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Antigen tests as part of the Austrian test strategy

SARS-CoV-2

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content

Executive summary

- Rapid antigen tests enable rapid and direct detection of SARSCoV-2

- Recommendations of the BMSGPK:
  - CE certified products
  - Sensitivity> 90%
  - Specificity ≥ 97%
  - Sampling: nasopharyngeal swab
- Areas of application:
  - Officially arranged tests,
  - Specific screening programs and
  - Population-wide screening programs
- If the pretest probability is low, especially if there are no symptoms and there was no contact with a confirmed case, positive test results are confirmed by means of a molecular biological test.
- A positive antigen test triggers the reporting obligation according to §§ 2 or 3b Epidemic Act.

An overview of the information on performance reviews and international evaluations of antigen tests is provided in the appendix to this document.

1 Introduction

Antigen tests / rapid antigen tests are used for the direct detection of SARS-CoV-2. In contrast to PCR tests - which are still considered the "gold standard" - rapid antigen tests do not detect the genetic makeup of the virus, but rather its protein or protein envelope.

Antigen tests have the following advantages over PCR tests: The analysis does not require any special equipment, which is why it can be carried out at the point of sampling without great effort and the result is available around 15 minutes after sampling. This rapid identification of SARS-CoV-2 positive people in particular effectively interrupts chains of infection. A disadvantage of antigen tests is their lower sensitivity compared to PCR tests.

This document is intended to enable users to make an informed decision on how to obtain a suitable antigen test and to provide interested citizens with information. The tables in the appendix summarize previously published test results for selected products.

2 basics

2.1 Performance parameters

The performance parameters of diagnostic tests that detect infections describe their ability to distinguish infected from non-infected. These properties are specified by the manufacturer in the package insert and are usually based on studies by the respective manufacturer. They can also be checked as part of independent performance reviews and evaluations.

2.1.1 Sensitivity

The sensitivity of a test describes the proportion of people tested with an infection who are correctly detected by the test and receive a positive test result. The sensitivity is usually given in%. A sensitivity of 80% means that 80% of the people actually infected are recognized as "positive".

2.1.2 Specificity

The specificity of a test describes the proportion of the tested subjects without infection who are correctly recognized by the test and receive a negative test result. The specificity is also given in%. A specificity of 99% means that 99% of the non-infected people are recognized as "negative".

2.1.3 Cross reactivity

Cross-reactivity is the undesired interaction of the test with other pathogens. In the case of high concentrations of related pathogens, undesired bonds and, as a result, a false signal (“false positive”) can occur. Cross-reactivity can be a reason for poor specificity when performing immunological tests. For example: Is the test able to reliably detect the pathogen of SARS-CoV-2 or does the test also react to related pathogens.

2.1.4 Interference

Interference effects are biochemical disturbances that lead to undesired bonds being formed in the test used and a false signal ("false positive") being generated. In contrast to cross-reactivity, which results in bonds with “related” viruses, the interference goes beyond this. For example: Is the test able to reliably detect the pathogen of SARS-CoV-2 or does the test react to other pathogens that cause similar symptoms or interfere with the test principle.

2.2 Performance reviews and evaluations

In practice, diagnostic tests deviate from the manufacturer's specifications for various reasons [1] on. In order to obtain independent information about clinical performance, examinations are carried out to determine whether the respective tests achieve the performance characteristics in the relevant environment. This information is essential for the assessment of the various products, which is why countries at the international and national level endeavor to initiate investigations and to continuously reflect on and share their results.

The type and scope of such performance assessments and evaluations can be designed differently. The strongest form of evidence here is validations from independent institutions such as the Foundation for Innovative Diagnostics (FINDDx). In Austria - as in Germany or other European countries - performance assessments of more available antigen tests are carried out by various institutions. Studies have already been carried out in member states at EU level [2] carried out in order to better research the performance and various possible uses. This is intended to determine the extent to which the manufacturer's performance characteristics are achieved in a clinically relevant environment. As part of these European developments, the BMSGPK is working to make a contribution to the discourse. The results of the studies and

[1] Manufacturer's information usually relates to comparisons with PCR results, but the information can be based on selected PCR samples (e.g. samples with a higher viral load)

[2] The term validation is not to be seen in the sense of the standard EN ISO 15189: 2014 for laboratory tests.

tests are continuously published in the EU's "COVID-19 In Vitro Diagnostic Devices and Test Methods Database". [3]

The results of these performance assessments as well as international evaluations carried out by independent institutions (see references) can be used as additional decision criteria for the use of antigen tests. In the appendix of this document there is an overview of the information which the BMSGPK has been made aware of.

