Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests / Comparative evaluation of the sensitivities of SARSCoV-2 antigen rapid tests

Ziel

Vergleich verschiedener Antigenschnelltests mit einheitlichem Probenmaterial

Material

Pools von naso- und oropharyngealen Abstrichen, die als Prüfproben für ein Panel verwendet werden.

Trockene Tupfer wurden in PBS aufgenommen, feuchte Tupfer waren bereits in Transport-medium unterschiedlicher Zusammensetzung. Pools sind zufällige Mischungen aus bis zu 10 Proben vergleichbarer Cq Werte, die 1:10 in negativen Proben in PBS verdünnt wurden (Cq = Quantifizierungscyclus; auch als CT = cycle threshold bezeichnet). Die Cq Werte eines Pools wurden mit verschiedenen PCR Assays bestimmt und die mutmaßliche Anzahl an RNA-Kopien mit Hilfe des INSTAND Standards berechnet. Bei den verwendeten PCRs entspricht ein Cq Wert von 25 etwa 10^6 RNA Kopien/mL. Vermehrung des Virus in Zellkultur wurde als mögliches Korrelat für Infektiosität als weiteres Merkmal der Proben bestimmt.

Aufgrund der hohen Anzahl an zu überprüfenden Tests mussten einzelne Proben des ersten Prüfpanels ersetzt werden (Panel 1 Versionen 1 und 2) bzw. in analoger Weise ein neues Panel (Panel 2) hergestellt werden. Für Panel 1 Versionen 1 bzw. 2 wurden 18 bzw. 17 Proben mit Cq ≤25, 23 Proben mit Cq 25 – 30 und 9 bzw. 10 Proben mit Cq ≥30 eingesetzt. Panel 2 setzt sich aus 20 Proben mit Cq ≤25, 20 Proben mit Cq 25 – 30 und 10 Proben mit Cq ≥30 zusammen.

Durchführung

Die Pools wurden aliquotiert, eingefroren, versendet, und zur Evaluierung der Tests aufgetaut. Für jeden Test wurden 50 µl eines Pools (Panel 1 V1, V2) bzw. 25 µl (Panel 2) mit den vom Test bereitgestellten Komponenten z. B. Tupfer und Puffer, analysiert. Wenn ein Test für mehrere Probentypen ausgelegt war (z. B. nasopharyngeal, nasal, Speichel, etc.),

Aim

Comparison of different antigen rapid tests using uniform sample material

Material

Pools from nasopharyngeal and oropharyngeal swabs which are used as test specimens included in an evaluation panel.

Dry swabs were included in PBS; moist swabs were already included in the transport media of various compositions. Pools are random mixtures obtained from up to 10 samples of comparable Cq values diluted 1:10 in negative samples in PBS (Cq = Quantification cycle; also reported as CT = cycle threshold). The Cq values of a pool were determined by means of different PCR assays, and the putative number of RNA copies calculated with the aid of the INSTAND standard. In the case of the PCRs used, a Cq value of 25 corresponds to around 10^6 RNA copies/mL. The replication of the virus in cell culture as another characteristic of the samples was determined as a possible correlate for infectiousness.

Due to the high number of tests under evaluation few specimens of the first panel were replaced (resulting in panel 1 versions 1 and 2), and a new panel (panel 2) was manufactured in analogous manner. For panel 1 versions 1 and 2, 18 or 17 samples, respectively, were characterized as Cq ≤25, 23 samples as Cq 25-30, and 9 or 10 samples, respectively, as Cq ≥30; the composition of panel 2 is: 20 samples with Cq ≤25, 20 samples with Cq 25-30, and 10 samples with Cq ≥30.

Method

The pools were aliquoted, frozen, shipped, and thawed for evaluation of the tests. For each test, 50µl of the pool (panel 1 versions 1 and 2), or 25µl (panel 2) were analysed using the components of the test provided, e.g. swabs and buffer. In case of tests designed for various sample types (e.g. nasopharyngeal, nasal, saliva, etc), the test specific swab dedicated for nasopharyngeal samples was used.

wurde der testspezifische Tupfer für die nasopharyngeale Probennahme verwendet. An der vergleichenden Evaluierung beteiligte Labors sind u. a. Robert Koch-Institut, Paul-Ehrlich-Institut, Konsiliarlabor für Coronaviren (Charité), Institut für Mikrobiologie der Bundeswehr.

Zusammenfassung

Diese vergleichende Evaluierung einer großen Anzahl von SARS-CoV-2 Antigenschnelltests (point of care tests; POCT) verschiedenen Designs und verschiedener Hersteller mit einem einheitlichen Probenset ermöglicht einen Überblick über den derzeitigen Stand der Technik hinsichtlich ihrer Sensitivität. Der derzeitige Stand der Technik wurde einer Mindestsensitivität von 75 % für die Pools mit einem Cq ≤25 gleichgesetzt. Die Ergebnisse lassen keine Rückschlüsse auf die Spezifität der Tests zu.

Tabelle 1 fasst die Ergebnisse der Antigenschnelltests zusammen, die als „dem Stand der Technik entsprechend“ bewertet wurden (alphabetische Reihenfolge der Hersteller).

Tabelle 2 fasst die Ergebnisse derjenigen Tests zusammen, die das Sensitivitäts-Kriterium nicht erfüllten und aus der Liste des BfArM (erstattungsfähige Tests) gestrichen wurden (alphabetische Reihenfolge der Hersteller).

Der erste Teil der Evaluierung wurde bereits wissenschaftlich veröffentlicht (1); in dieser Publikation sind weitere Details der vergleichenden Evaluierung zusammengefasst.

Es sei ausdrücklich darauf hingewiesen, dass diese vergleichende Evaluierung nur eine Stichprobe der beim BfArM gelisteten und somit erstattungsfähigen SARS-CoV-2 Antigenschnelltests berücksichtigen kann, und manche Tests bislang (noch) nicht berücksichtigt werden konnten, trotz entsprechendem Interesse seitens Herstellern / Vertreibern.

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Laboratories participating in the comparative evaluation included the Robert Koch-Institut, the Paul-Ehrlich-Institut, the reference laboratory for coronaviruses (Charité), and the Institute for Microbiology of the German Army (Bundeswehr).

Summary

This comparative evaluation of a large number of SARS-CoV-2 rapid antigen tests (point of care tests; POCT) of different designs and manufacturers using the uniform sample sets allows an overview of the current state of the art regarding sensitivity.
The current state of the art was defined as corresponding to a minimal sensitivity of 75% for the pools with Cq ≤25. The results do not allow any conclusions regarding specificity of the tests.

Table 1 summarizes the results of those POCTs assessed as reflecting the current state of the art (alphabetical order of manufacturers).

Table 2 summarizes the results of those POCT (alphabetical order of manufacturers) which do not fulfill the sensitivity criteria and consequently are deleted from the list of reimbursable tests (see the homepage of Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM).

The first part of this evaluation has already been published (1); this publication summarizes further details of the comparative evaluation.

