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 09.Dez.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: 9 December 2022

strongly encouraged:
rapid antigen tests included under Category A

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

ANNEX I: EU common list of COVID-19 antigen tests [17, 18]

Disclaimer: *The Technical Working Group strongly recommends that antigen tests are primarily used for preliminary testing for SARS-CoV-2 infection in symptomatic patients, and notes that antigen tests should in particular be used in the specific contexts and circumstances referred to by the Commission Recommendation (EU) 2020/1743 and the updated technical report by ECDC on 26 October 2021. The content of the EU common list is based on the clinical performance data and information that is available at this moment in time. The Technical Working Group stresses that the clinical performance data of devices included in the EU common list, resulting from independent validation studies meeting the agreed criteria, cannot be directly compared as absolute numbers.*

Category A: COVID-19 antigen tests evaluated by prospective clinical field studies

EU Member States are strongly encouraged to use, in particular, the antigen tests included under "Category A" of the EU common list for the issuance of EU Digital COVID certificates. The clinical performance of these devices – for the specimen type as indicated in the corresponding column - has been evaluated by (at least) one prospective clinical field study meeting the criteria and definitions as agreed by the Health Security Committee on 21 September 2021.

EU Member States are strongly encouraged to ensure that only test results from the evaluated specimen type(s) are used to issue EU Digital COVID certificates.

CATEGORY A.1: COVID-19 RAPID ANTIGEN TESTS

	Device ID # [19]	REF number [20, 21]	Name of submitting company [22]	Commercial name of the device [21]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [21] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
	1833	AS-COV-008, AS-COV-009	**AAZ-LMB**	**COVID-VIRO®**	**Prospective clinical field study** Study carried out in France on NP swabs. Sensitivity <7 days after onset of symptoms: 94.7%, specificity: 100%.	**Nasopharyngeal**	Nasal	Nucleocapsid protein	10/05/2021

[17] This is the list of COVID-19 antigen tests as referred to in Article 3 of the Regulation (EU) 2022/1034 of the European Parliament and of the Council of 29 June 2022, amending Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, OJ L 173, 30.6.2022, p. 37–45.

[18] The Medical Device Coordination Group Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices, which will form the basis for common specifications to be adopted according to Article 9 of Regulation (EU) 2017/746, has been considered by the Technical Working Group for the development of the EU common list of COVID-19 antigen tests.

[19] As registered in and used by the JRC database; see: https://covid-19-diagnostics.jrc.ec.europa.eu/.

[20] The reference number is the identification number issued by the manufacturer to identify the device. It is usually included in the device's labelling, instructions for use and/or declaration of conformity, and often preceded by the symbol 'REF'. Synonyms for reference numbers are: catalogue numbers, commercial product codes or reorder numbers. The reference number may vary in different markets. The REF number included in the EU common list may be followed by "{…}", which means this is generic number that will, in practice, be followed by further references, depending on the packaging, box, national market, etc. When a reference number is not issued, the device is typically identified by its commercial product name.

[21] It is the manufacturer's responsibility to ensure that the correct REF number is included in the EU common list. Neither the technical working group nor the Commission can be held responsible in case the REF number does not refer to the antigen test considered eligible for inclusion in the EU common list. In case any errors are detected, manufacturers should contact SANTE-TWG-RAT@ec.europa.eu as soon as possible.

[22] Identical to what is included in the Instructions For Use (IFU) and/or labelling of the antigen test.

