

Liste der zugelassenen CoV-2-Selbsttests

(Bundesinstitut für Arzneimittel und Medizinprodukte)

Aktenzeichen der Sonderzulassung des BfArM	Hersteller	Antragsteller	Testname	BfArM-AT-Nummer*
5640-S-004/21	Healgen Scientific LLC	Siemens Healthcare Diagnostics Products GmbH	CLINITEST Rapid COVID-19 Self-Test	AT001/20
5640-S-007/21	Xiamen Bosen Biotech Co., Ltd	Technomed Service GmbH	Rapid SARS-CoV-2 Antigen Test Card	AT116/20
5640-S-009/21	Hangzhou Laihe Biotech Ltd., Co.	Lissner Qi GmbH	LYHER® Covid-19 Antigen Schnelltest (Nasal)	AT011/20
5640-S-025/21	SD BIOSENSOR, INC.	MT Promedt Consulting GmbH	SARS-CoV-2 Rapid Antigen Test	AT307/21
5640-S-062/21	AMEDA Labordiagnostik GmbH	AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	AT033/20
5640-S-057/21	Beijing Hotgen Biotech Co., Ltd	Beijing Hotgen Biotech Co., Ltd	Coronavirus (2019-nCoV)-Antigentest	AT282/21
5640-S-022/21	Aesku.Diagnostic s GmbH & Co. KG	Aesku.Diagnostic s GmbH & Co. KG	AESKU.RAPID SARS-CoV-2	AT363/20
5640-S-061/21	AMEDA Labordiagnostik GmbH	AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag Sputum	AT033/20
5640-S-096/21	NanoRepro AG	NanoRepro AG	NanoRepro Antigen Schnelltest (Viromed)/ NanoRepro Antigen Rapid Test (Viromed)	
5640-S-076/21	MP Biomedicals Germany GmbH	MP Biomedicals Germany GmbH	Rapid SARS-CoV-2 Antigen Test Card	
5640-S-041/21	Biosynex Suisse SA	Biosynex Suisse SA	BIOSYNEX COVID-19 Ag BSS	AT025/20
5640-S-168/21	Hangzhou Clongene Biotech Co., Ltd.	Hangzhou Clongene Biotech Co., Ltd.	COVID-19 Antigen Rapid Test	AT373/21
5640-S-128/21	MEDICE Arzneimittel Pütter GmbH & Co. KG	MEDICE Arzneimittel Pütter GmbH & Co. KG	Medicovid-AG SARS CoV-2 Antigen SELBSTTEST NASE	

5640-S-116/21	amec GmbH	amec GmbH	COVID-19 Antigen Schnelltest (Spucktest)	
5640-S-147/21	MR Sanicom GmbH	MR Sanicom GmbH	COVID-19 Antigen-Schnelltest (Kolloidales Gold)	
5640-S-079/21	Teda Laukoetter Technologie GmbH	Teda Laukoetter Technologie GmbH	ANBIO Corona Antigen Nasentupfer	
5640-S-080/21	Beijing Hotgen Biotech Co.,Ltd	Beijing Hotgen Biotech Co.,Ltd	Coronavirus (2019-nCoV)-Antigentest - Speichel	AT095/21
5640-S-178/21	Haemato Pharm GmbH	Haemato Pharm GmbH	Wondfo 2019-nCoV Antigen Test (Lateral-Flow-Methode) Selbsttest	
5640-S-146/21	OFM GmbH	OFM GmbH	Sensitivo COVID-19 Antigen Test	
5640-S-104/21	Beijing Lepu Medical Technology Co., Ltd.	Beijing Lepu Medical Technology Co., Ltd.	NASOCHECKcomfort SARS-CoV-2 Antigen-Schnelltest	
5640-S-100/21	Aripa Biotec GmbH	Aripa Biotec GmbH	COVID-19-N-Antigen Schnelltest SARS-CoV-2 (vorderer Nasenabstrich)	
5640-S-140/21	OFM GmbH	OFM GmbH	Deni COVID-19 Antigen Test	
5640-S-036/21	Acura Kliniken Baden-Baden GmbH	Acura Kliniken Baden-Baden GmbH	Acura Speichel-Test Diagnos COVID-19 Antigen Saliva Test Kit	
5640-S-032/21	Shenzhen Watmind Medical Co., Ltd.	Shenzhen Watmind Medical Co., Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	AT-108/20
5640-S-049/21	Mexacare GmbH	Mexacare GmbH	MEXACARE Corona Home-Test Antigen	
5640-S-123/21	Safecare Biotech (Hangzhou) Co., Ltd.	NIC GmbH	COVID-19 Antigen Rapid Test kit(Swab) (self-testing)	
5640-S-015/21	Qingdao Hightop Biotech Co., Ltd.	Qingdao Hightop Biotech Co., Ltd.	HIGHTOP SARS-CoV-2 (COVID-19) Antigen Rapid Test	AT301/20
5640-S-053/21	Vitrosens Biyoteknoloji Ltd. Sti.	Vitrosens Biyoteknoloji Ltd. Sti.	RapidFor SARS-CoV-2 Rapid Antigen Test	AT507/20

