
AT1200/21	SARS-CoV-2 Antigen Test Kit (Kolloidales Gold)	Ja	ja	Genrui Biotech Inc.	CN	Lotus NL B.V.	NL	nasal	98,13	93,0 - 99,0	100	96,0 - 100,0	http://www.genrui-bio.com/u_file/images/21_08_06/8f85758dccc.pdf
AT1257/21	Einstufiger Test für SARS-CoV-2-Antigen (Kolloidales Gold) One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	Ja	ja	Getein Biotech, Inc	CN	CMC Medical Devices †	ES	nasal	97,06	93,30 - 98,74	98,71	96,73 - 99,50	http://49.51.180.188/AT1257-21%20IFU-SARS-CoV-2%20Antigen%20Self-test.pdf
AT1295/21	SARS-CoV-2 Antigen Kit (Colloidal Gold)	Ja	ja	Goldsite Diagnostics Inc.	CN	CMC MEDICAL DEVICE!	ES	nasal	92,44	86,13 - 96,48	99,32	96,29 - 99,98	https://drive.google.com/file/d/1JAx0M5H3K27N-1x6WfCs6Ebj4ZocBR-x/view?usp=sharing
AT1158/21	COVID-19 Ag Test	Ja	ja	Guangdong Wesail	CN	Lotus NL B.V.	NL	nasal	82,4	74,68 - 88,15	99,7	98,24 - 99,99	https://bio-gram.de/download/20210804_GA_CE-Test_Wesail.pdf
AT1338/21	2019-nCoV Ag Saliva Rapid Test Card (Immunochromatography)	Ja	ja	Guangzhou Decheng Biotechnology Co., Ltd	CN	Caretechion GmbH	DE	Speichel	92,14	88,39 - 94,75	98,83	97,47 - 99,46	https://www.dochekbio.com/uploadfile/2021/12208/weby.cc2021120810143439080949500264.pdf
AT1291/21	2019-nCoV Ag Rapid Test Kit (Immunochromatography)	Ja	ja	Guangzhou Decheng Biotechnology Co., Ltd	CN	Caretechion GmbH	DE	nasal	96,55	93,7 - 98,1	99,42	98,3 - 99,8	https://www.dochekbio.com//index.php?m=content&c=index&a=show&catid=41&id=135
AT1172/21	SARS-CoV-2-Antigen-Schnelltest (Nasenabstrich)for self testing	Ja	ja	Hangzhou AllTest Biotech Co., Ltd.	CN	MedNet GmbH	DE	nasal	96,6	94,7 - 97,9	99,4	98,5 - 99,8	http://www.alltests.com.cn/upload/20211216/bc5f23c-025d-4899-ba1c-02856db83bc3.pdf
AT1117/21	COVID-19 Antigen Rapid Test (Oral Fluid) for self testing	Ja	ja	Hangzhou AllTest Biotech Co., Ltd.	CN	MedNet GmbH	DE	Speichel	90,1	82,50 - 95,10	99,3	97,70 - 99,90	
AT1331/21	COVID-19 Antigen Rapid Test Cassette(Nasal Swab)	Ja	ja	Hangzhou Biotest Biotech Co., Ltd	CN	Shanghai International	DE	nasal	93,2	86,5 - 97,2	99,2	97,1 - 99,9	http://c101802623.bj.wezhan.cn/yibucategorypage/277754505?setprev=pc
AT1228/21	Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing	Ja	ja	Hangzhou Laihe Biotech Co., Ltd	CN	SUNGO Europe B.V.	NL	nasal	95	90,39 - 97,82	99,6	97,80 - 99,99	http://www.lissner-qi.de/ae396/gebrauchsanweisung.pdf
AT1269/21	SARS-CoV-2 Antigen Rapid Test Cassette	Ja	ja	Hangzhou Sejoy Electronics & Instruments Co.,Ltd	CN	Shanghai International	DE	nasal	94,5	88,5 - 97,5	99,9	99,7 - 100,0	https://www.sejoy.com/uploads/Package-Insert-of-SARS-CoV-2-Antigen-de1.pdf
AT1259/21	COVID-19 Test Kit (Colloidal Gold Method)	Nein		Hangzhou Singclean Medical Products Co., Ltd.	CN	SUNGO Europe B.V.	NL	nasal	97,99	94,25 - 99,31	99,71	98,40 - 99,95	http://de.hzxhe.net/covid-19-antigen-testing/covid-19-test-kit-kolloidale-gold-methode.html
AT1208/21	CLINITEST Rapid COVID-19 Antigen Self-Test	Nein		Healgen Scientific LLC	US	Shanghai International	DE	nasal	97,25	92,17 - 99,43	100	97,69 - 100,00	https://www.clinitest.siemens-healthineers.com/de/clinitest-self-test
AT1298/21	SARS-CoV-2 Antigen Test Kit (LFIA) self testing	Ja	ja	Jiangsu Medomics Medical Technology Co.,Ltd.	CN	R Sight B.V.	NL	nasal	91,82	85,04 - 96,19	100	99,19 - 100,00	https://v4.cecdn.yun300.cn/100001_1901235046/IFU-DE.pdf
AT1276/21	COVID-19 Antigen Rapid Test (Colloidal Gold) vorderer Nasenabstrich/ anterior nasal – Selbsttest	Ja	ja	Joinstar Biomedical Technology Co.,Ltd	CN	Lotus NL B.V.	NL	nasal	96,1	90,26 - 98,92	99,2	97,86 - 99,92	http://zhsten.joinstar.cn/upload/RPBH2003.pdf