	Device ID # [19]	REF number [20, 21]	Name of submitting company [22]	Commercial name of the device [21]	Clinical performance of the device *As evaluated by independent validation studies, meeting the agreed criteria*	Evaluated specimen type(s) *Eligible for issuing EU Digital COVID certificates*	Other specimen type(s) [21] *Not evaluated*	SARS-CoV-2 Target protein	Included in the EU common list since *D/M/Y*
	4057	L031-129G5, L031-129H5	**Acon Biotech (Hangzhou) Co., Ltd**	**Flowflex SARS-CoV-2 Antigen Rapid Test (Nasal/ Nasopharyngeal/ Saliva)**	**Prospective clinical field study** Study carried out in Italy. Unselected nasal samples: 144 positive and 342 negative samples. Sensitivity: 97.2%, specificity: 99.71%. Unselected NP samples: 145 positive and 332 negative samples. Sensitivity: 96.5%, specificity: 100%.	Nasal, Nasopharyngeal	! Saliva	Nucleocapsid protein	09/12/2022
	2108	REF 840001, REF 840003, REF 840005, REF 840007	**AESKU.Diagnostics GmbH & Co KG**	**AESKU.RAPID SARS-CoV-2**	**Prospective clinical field study** Study carried out in Germany, Nasal swab. Study size: 130 positive samples and 460 negative samples. Overall sensitivity: 88.5%, sensitivity Ct ≤ 25: 100%, specificity: 98.8%.	Nasal	-	Nucleocapsid protein	14/10/2022
	1822	A6061251, A6061252, A6061253	**Anbio (Xiamen) Biotechnology Co., Ltd**	**Rapid COVID-19 Antigen-Test (colloidal Gold)**	**Prospective clinical field study** Study carried out in France, NP swab, sensitivity: 90.16% (110/122), specificity: 99.67% (302/303). **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 100%.*	Nasopharyngeal	Nasal	Nucleocapsid protein	10/05/2021
	1736		**Anhui Deep Blue Medical Technology Co., Ltd**	**COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)**	**Prospective clinical field study** Study carried out in Poland, fresh, unselected samples. Overall sensitivity: 91.7%, specificity: 100%. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.8%.*	Nasopharyngeal, Oropharyngeal	Nucleocapsid protein	10/05/2021	
	1815		**Anhui Deep Blue Medical Technology Co., Ltd**	**COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Nasal swab**	**Prospective clinical field study** Study carried out in Poland, fresh, unselected samples. Overall sensitivity: 91.7%, specificity: 100%. **Retrospective in vitro study** Positive evaluation by Paul-Ehrlich-Institut (PEI) in Germany: Sensitivity of 100% at Ct ≤ 25; *Manufacturer specificity of 99.8%.*	Nasal, Anterior nasal	Nucleocapsid protein	10/05/2021	

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DECLARATION OF CONFORMITY

According Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex III.

Manufacturer: Anbio (Xiamen) Biotechnology Co.,Ltd.
Address: No.2016, Wengjiao West Road, Xinyang Street, Haicang District,361026 Xiamen, Fujian, China.

European Representative: Lotus NL B.V.

Contact person: Peter **E-mail**: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague, Netherlands.

In Vitro Diagnostic Directive:

- **Rapid COVID-19 Antigen Test (Colloidal Gold)**

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:04/09/2020

Place:Xiamen,China

Name of authorized signatory: Danny Wang
Position held in the company: General Manager
Seal/Stamp:

Anbio (Xiamen) Biotechnology Co.,Ltd.

Anbio (Xiamen) Biotechnology Co.,Ltd.
Add: No.2016, Wengjiao West Road, Xinyang Street,
Haicang District,Xiamen, Fujian 361026, China.

January 5, 2023

To whom it may concern,

We, Anbio(Xiamen) Biotechnology Co.,Ltd,as the manufacturer of Rapid COVID-19 Antigen Test(Colloidal Gold)（common list NO:1822）,here by declare that our test is effective for，but not limited to,the mutant strain and the following variants;SARS-CoV-2 of Alpha (B1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Epsilon (B.1.427/B.1.429), Zeta (P.2), Eta (B.1.525), Theta (P.3), Iota (B.1.526), Kappa (B.1.617.1), Lambda (C.37), Mu(B.1.621), Delta plus (AY.4.2), Omicron(B.1.1.529),Omicron(BA.4),Omicron(BA.5)Omicron(BA.5.2),Omicron(BA.2.75),Omicron(BA.2.12),Omicron(BA.2.12.1) ,,Omicron(XBB.1.5） .

The aforementioned variants have several mutations in the spike protein and minimal mutations in the nucleocapsid protein.

There is no obvious difference when testing with different recombinant nucleocapsid protein antigens (Alpha, Beta, Gamma, Delta, Epsilon, Zeta, Eta, Theta, Iota, Kappa, Lambda, Mu and Delta plus), based on these different variants of SARS-CoV-2.

The theoretical analysis of the mutations in the nucleocapsid protein suggests no apparent interference for the Rapid COVID-19 Antigen Test(Colloidal Gold) （common list NO:1822） with detecting the Omicron variant of COVID-19(Includes Omicron BA.1 ,Omicron BA.2 OmicronBA.4,Omicron(BA.5),Omicron(B.1.1.529),Omicron(BA.4),Omicron(BA.5)Omicron(BA.5.2),Omicron(BA.2.75),Omicron(BA.2.12),Omicron(BA.2.12.1),,Omicron(XBB.1.5 ） and all related variants).We anticipate our test will be able to detect these variants.

Sincerely

Anbio (Xiamen) Biotechnology Co.,Ltd.