You should be aware that this comparative evaluation can only cover a random sample of the SARS-CoV-2 rapid antigen tests listed by the BfArM, thus eligible for reimbursement, and that few other products could not (yet) be taken into account, despite the interests on the part of the manufacturers/distributors.

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Ergebnisse der Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests / Results of the Comparative Evaluation of the Sensitivity of SARS-CoV-2 Antigen Rapid Tests

(sortiert in alphabetischer Reihenfolge der Hersteller / sorted in alphabetical order of manufacturers)

Stand vom / dated: 14.12.2021

Tabelle 1: Ergebnisse der SARS-CoV-2 Antigenschnelltests, die das Sensitivitätskriterium erfüllen
Table 1: SARS-CoV-2 antigen rapid diagnostic tests passing the sensitivity criteria

					Sensitivität / Sensitivity		
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT005/20	41FK10	Abbott Rapid Diagnostics Jena GmbH	Panbio™ COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)	N	100,0%	60,9%	0,0%	64,0%
AT018/21	n.a.	Abioteq	Cora Gentest-19	N	100,0%	45,0%	0,0%	58,0%
AT084/21	ABT-IDTB367	AccuBioTech Co.,Ltd.	Accu-Tell Rapid In-vitro Diagnostiktest	N	100,0%	75,0%	0,0%	70,0%
AT155/20	L031-11815	ACON Biotech (Hangzhou) Co., Ltd	Flowflex SARS-CoV-2-Antigenschnelltest	N	94,1%	4,3%	0,0%	34,0%
AT1024/21	n.a.	Acro Diagnostics Co., Ltd	SARS-CoV-2 Antigen Rapid Detection Kit (LFA)	N	100,0%	100,0%	80,0%	96,0%
AT363/20	840001	Aesku Diagnostics GmbH	Aesku Rapid SARS-CoV-2 Rapid Test	N	82,4%	17,4%	0,0%	36,0%
AT181/21	1166-25	Affimedix	TestNOW® COVID-19-Antigen-Test	N	100,0%	47,8%	0,0%	58,0%
AT303/20	RICOV2	Amazing Biotech (Shanghai) Co., Ltd	CoroVisio Covid-19 Ag Versieglungsröhrchen Teststreifen (Kolloidales Gold)	N	76,5%	8,7%	0,0%	30,0%
AT033/20	RT2952	Ameda Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	N	100,0%	78,3%	0,0%	70,0%
AT412/21	MU00325	Amper,Inc.	Amper COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)	N	100,0%	100,0%	40,0%	88,0%
AT147/20	A6061202	Anbio (Xiamen) Biotechnology Co., Ltd	Rapid Covid-19 Antigen Test (Colloidal Gold)	N	100,0%	52,2%	0,0%	58,0%
AT031/20	n.a.	Anhui Deepblue Medical Technology Co. , Ltd.	COVID-19 (SARS CoV-2) Antigen Test Kit (Colloidal Gold)	N	100,0%	39,1%	0,0%	52,0%
AT785/21	FCB-103	Anhui Formaster Biosci Co., Ltd	New Coronavirus (COVID-19) Antigen Rapid Test	N	100,0%	50,0%	10,0%	62,0%
AT518/20	A03-50-422	Artron Laboratories Inc.	COVID-19 Antigentest	N	100,0%	95,0%	20,0%	82,0%
AT431/20	AM3474-K	ASAN PHARM.CO.,LTD.	Asan Easy Test COVID-19 Ag	N	100,0%	69,6%	0,0%	66,0%
AT286/20	NL-CA002-2020-52777	Assure Tech (Hangzhou) Co.,Ltd	ECOTEST COVID-19 Antigen Rapid Test Device	N	95,0%	50,0%	0,0%	58,0%
AT791/21	MY28	Asterion Otel Insaat Bilisim Medikal Maden Tic.Ltd.Sti.	AS-check COVID-19 Antigen Schnelltest	N	85,0%	5,0%	0,0%	36,0%

					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT132/20	nCOV-500	Atlas Link Technology Co.,Ltd.	Nova Test SARS-CoV-2 Antigen Rapid Test Kit	N	100,0%	60,9%	0,0%	62,0%
AT441/20	8004664	Avalun	Ksmart® SARS-COV2 Antigen Rapid Test	N	94,1%	13,0%	0,0%	38,0%
AT374/20	88 99 19	AXIOM Gesellschaft für Diagnostica und Biochemica mbH	Axiom Diagnostics COVID-19 Ag Schnelltest	N	100,0%	52,2%	0,0%	58,0%
AT061/20	B62000	Azure Biotech Inc.	Dia Sure Covid-19 Antigen Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)	N	76,5%	13,0%	20,0%	36,0%
AT200/20	256082	Becton Dickinson	BD Veritor™ System for Rapid Detection of SARS-CoV-2	N	83,3%	8,7%	0,0%	34,0%
AT074/20	n.a.	Beijing Beier Bioengineering Co., Ltd.	Covid-19 Antigen Schnelltest	N	77,8%	0,0%	0,0%	28,0%
AT967/21	P2311	Beijing Homa Biological Engineering Co., Ltd.	COVID-19 Antigen Test Kit	N	100,0%	35,0%	0,0%	54,0%
AT120/20	n.a.	Beijing Hotgen Biotech Co., Ltd.	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)	N	100,0%	47,8%	0,0%	56,0%
AT205/20	C3042	Beijing Jinwofu Bioengineering Technology Co.,Ltd.	Jinwofu Novel Coronavirus (SARS-COV-2) Antigen Rapid Test Kit	N	100,0%	50,0%	0,0%	60,0%
AT313/20	601460	Beijing Kewei Clinical Diagnostic Reagent Inc.	COVID-19 Antigen Rapid Test Kit	N	95,0%	0,0%	0,0%	38,0%
AT216/20 (AT052/20)	n.a.	Beijing Lepu Medical Technology Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	N	100,0%	26,1%	0,0%	46,0%
AT820/21	00013C	Beijing O&D Biotech Co., Ltd.	Covid-19 Antigen Rapid Test (Colloidal Gold)	N	100,0%	75,0%	10,0%	72,0%
AT122/21	TG1417	Beijing Tigsun Diagnostics Co.;Ltd.	Tigsun COVID-19 Saliva Antigen Rapid Test	N	100,0%	87,0%	30,0%	80,0%
AT022/21	WJ-2850	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	Wantai SARS-CoV-2 Ag Rapid Test (FIA)	N	100,0%	78,3%	0,0%	72,0%
AT496/20	WJ-2910	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	Wantai SARS-CoV-2 Ag Schnelltest (Kolloidales Gold)	N	100,0%	25,0%	0,0%	50,0%
AT284/21	B255C	Biocan Diagnostics Inc.	Tell Me Fast Rapid Diagnostic Test	N	95,0%	10,0%	0,0%	42,0%
AT787/21	GMT102	BioDetect (Xiamen) Biotechnology Co., Ltd	SARS-Cov-2-Antigen-Schnelltest-Karte	N	95,0%	15,0%	0,0%	44,0%
AT879/21	209.01.25.01	Biohit Healthcare (Hefei) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method)	N	100,0%	95,0%	20,0%	82,0%
AT172/21	1-367-K020	BioMaxima S.A.	SARS-CoV-2 Ag Rapid Test	N	100,0%	60,0%	0,0%	64,0%
AT007/21	1509A-I	BIOMERICA Inc.	COVID-19-Antigen-Schnelltest (Nasopharyngeal-Abstrich)	N	100,0%	30,4%	0,0%	48,0%
AT014/20	RG1901DG	BIONOTE	NowCheck® COVID-19 Ag Test	N	100,0%	65,2%	0,0%	66,0%
AT219/20	COV-201	BioRepair GmbH	Covid 19 Antigen Schnelltest	N	100,0%	78,3%	0,0%	70,0%

