Anspruch nach TestV
Vom 29.Juni.2022

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BAnz AT 29.06.2022 V1

Bundesministerium für Gesundheit

Dritte Verordnung zur Änderung der Coronavirus-Testverordnung

Vom 29. Juni 2022

Auf Grund des § 20i Absatz 3 Satz 2 Nummer 1 Buchstabe b und Nummer 2, Satz 3, 9, 12, 13 Nummer 1 bis 3, Satz 15 und 17 des Fünften Buches Sozialgesetzbuch, dessen Absatz 3 Satz 3 und 15 durch Artikel 2a Nummer 1 Buchstabe a und c des Gesetzes vom 28. Mai 2021 (BGBl. I S. 1174) geändert und dessen Absatz 3 Satz 17 durch Artikel 2a Nummer 1 Buchstabe d des Gesetzes vom 28. Mai 2021 (BGBl. I S. 1174) eingefügt worden ist, verordnet das Bundesministerium für Gesundheit nach Anhörung des Spitzenverbandes Bund der Krankenkassen, der Kassenärztlichen Bundesvereinigung und des Verbandes der Privaten Krankenversicherung:

Artikel 1

Die Coronavirus-Testverordnung vom 21. September 2021 (BAnz AT 21.09.2021 V1), die zuletzt durch Artikel 1 der Verordnung vom 29. März 2022 (BAnz AT 30.03.2022 V1) geändert worden ist, wird wie folgt geändert:

1. § 1 Absatz 1 Satz 5 und 6 wird durch den folgenden Satz ersetzt:

„Der Anspruch nach Satz 1 in Bezug auf eine Diagnostik mittels PoC-Antigen-Tests beschränkt sich auf Antigen-Tests, die in der vom Gesundheitssicherheitsausschuss der Europäischen Union beschlossenen Gemeinsamen Liste von Corona-Antigen-Schnelltests, die auf der Internetseite des Paul-Ehrlich-Instituts unter www.pei.de/sars-cov-2-ag-tests abrufbar ist, verzeichnet sind.“

2. § 4a wird wie folgt gefasst:

„§ 4a

Bürgertestung

(1) Folgende asymptomatische Personen haben Anspruch auf Testung mittels PoC-Antigen-Tests:

1. Personen, die zum Zeitpunkt der Testung das fünfte Lebensjahr noch nicht vollendet haben,
2. Personen, die aufgrund einer medizinischen Kontraindikation, insbesondere einer Schwangerschaft im ersten Schwangerschaftsdrittel, zum Zeitpunkt der Testung nicht gegen das Coronavirus SARS-CoV-2 geimpft werden können oder in den letzten drei Monaten vor der Testung aufgrund einer medizinischen Kontraindikation nicht gegen das Coronavirus SARS-CoV-2 geimpft werden konnten,
3. Personen, die zum Zeitpunkt der Testung an klinischen Studien zur Wirksamkeit von Impfstoffen gegen das Coronavirus SARS-CoV-2 teilnehmen oder in den letzten drei Monaten vor der Testung an solchen Studien teilgenommen haben,
4. Personen, die sich zum Zeitpunkt der Testung aufgrund einer nachgewiesenen Infektion mit dem Coronavirus SARS-CoV-2 in Absonderung befinden, wenn die Testung zur Beendigung der Absonderung erforderlich ist,
5. Personen nach § 4 Absatz 1 Satz 1 Nummer 3 und 4,
6. Personen, die an dem Tag, an dem die Testung erfolgt,
   a) eine Veranstaltung in einem Innenraum besuchen werden oder
   b) zu einer Person Kontakt haben werden, die
      aa) das 60. Lebensjahr vollendet hat oder
      bb) aufgrund einer Vorerkrankung oder Behinderung ein hohes Risiko aufweist, schwer an COVID-19 zu erkranken,