AT1284/21	SARS-CoV-2 Antigen Rapid Test Kit	Ja	ja	Labnovation Technologies, Inc.	CN	MedNet EC-REP GmbH	DE	nasal	95,45	89,71 - 98,51	100	99,18 - 100,00	http://www.labnovation.com/products/1415.html
AT1280/21	Mexacare CORONA Home-Test Antigen	Nein		MEXACARE GmbH	DE		DE	nasal	96,19	92,53 - 99,85	99,2	97,64 - 99,99	https://mexacare.com/wp-content/uploads/2021/12/MX-CoV19AgOTC-cass-IFU-021221-1.11DE-1.pdf
AT1293/21	NADAL COVID-19 Ag Test	Ja	ja	nal von minden GmbH	DE		DE	nasal	94,1	87,64 - 97,81	99,9	97,36 - 100	https://www.nal-vonminden.com/pdf/Gebrauchsanweisunggen%20NADAL%20COVID-19%20Ag%20Test%20243117%20_CE0197.pdf
AT1155/21	NanoRepro SARS-CoV-2 Antigen Schnelltest (Viromed)	Ja	ja	NanoRepro AG	DE		DE	nasal	97,33	93,31 - 99,27	99,33	96,34 - 99,98	https://www.nanorepro.com/media/NanoRepro_SARS-CoV-2_PB_VIROMED_mdcc.pdf
AT1234/21	ZuhauseTEST Corona	Nein		NanoRepro AG	DE		DE	Speichel	94,29	87,98 - 97,87	99	97,46 - 99,73	https://www.nanorepro.com/media/ZuhauseTEST_Corona_PB.pdf
AT1210/21	COVID-19 Antigen-Nachweis-Kit – Nasenabstrich	Ja	ja	New Gene (Hangzhou) Bioengineering Co., Ltd.	CN	SUNGO Europe B.V.	NL	nasal	97,11	93,38 - 99,06	99,24	97,29 - 99,90	https://www.new-gene.net/self-test-ifu-and-clinical-study-report
AT1224/21	SARS-CoV-2 Antigen Rapid Test	Ja	ja	QINGDAO HIGHTOP BIOTECH CO.,LTD.	CN	MedNet EC-REP GmbH	DE	nasal	98,04	93,13 - 99,44	100	98,74 - 100	https://mailing.com/free/?e=dwDoEka5nO6Uo6
AT1154/21	SARS-CoV-2 Antigen Self Test Nasal	Ja	ja	SD Biosensor Inc.	KR	MT Promed†	DE	nasal	86,4	78,50 - 92,20	99,6	97,9 - 100,00	http://www.roche.de/ag-patient
AT1308/21	SARS-CoV-2 Antigen Test Kit (Colloidal Gold) Chromatographic Immunoassay)	Ja	ja	Shenzhen Microprofit Biotech Co., Ltd.	CN	CMC MEDICAL DEVICE!	ES	nasal	92,93	89,82 - 95,33	100	98,78 - 100	https://www.dropbox.com/s/3tcwrz5icnnavbm/MF-68%20IFU%20SELFTEST-DE.pdf?dl=0
AT1222/21	TEST IT COVID-19 Ag Home Test RAPIDAN TESTER COVID-19 Ag Home Test TOYO COVID-19 Ag Home Test INFO CC	Ja	ja	TÜRKLAB TIBBI MALZEMELER SAN. ve TIC. A.S.	TR		TR	nasal	92,65	88,87 - 95,45	99,38	97,79 - 99,93	https://www.turklab.com.tr/upload/covid/3-testit-covid-home.pdf
AT1281/21	SARS-CoV-2-Ag-Schnelltest VivaDiagTM Pro SARS-CoV-2 Ag Rapid Test (self-test)	Ja	ja	VivaChek Biotech (Hangzhou) Co., Ltd.	CN		CN	nasal	99,13	95,24 - 99,85	100	99,17 - 100	https://www.vivachek.com/en/prods/Package-Insert.html
AT1289/21	Medicovid-AG COVID-19 (SARS-CoV-2) Antigen-Testkit	Nein		Wuhan EasyDiagnosis Biomedicine Co., Ltd.	CN	Osmuda Medical Techn	DE	nasal	91,3	85,2 - 95,1	100	96,0 - 100	
AT1279/21	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	Ja	ja	Xiamen AmonMed Biotechnology Co., Ltd.	CN	SUNGO Europe B.V.	NL	Speichel	96,55	93,05 - 98,32	100	99,20 - 100,00	https://amonmed-schreiner.com/wp-content/uploads/2021/11/IFU_DE_Version_6.pdf
AT1165/21	Rapid SARS-CoV-2 Antigen Test Card	Ja	ja	Xiamen Boson Biotech Co., Ltd.	CN		CN	nasal	96,19	92,53 - 99,85	99,2	97,64 - 99,99	https://technomed.at/files/technomed_covid-19_ag_selbsttest_ce0123_boson_ifu_19082021.pdf
AT1297/21	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	Ja	ja	Xiamen Wiz Biotech Co., Ltd.	CN	Qarad EC-REP BV	BE	nasal	98,26	93,86 - 99,79	100	99,19 - 100,00	https://mailing.com/free/?e=dnchPo9dOOql66
AT1290/21	COVID-19 Antigentest Kit (Kolloidal Gold)	Ja	ja	Zhuohai Lituo Biotechnology Co., Ltd.	CN	CMC MEDICAL DEVICE!	ES	nasal	94,53	88,80 - 97,41	98,02	97,93 - 99,97	https://drive.google.com/drive/folders/16LwOC1pJAON5pgMrr8Vttx4DINRtyDw8