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					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT805/21	n.a.	Bioscience (Tianjin) Diagnostic Technology Co., Ltd	Novel Coronavirus(2019-nCoV) Antigen Rapid Test	N	100,0%	100,0%	60,0%	92,0%
AT025/20	SW4000605	BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	N	100,0%	78,3%	11,1%	74,0%
AT349/21	400-678-8982	BioTeke Corporation (Wuxi) Co.,Ltd.	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)	N	95,0%	10,0%	0,0%	42,0%
AT373/20	COV-19C25	BTNX, Inc.	Rapid Response COVID-19 Rapid Test Device	N	94,1%	13,0%	10,0%	40,0%
AT924/21	C2104N01	Cesna Biyoteknoloji Arastirma Gelistirme Laboratuvar Sist.	Check Up SARS-CoV-2 Nasal Antigen Rapid Test	N	100,0%	45,0%	10,0%	60,0%
AT1010/21	n.a.	Changzhou Biowin Pharmaceutical Co.,Ltd.	Novel Coronavirus(COVID-19) Antigen Test Kit (Colloidal Gold)	N	100,0%	35,0%	0,0%	54,0%
AT337/20	CCOV-201	Chil Tibbi Mal. San. Tic. Ltd. Şti	COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette)	N	100,0%	60,9%	0,0%	62,0%
AT635/21	n.a.	Chongqing ISIA BIO-Technology Co.,Ltd	ISIA SARS-CoV-2 Antigen Rapid Test Kit	N	90,0%	15,0%	0,0%	42,0%
AT595/21	n.a.	Chongqing M&D Biotechnology Co. Ltd.	2019-nCoV Antigen Test Kit	N	95,0%	25,0%	0,0%	48,0%
AT889/21	n.a.	CITEST Diagnostics Inc.	COVID-19 Antigen Rapid Test (Oral Fluid)	N	100,0%	100,0%	90,0%	98,0%
AT409/20	7200331	Co-Innovation Biotech Co. Ltd	Whole Power One Step 2019-Novel Coronavirus(2019-nCoV) Antigen Test	N	100,0%	20,0%	0,0%	48,0%
AT498/20	1100-5330	Convergent Technologies	Convergys® COVID-19 Rapid Antigen Test	N	100,0%	35,0%	10,0%	56,0%
AT267/20	n.a.	Core Technology Co., Ltd.	Canea COVID-19 Antigen Schnelltest	N	88,2%	26,1%	0,0%	42,0%
AT390/21	R0182C	CTK Biotech, Inc.	OnSite COVID-19 Ag Rapid Test	N	100,0%	50,0%	0,0%	60,0%
AT085/21	CV19IC	DNA Diagnostic A/S.	Covid-19 Antigen Detection Kit	N	100,0%	39,1%	10,0%	54,0%
AT1173/21	3715270	Dräger Safety AG & Co. KGaA	Dräger Antigen Test SARS-CoV-2	N	95,0%	10,0%	0,0%	42,0%
AT342/21	DNK-1425-1	Dynamiker Biotechnology (Tianjin) Co., Ltd.	Dynamiker SARS-CoV-2 AG Rapid Test	N	100,0%	100,0%	60,0%	92,0%
AT032/20	EGCV0101B	Edinburgh Genetics Limited	Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit	N	100,0%	34,8%	0,0%	50,0%
AT491/20	EBS 1020	Eurobio Scientific	EBS SARS-CoV-2 Ag Rapid Test	N	94,1%	34,8%	0,0%	48,0%
AT767/21	PCSYHN02	Fosun Diagnostics (Shanghai) Co., Ltd (ehemals Shanghai Fosun Long March Medical Science Co., Ltd.)	Fosun Covid-19 Ag Card	N	100,0%	20,0%	0,0%	48,0%
AT587/21	16696722	FUJIFILM Corporation	FUJIFILM COVID-19 Ag Test	N	85,0%	10,0%	0,0%	38,0%
AT029/20	231906	Fujirebio Inc. (Mast Diagnostica GmbH)	ESPLINE® SARS-CoV-2	N	100,0%	21,7%	0,0%	46,0%

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					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT019/20	COVAG025	GenBody Inc.	GenBody COVID-19 Ag	N	94,4%	26,1%	0,0%	46,0%
AT1100/21	CoVSLFA-20	Genobio Pharmaceutical Co., Ltd.	Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Saliva/Swab)	N	100,0%	95,0%	40,0%	86,0%
AT111/20	52026075	Genrui Biotech Inc.	Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	N	94,1%	56,5%	0,0%	58,0%
AT161/20	P2004	GenSure Biotech Inc.	DIA-COVID® COVID-19 Ag Rapid Test Kit	N	94,1%	13,0%	0,0%	38,0%
AT166/20	CG2061	Getein Biotech, Inc.	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	N	100,0%	82,6%	0,0%	72,0%
AT755/21	600008	Glallergen CO., LTD.	Novel Corona Virus (2019-nCoV) Ag Rapid Test Kit	N	100,0%	100,0%	60,0%	92,0%
AT533/21	CG123005	Goldsite Diagnostics Inc.	Goldsite COVID-19 SARS-CoV-2 Antigen Kit (Colloidal Gold)	N	100,0%	35,0%	0,0%	54,0%
AT018/20	n.a.	Green Cross Medical Science Corp. (Weko Pharma GmbH)	Genedia W Covid-19 Ag	N	83,3%	8,7%	0,0%	34,0%
AT542/20	n.a.	Guangdong Hecin Scientific,Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	N	82,4%	13,0%	0,0%	34,0%
AT731/21	LS-C-T-009	Guangdong Longsee Biomedical Co.,Inc.	Longsee 2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	N	100,0%	100,0%	100,0%	100,0%
AT086/20	BE0040	Guangdong Wesail Biotech Co., Ltd.	COVID-19 Ag Test Kit	N	100,0%	52,2%	11,1%	62,0%
AT582/21	n.a.	Guangzhou Tebsun Bio-Tech Development Co., Ltd.	Tebsun 2019-nCoV Antigen Test Kit	N	95,0%	65,0%	0,0%	64,0%
AT125/20	W196	Guangzhou Wondfo Biotech Co. Ltd	Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	N	88,2%	0,0%	0,0%	30,0%
AT276/21	ICOV-802	Hangzhou AllTest Biotech Co., Ltd.	Covid-19 Antigen Rapid Test (Oral fluid)	N	100,0%	55,0%	0,0%	62,0%
AT766/21	INCP-502-N	Hangzhou AllTest Biotech Co.,Ltd.	AllTest SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	N	90,0%	20,0%	0,0%	44,0%
AT568/21	302281	Hangzhou Biotest Biotech Co., Ltd	Sienna COVID-19 Antigen-Schnelltestkassette (Nasenabstrich)	N	100,0%	95,0%	60,0%	90,0%
AT825/21	n.a.	Hangzhou Careomedic Tech Co., Ltd.	SARS-CoV-2-Antigen-Schnelltest	N	75,0%	0,0%	0,0%	30,0%
AT079/20	2020110090	Hangzhou Clongene Biotech Co., Ltd.	Clungene COVID-19 Antigen Rapid Test	N	94,4%	34,8%	0,0%	50,0%
AT816/21	n.a.	Hangzhou DIAN Biotechnology Co., Ltd.	GENEDIAN COVID-19 Antigen Test Cassette	N	90,0%	5,0%	0,0%	38,0%
AT415/21	n.a.	Hangzhou Funworld Biotech. Co., Ltd	SARS-CoV-2-Antigen-Schnelltestgerät	N	100,0%	75,0%	0,0%	70,0%
AT818/21	P211128	Hangzhou Genesis Biodetection & Biocontrol Co., Ltd.	KaiBiLi COVID-19 Antigen Pro	N	100,0%	90,0%	0,0%	76,0%
AT228/20	YMC050G	Hangzhou Immuno Biotech Co.,Ltd.	IMMUNOBIO SARS-CoV-2 Antigen-Schnelltest (COVID-19 Ag)	N	88,2%	13,0%	0,0%	36,0%