HSC common list
Vom 14.Oktober.2022

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

EU HEALTH PREPAREDNESS

EU Common list of COVID-19 antigen tests

Agreed by the Health Security Committee

Last update: 14 October 2022

MedRhein

2. The EU common list of COVID-19 antigen tests

2.1 Category A and Category B devices

The EU common list of COVID-19 antigen tests has been split up in two categories:

- **Category A**: Antigen tests for which their performance has been evaluated through prospective clinical field studies and that meet the criteria agreed on 21 September 2021 (see section 2.2) have been placed under the "A-category" of the EU common list. **Category A.1** sets out the eligible COVID-19 rapid antigen tests and **Category A.2** sets out the eligible COVID-19 laboratory-based antigenic assays.
- **Category B**: Antigen tests for which their performance has been evaluated through retrospective in vitro studies and that meet the criteria agreed on 21 September 2021 (see section 2.2) have been placed under the "B-category" of the EU common list. **Category B.1** sets out the eligible COVID-19 rapid antigen tests and **Category B.2** sets out the eligible COVID-19 laboratory-based antigenic assays.

EU Member States are strongly encouraged to use, in particular, antigen tests included under Category A of the EU common list for the issuance of EU Digital COVID certificates.

Secondly, EU Member States should pay particular attention to the issuance of EU Digital COVID recovery certificates based on the result of devices listed under Category B and that have solely been evaluated by the Paul-Ehrlich-Institut (PEI) in Germany, as only the sensitivity of these antigen tests has been evaluated.

Thirdly, EU Member States are strongly encouraged to ensure that only test results from the evaluated specimen type(s) as indicated for Category A devices are used for the issuance of EU Digital COVID test and recovery certificates. As regards the Category B devices, in general, retrospective in vitro studies do not aim to evaluate the clinical performance of an antigen test based on a specific specimen type. Therefore, the clinical performance of devices listed under Category B cannot be linked to a specific specimen type, which should be taken into consideration by EU Member States when using these antigen tests for the issuance of EU Digital COVID certificates.

2.2 Criteria to be met

Based on a proposal by their Technical Working Group and taking into account the criteria presented by the Council Recommendation of 21 January 2021, the following section sets out the scope, definitions and criteria that were agreed by the Health Security Committee agreed on 21 September 2021 and that should be met by devices in order to be included in the EU common list of COVID-19 antigen tests.

The Technical Working Group of the Health Security Committee monitors technical and epidemiological developments in the field of antigen testing on a continuous basis and will, if deemed necessary, reconsider the scope, definitions and criteria to be met by devices included in the EU common list. Particular attention will be paid to breakthrough infections among vaccinated individuals and the possible impact of such cases on the clinical performance of

Category B: COVID-19 antigen tests evaluated by retrospective in vitro studies

The clinical performance of the following antigen tests listed under "Category B" has been evaluated by retrospective in vitro studies, meeting the criteria and definitions as agreed by the Health Security Committee on 21 September 2021.

Important notes to be taken into account by EU Member States:

- ➔ In case of retrospective in vitro evaluation studies carried out by the Paul-Ehrlich-Institut in Germany, only the sensitivity of the device has been evaluated. The specificity as reported by the manufacturer has been indicated in the corresponding column. EU Member States should pay particular attention to the issuance of EU Digital COVID recovery certificates based on the result of these devices, as the specificity of the device has thus not been evaluated by an independent validation study meeting the agreed criteria.
- ➔ In general, retrospective in vitro studies do not aim to evaluate the clinical performance of an antigen test based on a specific specimen type. Therefore, the clinical performance of devices listed under Category B *cannot* be linked to a specific specimen type, which should be taken into consideration by countries when using these antigen tests for the issuance of EU Digital COVID certificates. Instead, the table below makes a general reference to the specimen type(s) that can be used for the device as stated in the Instructions For Use of the device.