5640-S-045/21	nal von minden GmbH	nal von minden GmbH	NADAL® COVID-19 Ag Test	AT021/20
5640-S-216/21	Abbott Rapid Diagnostics Jena GmbH	Abbott Rapid Diagnostics Jena GmbH	Panbio™ COVID-19 Antigen Self-Test	AT116/21
5640-S-058/21	Anbio (Xiamen) Biotechnology Co., Ltd.	Anbio (Xiamen) Biotechnology Co., Ltd.	COVID-19 Antigen Schnelltest (Kolloidales Gold)	AT195/21
5640-S-156/21	WQS Management Consultants GmbH	WQS Management Consultants GmbH	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	
5640-S-171/21	ACON Biotech(Hangzhou) Co., Ltd	ACON Biotech(Hangzhou) Co., Ltd	SARS-CoV-2-Antigenschnelltest (Selbsttest)	
5640-S-179/21	Guangzhou Wondfo Biotech Co., Ltd.	Guangzhou Wondfo Biotech Co., Ltd.	2019-nCoV Antigen Test (Lateral Flow Method)	
5640-S-031/21	PerGrande BioTech Development Co., Ltd.	JingCheng Asia Group Limited	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic assay)	
5640-S-118/21	Bio-Gram Diagnostics GmbH	Bio-Gram Diagnostics GmbH	COVID-19 Ag Test Kit	
5640-S-094/21	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ag Schnelltest (Kolloidales Gold)	
5640-S-063/21	PCL Inc.	Haemo Pharma GmbH	PCL COVID19 Ag Gold	
5640-S-151/21	JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.	JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.	COVID-19 Antigen Schnelltest (kolloidales Gold) Probenmaterial: vorderer Nasenabstrich	
5640-S-028/21	Icon Medlab GmbH	Icon Medlab GmbH	SARS-CoV-2 Antigen Rapid Test Kit	
5640-S-214/21	Brawa GmbH	Brawa GmbH	COVID-19 (SARS-CoV-2) Antigen Schnelltest	
5640-S-086/21	Anhui Deepblue Medical Technology Co. Ltd.	Anhui Deepblue Medical Technology Co. Ltd.	COVID-19 (SARS-CoV-2) Antigentest (kolloidales Gold)	

5640-S-087/21	Anhui Deepblue Medical Technology Co. Ltd.	Anhui Deepblue Medical Technology Co. Ltd.	COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold) - Speichel	
5640-S-240/21	Joinstar Biomedical Technology Co., Ltd	Joinstar Biomedical Technology Co., Ltd	Covid-19 Antigen Rapid Test (Colloidal Gold)	
5640-S-164/21	EJOY-GmbH	EJOY-GmbH	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)	
5640-S-210/21	Xiamen WIZ BIOTECH Co., Ltd.	Xiamen WIZ BIOTECH Co., Ltd.	WizDx COVID-19 Antigen Schnelltest	
5640-S-245/21	Günter Keul GmbH	Günter Keul GmbH	SARS-CoV-2 Antigentest Kit (Kolloidales Gold) - Laientest / Selbsttest	
5640-S-064/21	Zhejiang Anji Saianfu Biotech Co., Ltd.	Zhejiang Anji Saianfu Biotech Co., Ltd.	„AndLucky“ SARS CoV-2 Antigen Rapid Test, Anterior Nasal Check (minimal-invasiv)	
5640-S-225/21	Lama Licensing GmbH	Lama Licensing GmbH	LAMA SARS-Cov-2-Antigen-Saliva/Sputum-Test Spucktest zur Eigenanwendung	
5640-S-206/21	XIAMEN WIZ BIOTECH Co., Ltd.	XIAMEN WIZ BIOTECH Co., Ltd.	WizDx COVID-19 Antigen Schnelltest	
5640-S-185/21	Getein Biotech Inc.	Getein Biotech Inc.	Einstufiger Test für SARS-COV-2-Antigen	
5640-S-230/21	Guangdong Longsee Biomedical Co., Ltd.	Guangdong Longsee Biomedical Co., Ltd.	2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	
5640-S-103/21	Guangzhou Wondfo Biotech Co., Ltd	Guangzhou Wondfo Biotech Co., Ltd	SARS-CoV-2 Antigen-Saliva / Sputum-Test Spucktest	
5640-S-056/21	Sugentech, Inc.	Sugentech, Inc.	SGTi-flex COVID-19 Ag	
5640-S-020/21	Pierenkemper GmbH	Pierenkemper GmbH	(SARS-CoV-2) Antigen Rapid test COVIDENT COVID-19	