					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT961/21	n.a.	Hangzhou Jucheng Medical Products Co., Ltd	SARS-CoV-2 Ag Schnelltestkit	N	100,0%	100,0%	80,0%	96,0%
AT011/20	n.a.	Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)	Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	N	94,4%	17,4%	0,0%	42,0%
AT060/20	COV-201	Hangzhou Lysun Biotechnology Co., Ltd.	Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)	N	100,0%	78,3%	0,0%	70,0%
AT628/21	COVG-602	Hangzhou Sejoy Electronics & Instruments Co.,Ltd.	SARS-CoV-2 Antigen Schnelltestkassette	N	100,0%	50,0%	0,0%	60,0%
AT082/20	n.a.	Hangzhou Testsea Biotechnology Co., Ltd	Testsealabs® Rapid Test Kit COVID-19 Antigen Test Cassette	N	100,0%	47,8%	0,0%	56,0%
AT821/21	IFC-SCoV2-AG	Hangzhou Zheda Dixun Biological Gene Engineering Co., Ltd.	SARS-Cov-2 Nucleocapsid(N) Antigen Rapid Test Cassette	N	100,0%	55,0%	0,0%	62,0%
AT934/21	G-C-0104	Hangzhou Zheda Dixun Biological Gene Engineering Co., Ltd.	Bisdeal SARS-CoV-2 Antigen-Schnelltest	N	100,0%	25,0%	0,0%	50,0%
AT001/20	GCCOV-502a-H5	Healgen Scientific Limited Liability Company (Siemens Healthineers)	CLINITEST® Rapid COVID-19 Antigen Test	N	100,0%	87,0%	0,0%	76,0%
AT563/21	HYT-G01	Hoyotek Biomedical Co., Ltd.	Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)	N	90,0%	10,0%	0,0%	40,0%
AT1076/21	n.a.	Hubei Jinjian Biology Co.,Ltd.	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)	N	100,0%	65,0%	0,0%	66,0%
AT083/20	ACOVA-7025	Humasis Co., Ltd.	Humasis COVID-19 Ag Test	N+S	88,2%	21,7%	0,0%	40,0%
AT637/21	BT1389	Innova Medical Group,Inc.	INNOVA SARS-CoV-2 Selbsttest (Qualitativer-Antigen-Schnelltest)	N	100,0%	100,0%	80,0%	96,0%
AT1073/21	n.a.	Innovation Biotech (Beijing) Co. LTD	INVBIO One Step Diagnostic Rapid Test Cassette	N	100,0%	100,0%	70,0%	94,0%
AT247/21	n.a.	Innovation Biotech (Beijing) Co.,Ltd	INVBIO Antigen Rapid Test Device (Saliva)	N	95,0%	25,0%	0,0%	48,0%
AT199/21	n.a.	Innovita (Tangshan) Biological Technology Co.; LTD.	2019-nCoV Ag Test (Latex Chromatography Assay)	N	85,0%	5,0%	0,0%	36,0%
AT981/21 (AT574/21)	ITP16010-TC25	InTec Products, Inc.	Rapid SARS-CoV-2 Antigen Test Colloidal Gold (Nasopharyngeal/Nasal specimen)	N	100,0%	95,0%	30,0%	84,0%
AT849/21	n.a.	Jiangsu Bioperfectus Technologies Co., Ltd.	Novel Coronavirus (SARS-CoV-2) Ag Rapid Test Kit	N	100,0%	75,0%	0,0%	70,0%
AT418/20	n.a.	Jiangsu Diagnostics Biotechnology Co., Ltd	COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)	N	100,0%	78,3%	0,0%	68,0%
AT231/20	n.a.	Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd	Konsung COVID-19 Antigen Rapid Test Kit	N	100,0%	70,0%	30,0%	74,0%
AT244/20	1031-02	Jiangsu Medomics Medical Technology Co., Ltd	SARS-CoV-2-Antigen-Testkit (LFIA)	N	94,1%	21,7%	0,0%	42,0%
AT1082/21	R220T001B0C0	Jiangsu Mole Bioscience Co., Ltd	SARS-CoV-2 Antigen Test Cassette	N	100,0%	65,0%	0,0%	66,0%
AT883/21	CO-05	Jiangsu Well Biotech Co., Ltd.	COVID-19 Schnelltestgerät	N	100,0%	95,0%	40,0%	86,0%