CATEGORY B.1: COVID-19 RAPID ANTIGEN TESTS

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2374	7427245282658	**ABIOTEQ**	**Cora Gentest-19**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.8%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal, Throat	Nucleocapsid protein	20/10/2021
2579	ABT-IDT-B367	**AccuBioTech Co.,Ltd**	**Accu-Tell SARS-CoV-2 Ag Cassette**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Nasopharyngeal	Nucleocapsid protein	20/10/2021
1865	L031-12515, L031-125D5	**Acon Biotech (Hangzhou) Co., Ltd**	**Flowflex SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 99.5%.*	Nasal ! Saliva	Nucleocapsid protein	10/02/2022
1468	L031-11815	**ACON Laboratories, Inc.**	**Flowflex SARS-CoV-2 Antigen Rapid Test**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 94.1% at Ct ≤ 25; *Manufacturer specificity of 98.7%.*	Nasal	Nucleocapsid protein	10/05/2021

Device ID # [15]	REF number [16]	Name of submitting company [17]	Commercial name of the device [17]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Specimen type(s) [17]	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
2941	150129	**Shenzhen Kingfocus Biomedical Engineering Co., Ltd.**	**COVID-19 Antigen Detection Kit (Quantum Dots-Based Immunofluorescence Chromatography)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.28%.*	Nasal	Nucleocapsid protein	08/04/2022
1813	K602-20	**Shenzhen Kisshealth Biotechnology Co., Ltd**	**SARS-CoV-2 Antigen Test Kit (GICA)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.2%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	20/10/2021
2109	GF102B1	**Shenzhen Lvshiyuan Biotechnology Co., Ltd.**	**Green Spring SARS-CoV-2 Antigen-Rapid test-Set**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Anterior nasal, Nasal, Nasopharyngeal, Oropharyngeal ! Saliva	Nucleocapsid protein	10/05/2021
1967	MF-68	**Shenzhen Microprofit Biotech Co., Ltd**	**SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	07/07/2021
1178	MF-60	**Shenzhen Microprofit Biotech Co., Ltd.**	**SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasal, Nasopharyngeal, Oropharyngeal	Spike protein	23/07/2021
1228	MF-63	**Shenzhen Microprofit Biotech Co., Ltd.**	**SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasopharyngeal	Nucleocapsid protein, Spike protein (S1)	08/12/2021
2026	RNS92048B	**Shenzhen Reagent Technology Co.,Ltd.**	**SARS-CoV-2 antigen IVD kit SWAB**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 98.1%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	20/10/2021
1769	LFA0401-25N	**Shenzhen Watmind Medical Co., Ltd**	**SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.12%.*	Nasal, Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2021
1768	LFB0401-25N	**Shenzhen Watmind Medical Co., Ltd**	**SARS-CoV-2 Ag Diagnostic Test Kit (Immuno-fluorescence)**	**Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.13%.*	Nasal	Nucleocapsid protein	07/07/2021

深圳市绿诗源生物技术有限公司
Green Spring Shenzhen Lvshiyuan Biotechnology Co.,Ltd

Datum: 05. August. 2022

Herstellererklärung

Die Referenznummer ist eine vom Hersteller vergebene Identifikationsnummer zur Identifizierung des Gerätes. Referenznummern können in verschiedenen Märkten variieren. Wir, Shenzhen Lvshiyuan Biotechnology Co.,Ltd., Firmensitz an 101,201,301, D Building, No.2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen, 518120 China, als Hersteller bestätigen hiermit, dass das von HSC gelistete Produkt

Geräte ID #: 2109
Einreichender Firmenname: Shenzhen Lvshiyuan Biotechnology Co., Ltd.
Handelsname des Geräts: Green Spring SARS-CoV-2 Antigen-Rapid test-Set

hat die folgenden unterschiedlichen REF-Nummern:
GF102B1
MAT0125

Mit freundlichen Grüßen,

Fangxiu Wang
CEO
Shenzhen Lvshiyuan Biotechnology Co.,Ltd.