					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT770/21	n.a.	Jiangxi Province JinHuan Medical Instrument Co.,LTD.	COVID-19 antigen Schnelltest (Kolloidales Gold) / Novel Coronavirus(SARS-CoV-2) Antigen Rapid Detection Kit	N	100,0%	95,0%	60,0%	90,0%
AT882/21	n.a.	Jiaxing Wisetest Bio-Tech Co., Ltd.	Saliva SARS-CoV-2 (2019-nCoV) Antigen Test Kit (Nanocarbon Assay)	N	85,0%	15,0%	10,0%	42,0%
AT559/21	n.a.	Jinan Babio Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method)	N	100,0%	35,0%	0,0%	54,0%
AT236/20	n.a.	Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb)	COVID-19 Antigen Schnelltest (Colloidal Gold)	N	100,0%	60,9%	0,0%	64,0%
AT527/20	COV-AG-20 / G10313	JOYSBIO (Tianjin) Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) SPUCKTEST	N	100,0%	90,0%	0,0%	76,0%
AT692/21	G10322	JOYSBIO (Tianjin) Biotechnology Co.,Ltd.	Joysbio SARS-CoV-2 Antigen rapid test kit -PRO (Colloidal Gold)	N	100,0%	35,0%	0,0%	54,0%
AT127/20	B63000	Labnovation Technologies, Inc.	Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	N	94,1%	17,4%	0,0%	40,0%
AT1054/21	n.a.	Lifecosm Biotech Limited	COVID-19 Rapid Test Cassette Antigen Test Kit	N	100,0%	100,0%	100,0%	100,0%
AT455/20	PR210101	Lumigenex (Suzhou) Co., Ltd.	PocRoc SARS-CoV-2, Antigen Schnelltest Set (Kolloidales Gold)	N	100,0%	65,2%	0,0%	64,0%
AT151/20	71110	LumiQuick Diagnostics, Inc.	Quick Profile Covid-19 Antigen Test Card	N	100,0%	91,3%	20,0%	80,0%
AT075/20	SPEC-32312 R2 ART-00571 R4	LumiraDX	LumiraDx SARS-CoV-2 Ag Test	N	100,0%	52,2%	0,0%	60,0%
AT012/20	76748	MEDsan GmbH	MEDsan® SARS-CoV-2 Antigen Rapid Test	N	100,0%	47,8%	0,0%	58,0%
AT214/20	CP01810011	Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	N	100,0%	82,6%	0,0%	72,0%
AT790/21	CP02150011	Merlin Biomedical (Xiamen) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Cassette	N	100,0%	55,0%	0,0%	62,0%
AT047/20	0230005SP	Mölab GmbH	mö-screen Corona Antigen Test	N	100,0%	47,8%	0,0%	58,0%
AT198/20	07AG6020B	MP Biomedicals Germany GmbH	Rapid SARS-CoV-2 Antigen Test Card	N	100,0%	43,5%	0,0%	54,0%
AT823/21	0000000168	MSP bodmann GmbH	MSP SARS-CoV-2 Antigen-Schnelltest	N	100,0%	20,0%	0,0%	48,0%
AT021/20	243103N-20	nal von minden gmbh	NADAL® COVID-19 Ag Schnelltest	N	83,3%	13,0%	0,0%	36,0%
AT593/21	500200	Nanjing Liming Bio-Products Co., Ltd.	StrongStep® SARS-COV2 Antigen Rapid Test	N	95,0%	80,0%	0,0%	70,0%
AT462/20	n.a.	Nanjing Norman Biological Technology Co., Ltd	Novel Coronavirus (2019-nCOV) Antigen Testing Kit (Colloidal Gold)	N	94,1%	26,1%	0,0%	44,0%
AT678/21	RQ005	Nanjing Synthgene Medical Technology Co., Ltd.	Synthgene Neues Coronavirus (SARS-CoV-2) Antigen-Schnellerkennungskit (Collate Gold-Methode)	N	100,0%	35,0%	0,0%	54,0%
AT255/20	C8602C	Nanjing Vazyme Medical Technology Co., Ltd.	Vazyme SARS-CoV-2 Antigen Detection Kit (Colloidal Gold-Based)	N+S	85,0%	5,0%	0,0%	36,0%

					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT090/20	FRC0G 020P	NanoEntek Inc	FREND™ COVID-19 Ag	N	88,2%	8,7%	0,0%	34,0%
AT517/20	17252668	Nantong Diagnos Biotechnology Co., Ltd.	COVID-19 Antigen Saliva Test Kit (Colloidal Gold)	N	100,0%	56,5%	0,0%	60,0%
AT425/21	n.a.	Nantong Egens Biotechnology	SARS-CoV-2 Antigen Rapid Test	N	100,0%	100,0%	50,0%	90,0%
AT722/21	SVRAG	Neo-nostics (Suzhou) Bioengeneering Co., Ltd.	COVID 19 Antigen Test Kit (Colloidal Gold Method)	N	100,0%	75,0%	10,0%	72,0%
AT331/21	COVID-19-NG08	New Gene (Hangzhou) Bioengineering Co., Ltd.	Covid-19-Antigen-Testkit	N	100,0%	87,0%	20,0%	78,0%
AT989/21	NBMLRS-XG-S2	Ningbo Beautiful Life Medical Biotechnology	Saliva SARS-CoV-2(2019-nCoV) Antigen Test Kit (Nanocarbon Assay)	N	100,0%	35,0%	0,0%	54,0%
AT036/21	MY28	Novatech Tibbi Cihaz Ürünleri San. Ve Tic.A.S.	novacheck®-Ag SARS-CoV-2 Covid-19 Antigen Rapid Test	N	94,1%	21,7%	0,0%	42,0%
AT117/20	CAT-01	Oncosem Onkolojik Sistemler San. Ve Tic.A.S.	CAT Antigen Covid Rapid Test	N	94,1%	30,4%	0,0%	46,0%
AT362/20	COV04S	PCL, Inc.	PCL COVID19 Ag Gold Saliva	N	100,0%	52,2%	0,0%	58,0%
AT209/20	n.a.	PerGrande BioTech Development Co., Ltd.	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)	N+S	100,0%	17,4%	0,0%	42,0%
AT078/20	PR-FC13	Precision Biosensor Inc. (Axon Lab AG)	Exdia COVID-19-Ag-Test	N	100,0%	60,9%	0,0%	64,0%
AT376/20	V1330	ProGnosis Biotech	Rapid Test Ag 2019-nCoV	N	94,1%	65,2%	10,0%	64,0%
AT863/21	n.a.	Pro-med (Beijing) Technology Co.,Ltd.	Pro-med COVID-19 Antigen Rapid Detection Kit	N	80,0%	5,0%	0,0%	34,0%
AT935/21	n.a.	Qingdao AIBO Diagnostic CO., Ltd.	Novel Coronavirus (COVID-19) Antigen Rapid Test Kit	N	100,0%	20,0%	0,0%	48,0%
AT320/20	H100G	Qingdao Hightop Biotech Co., Ltd.	Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	N	100,0%	43,5%	0,0%	54,0%
AT008/20	N6803	R-Biopharm AG	RIDA®QUICK SARS-CoV-2 Antigen	N	100,0%	17,4%	0,0%	44,0%
AT199/20	COV Ag-6012	Safecare Biotech Hangzhou Co., Ltd.	Safecare COVID-19 Ag Rapid Test Kit (Swab)	N	100,0%	60,9%	0,0%	62,0%
AT106/20	COV-06-S	Salofa OY	salocor SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal swab)	N	82,4%	13,0%	0,0%	34,0%
AT506/21	S3109E	Sansure Biotech Inc.	SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)	N	100,0%	25,0%	0,0%	50,0%
AT069/20	34	ScheBo Biotech AG	ScheBo SARS-CoV-2 Quick Antigen	N	100,0%	91,3%	10,0%	78,0%
AT023/20 (AT004/20)	Q-NCOV-01G (9901-NCOV-01G)	SD Biosensor, Inc. (Roche Diagnostics GmbH)	STANDARD Q COVID-19 Ag Test (SARS-CoV-2 Rapid Antigen Test)	N	88,9%	30,4%	0,0%	46,0%
AT022/20	F-NCOV-01G	SD Biosensor, Inc.	STANDARD F COVID-19 Ag FIA	N	100,0%	65,2%	0,0%	66,0%

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					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT1064/21	2.13.1.587	Senova Gesellschaft für Biowissenschaft und Technik mbH	GreenLight SARS-CoV-2 Antigen-Test	N	95,0%	10,0%	0,0%	42,0%
AT918/21	SCVC02	SGA Mühendislik DAN. EG. Icve DIS.Ltd.STI	V-Chek SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)	N	94,1%	26,1%	0,0%	44,0%
AT748/21	n.a.	Shanghai Liangrun Biomedicine Technology Co., Ltd.	LionRun™ SARS-CoV-2 Antigen Rapid Test Kit (Lateral Flow Immunoassay)	N	100,0%	85,0%	0,0%	74,0%
AT857/21	n.a.	Shen Zhen Zi Jian Biotechnology Co., Ltd.	Zijian SARS-CoV-2 (COVID-19) Antigen Rapid Detection Kit (Lateral Flow Method)	N	80,0%	10,0%	0,0%	36,0%
AT928/21	CG201A	Shenzhen CAS-Envision Medical Technology Co., Ltd.	SARS-Cov-2 Antigen Rapid Detection Kit	N	100,0%	100,0%	70,0%	94,0%
AT260/21	n.a.	Shenzhen Dymind Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	N	100,0%	30,0%	0,0%	52,0%
AT829/21	n.a.	Shenzhen Dymind Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	N	100,0%	30,0%	0,0%	52,0%
AT458/21	HRK-6820	Shenzhen Huaree Technology Co., Ltd.	SARS-CoV-2 Antigen Saliva Rapid Test Kit	N	100,0%	90,0%	10,0%	78,0%
AT424/21	HRK-6620	Shenzhen Huaree Technology Co.,Ltd.	SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	N	100,0%	45,0%	0,0%	58,0%
AT472/21	203-020	Shenzhen Huian Biosci Technology Co., Ltd.	SARS-CoV-2Antigen Test Kit (Colloidal Gold)	N	100,0%	60,0%	0,0%	64,0%
AT1065/21	808151-1	Shenzhen Kang Sheng Bao Bio- Technology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test (Lateral Flow Assay)	N	95,0%	10,0%	0,0%	42,0%
AT1019/21	150129	Shenzhen Kingfocus Biomedical Engineering Co., Ltd.	COVID-19 Antigen Detection Kit (Quantum Dots-Based Immunofluorescence Chromatography)	N	100,0%	95,0%	60,0%	90,0%
AT420/21	K602-20	Shenzhen Kisshealth Biotechnology Co., Ltd.	KISSH SARS-CoV-2 Antigen Test Kit (GICA)	N	100,0%	85,0%	10,0%	76,0%
AT417/20	n.a.	Shenzhen Lvshiyuan Biotechnology Co., Ltd.	Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	N	100,0%	95,7%	40,0%	86,0%
AT070/20	MF-60	Shenzhen Microprofit Biotech Co., Ltd.	fluorecare COVID-19 SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	S	100,0%	47,8%	10,0%	58,0%
AT071/20	MF-63	Shenzhen Microprofit Biotech Co., Ltd.	SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)	S	100,0%	85,0%	10,0%	76,0%
AT544/21	MF-68	Shenzhen Microprofit Biotech Co., Ltd.	fluorecare SARS-CoV-2 Antigen Test Kit	N	90,0%	15,0%	0,0%	42,0%
AT844/21	RNS92048B	Shenzhen Reagent Technology Co., Ltd.	SARS-CoV-2 Antigen IVD kit SWAB	N+S	100,0%	50,0%	0,0%	60,0%
AT108/20	LFA0401-25N	Shenzhen Watmind Medical Co., Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)	N	100,0%	95,7%	20,0%	82,0%
AT385/20	LFB0401-25N	Shenzhen Watmind Medical Co., Ltd.	SARS-CoV-2 Ag Diagnostic Test Kit (Immunofluorescence)	N	100,0%	60,9%	0,0%	62,0%
AT409/21	G86247	Shenzhen YHLO Biotech Co., Ltd.	GLINE-2019-nCoV Ag	N	90,0%	30,0%	0,0%	48,0%
AT211/20	n.a.	Shenzhen Zhenrui Biotech Co., Ltd.	Zhenrui COVID-19 (SARS-COV-2) Antigen Test Kits	N	82,4%	13,0%	0,0%	34,0%