CE

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

Company Name: Shenzhen Lvshiyuan Biotechnology Co., Ltd.
Address: 101, 201, 301, D Building, No. 2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen 518120 China

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

List of Products:

1. SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- **ISO 9001: 2015**

Corporate Contact Information

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Position: Vice General Manager
SIGNATURE : Yongqing Jiang
Date : 2020/11/09
Stamp

European Authorized Representative:
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E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

The Statement on Detection of Mutant Viruses

Date： 31th October, 2022

Product：Green Spring® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

We, Shenzhen Lvshiyuan Biotechnology Co., Ltd., as the manufacturer, hereby declare that Green Springs SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) can detect the following SARS-CoV-2 Virus variants which is listed as 'variants of concern (VOC)'& 'variants of interest (VOI) & Variants under monitoring (VUMs)'by the World Health Organization. VOC refers to the large number and wide range of cases caused worldwide, and data confirms its transmission ability, strong toxicity, or reduced effectiveness of vaccines and clinical treatments. VOI refers to a confirmed case of community transmission, or has been found in multiple countries, but has not yet formed a large-scale infection. VUM refers to a SARS-CoV-2 variant with genetic changes that are suspected to affect virus characteristics with some indication that it may pose a future risk, but evidence of phenotypic or epidemiological impact is currently unclear, requiring enhanced monitoring and repeat assessment pending new evidence.

WHO Categories	WHO Label	Pango Lineage	Date of Designation
Variants Of Concern (VOC)	Alpha	B.1.1.7	September, 2020
	Beta	B.1.351	May 2020
	Gamma	P.1	November 2020
	Delta	B.1.617.2	October 2020
	Omicron	B.1.1.529	November 2021
Variants Of Interest (VOI)	Epsilon	B.1.427	February, 2021
		B.1.429	June 2021
	Eta	B.1.525	February 2021
	Iota	B.1.526	February 2021
	Kappa	B.1.617.1	May, 2021
	N/A	B.1.617.3	May, 2021
	Zeta	P.2	February 2021
	Mu	B.1.621, B.1.621.1	September, 2021
	IHU	B.1.640.2	September, 2021
Variants under monitoring (VUMs)		BA.1 x AY.4 recombinant	09-Mar-2022

		B.1.640	22-Nov-2021
		BA.1	Nov-2021
		BA.2	Feb-2022
		BA.2.12.1	Feb-2022
		BA.3	Feb-2022
		BA.4	Jan-2022
		BA.5	Jan-2022
		BF.7	Mar-2022
		BA.2.75	May-2022
		BQ.1.1	Aug-2022
		XBB	Sep-2022
		BQ.1	Sep-2022

The new coronavirus (SARS-CoV-2 or 2019-nCoV) is a non-segmented forward RNA virus. This is the cause of the new type of coronavirus pneumonia (COVID-19), which is highly contagious in humans. The SARS-CoV-2 virus has several structural proteins, including spikes (S), envelope (E), membrane (M) and nucleocapsid (N).

The SARS-CoV-2 virus has the characteristics of strong nucleocapsid (N) protein stability. The mutant virus strains that have been found worldwide are derived from the SARS-CoV-2 20B/GR evolutionary strain (lineage B.1.1.7), including many mutation, the mutation location is the spike (S) protein of the new coronavirus, which is the location where the SARS-CoV-2 virus uses to bind to the cell's ACE2 receptor.

The SARS-CoV-2 Antigen Rapid Test Kit produced by Shenzhen Lvshiyuan Biotechnology Co., Ltd. is used for in vitro qualitative detection of SARS-CoV-2 virus nucleocapsid (N) protein in human nasopharyngeal , oropharyngeal , anterior -nasal or saliva samples.

It can be seen that the mutation sites of mutated virus strains including BQ.1.1 strain have no effect on the detection rate of the kits produced by our company. The kit is suitable for assay of the SARS-CoV-2 variant virus as listed in the table above.

Shenzhen Lvshiyuan Biotechnology .Co., Ltd.

Chief Executive Officer Fangxiu Wang

Signature : Fangxiu Wang

medRxiv preprint doi: https://doi.org/10.1101/2021.05.11.21257016; this version posted May 12, 2021.

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 Kassette)	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. Icve 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	FRENDTM 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 (Nasopharynxtupfer)	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%