					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT941/21	T3701W, T3702W, T3706W	Sichuan Xincheng Biological Co., Ltd.	SARS-CoV-2 Antigen Assay Kit by Latex Immunochromatography method	N	100,0%	95,0%	40,0%	86,0%
AT010/20	CAGT025E0	Sugentech, Inc.	SGTi-flex COVID-19 Ag	N	100,0%	73,9%	0,0%	68,0%
AT789/21	COVID19AGVCG	SureScreen Diagnostics Ltd.	COVID-19 Antigen Rapid Test Cassette (Nasal Swab)	N	100,0%	20,0%	0,0%	48,0%
AT765/21	n.a.	Surge Medical Inc.	COVID-19 Antigen Test Kit	N	100,0%	40,0%	0,0%	56,0%
AT830/21	n.a.	Suzhou Soochow University Saier Immuno Biotech Co., Ltd.	InstantSure Covid-19 Ag CARD	N	100,0%	100,0%	80,0%	96,0%
AT848/21	04A024	TBG Biotechnology Xiamen Inc.	TBG SARS-CoV-2 Antigen Rapid Test	N	95,0%	80,0%	10,0%	72,0%
AT379/20	2276-20	Toda Pharma	Toda Coronadiag Ag	N	100,0%	95,7%	40,0%	86,0%
AT044/21	C011906	Triplex International Biosciences (China) Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	N	100,0%	87,0%	20,0%	78,0%
AT492/20	RTCV03	Türklab Tibbi Malzemeleri San. Ve Tic. A.S	Rapidan Tester COVID-19 Ag Test	N	90,0%	10,0%	0,0%	40,0%
AT075/21	012G521	ulti med Products (Deutschland) GmbH	COVID-19 Antigen Speicheltest (Immunochromatographie)	N	100,0%	95,7%	20,0%	82,0%
AT507/20	VSCD02	Vitrosens Biyoteknoloji Ltd. Sti	RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold	N	100,0%	30,4%	0,0%	48,0%
AT711/21	n.a.	Weihai Kangzhou Biotechnology Engineering Co., Ltd.	Kanzone COVID-19 Antigen Rapid Test	N	90,0%	5,0%	0,0%	38,0%
AT430/20	W-Ag03-20	Wuhan EasyDiagnosis Biomedicine Co., Ltd.	COVID-19 (SARS-CoV-2) Antigen Test Kit	N	100,0%	73,9%	0,0%	68,0%
AT997/21	FP-318	Wuhan HealthCare Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	N	90,0%	0,0%	0,0%	36,0%
AT172/20	SF24025	Wuhan Life Origin Biotech Joint Stock Co., Ltd.	SARS-CoV-2 Antigen Assay Kit (Immunochromatography)	n.a.	100,0%	56,5%	0,0%	60,0%
AT429/20	CoV2Ag-25	Wuhan UNscience Biotechnology Co., Ltd.	SARS-CoV-2 Antigen Rapid Test Kit	N	88,2%	17,4%	0,0%	38,0%
AT847/21	COV-S31	Wuxi Biohermes Bio & Medical Technology Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Lateral Flow Assay)	N	100,0%	60,0%	0,0%	64,0%
AT246/21	CG01Ag-25	Xiamen AmonMed Biotechnology Co., Ltd.	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	N	100,0%	87,0%	30,0%	80,0%
AT116/20	07AG6020B	Xiamen Boson Biotech Co., Ltd.	SARS-CoV-2 Antigen Schnelltest	N	100,0%	43,5%	0,0%	54,0%
AT109/20	51232012	Xiamen WIZ Biotech Co., Ltd.	Wizbiotech SARS-CoV-2 Antigen Rapid Test	N	88,2%	13,0%	0,0%	36,0%
AT311/21	n.a.	ZandCell AB	ZandCell COVID-19 Saliva Antigen-Test	N	90,0%	5,0%	0,0%	38,0%
AT167/20	n.a.	Zet Medikal Tekstil Dis Ticaret Ltd. STI.	softec SARS COV-2 (Covid-19) Antigen Test Kit	N	82,4%	21,7%	10,0%	40,0%

					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT102/20	COVG10S	Zhejiang Anji Saianfu Biotech Co.,Ltd.	reOpenTest COVID-19 Antigen Rapid Test (Colloidal Gold)	N	94,1%	30,4%	0,0%	46,0%
AT516/21	n.a.	Zhejiang Gene Science Co., Ltd.	Novel Coronavirus (COVID-19) Antigen Detection Kit (Latex Immunochromatography)	N	100,0%	70,0%	40,0%	76,0%
AT039/20	GCCOV-502a	Zhejiang Orient Gene Biotech Co.,Ltd	Coronavirus Ag Rapid Test Cassette (Swab)	N	100,0%	87,0%	0,0%	76,0%
AT839/21	n.a.	Zhongxiu Science and Technology Co., Ltd	Neuartiges Coronavirus (2019-nCoV) Antigendetektions-reagenz (immunochromatographischer Assay)	N	100,0%	70,0%	10,0%	70,0%
AT583/21	RDC-802	Zhuhai Encode Medical Engineering Co., Ltd.	ENCODE SARS-COV-2 Antigen Rapid Test Device	N	95,0%	15,0%	0,0%	44,0%
AT542/21	n.a.	Zhuhai Lituo Biotechnology Co., Ltd.	COVID-19 Antigen Detection Kit (Colloidal Gold)	N	100,0%	80,0%	0,0%	72,0%

Abkürzungen und Zeichenerklärung / Abbreviations and explanation of symbols:
Cq = Quantifizierungszyklus / quantitative cycle
n.a. = nicht verfügbar / not available
* Ref-Nr. oder Katalog-Nummer wie bei Einreichung zur Evaluierung / Ref. No. or catalog number as submitted for evaluation

Tabelle 2: Ergebnisse der SARS-CoV-2 Antigenschnelltests, die das Sensitivitätskriterium nicht erfüllen

Hinweis: alle hier gelisteten Tests wurden von der BfArM Liste gestrichen, diese Produkte sind auf dem Markt ggf. auch nicht mehr erhältlich

Table 2: SARS-CoV-2 antigen rapid diagnostic tests missing the sensitivity criteria

Note: all tests listed here have been removed from the BfArM list, these products may no longer be available on the market

					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT506/20	ABCAR-020	Absology Co.,Ltd.	INIST COVID-19 Ag Rapid	N	0,0%	0,0%	0,0%	0,0%
AT054/20	INCP-ACO502	Acro Biotech, Inc.	Acro COVID-19 Antigen Rapid Test	n.a.	16,7%	0,0%	0,0%	6,0%
AT469/20	AKBR4019020	Aikang Diagnostics Co., Ltd.	SARS-CoV-2 Antigen Test Kit (Immunochromatography)	N	11,8%	0,0%	0,0%	4,0%
AT163/20	MPV: M30020-01 / -02	Beijing Savant Biotechnology Co., Ltd.	New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunchromatography)	N	0,0%	0,0%	0,0%	0,0%
AT586/21	RAPG-CVA-019	Biopanda Reagents	COVID-19 Antigen-Schnelltest	N	60,0%	0,0%	0,0%	24,0%
AT051/20	SC820001PC	CertestT Biotec S. L.	CerTest Biotec SARS-CoV-2 Ag Test	N	29,4%	0,0%	0,0%	10,0%
AT543/21	n.a.	Changsha Sanji Bio-technology Co., Ltd	SARS-CoV-2 Antigen Rapid Test (Laterial Flow Method)	N	20,0%	0,0%	0,0%	8,0%
AT048/20	C-1023	Coris BioConcept	COVID-19 Ag Respi-Strip	N	33,3%	0,0%	0,0%	12,0%
AT715/21	DCOV-201	Dejavu Medikal San. Ve Tic. Ltd. Sti.	COVID-19 Antigen Schnelltest	N	70,0%	0,0%	0,0%	28,0%
AT573/21	S03#	Diasia Biomedical Technology Co., Ltd.	DIASIA SARS-CoV-2 Antigen Rapid Test Kit	N	55,0%	0,0%	0,0%	22,0%
AT712/21	n.a.	Essa Commerce Bilisim ve Ithalat Ihracat Tic.A.S.	Bioessa SARS-CoV-2 Antigen Schnelltest	N	0,0%	0,0%	0,0%	0,0%
AT899/21	FRTFT02	FAGO MEDIKAL San. Tic. Ltd	FAMEX® SARS-CoV-2 Ag Rapid Nasopharyngeal Test Kit	N	20,0%	0,0%	0,0%	8,0%
AT819/21	BQ-03012	Foregene Co.,Ltd.	FOREGENE SARS-CoV-2 Antigen Test Kit	N	30,0%	0,0%	0,0%	12,0%
AT201/20	ICOV-502	Hangzhou AllTest Biotech Co. Ltd.	COVID-19 Antigen Rapid Test (Nasopharyngeal swab)	n.a.	16,7%	0,0%	0,0%	6,0%
AT972/21	BSK01S1S	Hangzhou Bioer Technology Co., Ltd.	BIOflux SARS-CoV-2 Antigen Test Kit (colloidal gold method)	N	60,0%	0,0%	0,0%	24,0%
AT041/20	INCP-C81-20	Hangzhou Biotest Biotech Co., Ltd.	Lumiratek SARS-CoV-2 Antigen Rapid Test Cassette	N	29,4%	0,0%	0,0%	10,0%
AT662/21	n.a.	Hangzhou Fanttest Biotech Co.,Ltd.	Fanttest Novel Coronavirus(SARS-CoV-2) Antigen Rapid Test Cassette	N	0,0%	0,0%	0,0%	0,0%
AT015/20	K511416D	Hangzhou Realy Tech Co., Ltd.	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	n.a.	58,8%	0,0%	0,0%	20,0%

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					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT088/21	K590516D	Hangzhou Realy Tech Co., Ltd.	Heinzer Antigen Covid19 Spucktest Schnelltest [Original Name: Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Device (saliva)]	N+S	65,0%	5,0%	0,0%	28,0%
AT437/21	n.a.	Hangzhou Singclean Medical Products Co., Ltd.	COVID-19 Test Kit (Colloidal Gold Method)	N	0,0%	0,0%	0,0%	0,0%
AT160/20	P211134	Hangzhou Genesis Biocontrol Co., Ltd	KaiBiLi COVID-19 Antigen Rapid Test Device	N	52,9%	0,0%	0,0%	18,0%
AT139/20	BCOV-502	Inzek International Trading B.V	BIOZEK COVID-19-Antigen-Schnelltestkassette	n.a.	52,9%	0,0%	0,0%	18,0%
AT178/20	n.a.	Joinstar Biomedical Technology Co., Ltd	COVID-19 Antigen Rapid Test (Latex)	S	0,0%	0,0%	0,0%	0,0%
AT046/20	G10313	Joysbio (Tianjin) Biotechnology Co., Ltd.	Joysbio SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	N	47,1%	4,3%	0,0%	18,0%
AT487/21	NCV11	Koch Biotechnology (Beijing) Co., Ltd.	COVID-19 Antigen Rapid Test Kit	N	60,0%	0,0%	0,0%	24,0%
AT684/21	n.a.	LiClear Biotech (Hangzhou) Co., Ltd.	SARS-COV-2 Nucleocapsid (N) Antigen Rapid Test (VIDA TEST Rapid Diagnostic Test)	N	0,0%	0,0%	0,0%	0,0%
AT400/20	I00053	Lionex GmbH	Lionex COVID-19 Ag Rapid Test	S	0,0%	0,0%	0,0%	0,0%
AT171/20	MICOG-502 (B2503)	Medicon Co., Ltd.	Trueline COVID-19 Ag Rapid Test	N+S	58,8%	4,3%	0,0%	22,0%
AT007/20	3011030	Mexacare GmbH Heidelberg	QuickTestCorona COVID-19 Antigen Schnelltest	N	52,9%	4,3%	0,0%	20,0%
AT470/20	243104D-20	nal von minden GmbH	dedicio Medical Test COVID-19 Ag plus Test	N	35,3%	0,0%	0,0%	12,0%
AT013/20	n.a.	RapiGEN, Inc.	Biocredit COVID-19 Ag	n.a.	16,7%	0,0%	0,0%	6,0%
AT302/21	RCCOVAG	Redcell Bioteknoloji Anim Sirketi	COVID-19 Antigen Test	N	0,0%	0,0%	0,0%	0,0%
AT036/20	C34800-100	Servoprax GmbH	Cleartest Corona-Antigen	n.a.	66,7%	0,0%	0,0%	24,0%
AT242/21	SG0010A	SG Diagnostics Pte Ltd	SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based)	N	50,0%	0,0%	0,0%	20,0%
AT932/21	n.a.	ShanDong ThinkLabor Biotechnology Co.,Ltd.	Coronavirus Ag Schnelltest Kassette (Tupfer)	N	0,0%	0,0%	0,0%	0,0%
AT777/21	n.a.	Shenzhen Landwind Biotechnology Co., Ltd.	Landwind SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	N	55,0%	0,0%	0,0%	22,0%
AT225/20	SP-SW 106	Spring Healthcare Services Sp zoo	SARS-Cov-2 Antigen Rapid Test Cassette (swab)	N+S	29,4%	0,0%	0,0%	10,0%
AT186/20	COVID19AGVC	SureScreen Diagnostics Ltd.	COVID-19 Antigen Rapid Test Cassette	N	52,9%	0,0%	0,0%	18,0%

					Sensitivität / Sensitivity			
AT-Nr. / AT-No.	**Ref-Nr./ ID-No. ***	**Hersteller / Manufacturer**	**Testname / Test name**	**Zielantigen / target antigen**	**Cq ≤25**	**Cq 25-30**	**Cq ≥30**	**Gesamt-Sensitvität / total sensitivity**
AT128/20	n.a.	TaiDoc Technology Corporation	FORA COVID-19 ANTIGEN RAPID TEST	N	27,8%	0,0%	0,0%	10,0%
AT002/20	B25SY0E1L	Unioninvest	Unibioscience COVID-19 Rapid Antigen Test	N	0,0%	0,0%	0,0%	0,0%
AT315/21	VS200602	Vision Biyoteknologi Arastirma Gelistirme Labt. Sist. San ve Tic LTD STI	VISION® SARS-CoV-2 Saliva Antigen Rapid Test Kit	N	45,0%	10,0%	0,0%	22,0%
AT062/20	VCD05-01-011	VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag SARS-CoV-2 Ag Rapid Test	N	50,0%	0,0%	0,0%	18,0%
AT294/20	VCD16-01-011	VivaChek Biotech (Hangzhou) Co., Ltd.	VivaDiag Pro SARS-CoV-2 Ag Rapid Test	N	64,7%	0,0%	0,0%	22,0%
AT218/20	FSSA-CK20	W.H.P.M, Inc.	First Sign SARS-CoV-2 Antigen Test	N	47,1%	0,0%	0,0%	16,0%
AT001/21	n.a.	Xiamen Jiqing Biomedical Technology Co., Ltd.	Gruenbanka SARS-CoV-2 Antigen detection Kit (colloidal gold method)	N	25,0%	0,0%	0,0%	10,0%
AT012/21	n.a.	Xiamen Zhongsheng Langjie Biotechnology Co., Ltd	Covid-19 Antigen Test Cassette	N	11,8%	0,0%	0,0%	4,0%

Abkürzungen und Zeichenerklärung / Abbreviations and explanation of symbols:
Cq = Quantifizierungszyklus / quantitative cycle
n.a. = nicht verfügbar / not available
* Ref-Nr. oder Katalog-Nummer wie bei Einreichung zur Evaluierung / Ref. No. or catalog number as submitted for evaluation