New findings in the field of rapid antigen tests as well as the results of application documentation can be communicated to the ministry at the following email address: corona@gesundheitsministerium.gv.at

2.3 Pre-test probability

The pretest likelihood is the likelihood that a particular condition will be present before a diagnostic test is performed. It corresponds at least to the frequency of the disease in the population (prevalence), but can increase further due to various factors (e.g. symptoms, contact person).

The so-called predictive value of a test results from the interaction of these parameters. The positive predictive value is the probability that an infection is actually present if the test is positive. If the performance characteristics of the test used remain the same, the higher the pre-test probability, the higher this is. Conversely, the negative predictive value is the probability with which an infection can be excluded if the test is negative. If the performance characteristics of the test used remain the same, the lower the pretest probability, the higher this is. [4]).

[3] Available at https://covid-19-diagnostics.jrc.ec.europa.eu/

[4th] In published international studies on performance characteristics, such values have been achieved for the entire sample; for samples with a high viral load, they are even higher.

Table 1: Overview of the relationship between pre-test probability, positive and negative predictive value

Pre-test probability (= How high is the clinical input estimate before the test that an infection is actually present prior to COVID-19 disease?)	**Positive predictive value (= Probability with the infection is actually present if the test is positive)**	**Negative predictive value (= Probability with which an infection can be excluded can if the test is negative)**
1% (i.e. every hundredth person 25% **is actually infected)**		> 99%
5% (i.e. every twentieth person 57% **is actually infected)**		98%
10% (i.e. every tenth person is actually infected)	72%	97%
25% (i.e. every fourth person is actually infected)	90%	93%
50% (i.e. every second person is actually infected)	97%	83%

In the appendix there is a further list of the ECDC with even more detailed information on the relationship between predictive value, sensitivity and specificity at certain prevalences.

The situations described illustrate that the pre-test probability is a relevant parameter. When interpreting test results from antigen tests, factors that influence the value of the pre-test probability should therefore be taken into account whenever possible. When testing asymptomatic persons, the pre-test probability approaches the prevalence of the disease (~ 1%). In this scenario, only one in four positive antigen test results would actually be correct. Clinical (symptoms) or epidemiological factors (contacts with infected people) can increase the pretest probability, which in turn has an impact on the predictive value. In the context of a low (2% –10%) or very low (<

3 test requirements

3.1 Marketability and CE certification

The legal framework for bringing rapid antigen tests to the market is regulated by Directive 98/79 / EC. This stipulates that manufacturers must submit a declaration of conformity which clarifies the following aspects of the test application: intended use, user, clinical aspects (e.g. target group) and performance characteristics. Manufacturers are required to carry out independent performance evaluations beforehand. The CE certification is mainly based on these independent records and declarations by the manufacturer.

3.2 Minimum criteria

Various organizations have established minimum criteria for antigen testing. These are based on the manufacturer's information on performance data (sensitivity, specificity, cross-reactivity) as well as on the results of comparative evaluations by various institutions. The minimum criteria set by the organizations are helpful guidelines for the selection of antigen tests:

Minimum criteria of the Paul Ehrlich Institute:

- Sensitivity:> 70% of unselected PCR-confirmed positive samples
- Specificity:> 97%
- Cross-reactivity: Information on the determined cross-reactivities with other human coronaviruses in the package insert
- Interference: Details of the detected interferences in the package insert

World Health Organization (WHO) minimum criteria [2]:

- Sensitivity ≥ 80%
- Specificity ≥ 97%

Minimum criteria of the European Center for Diseases Prevention and Control (ECDC) [5]:

- Sensitivity> 90%
- Specificity ≥ 97%

The **BMSGPK** recommends sensitivity to the performance characteristics of antigen testing

> 90% and specificity of ≥ 97% according to the manufacturer's information.

[5] https://http.ecdc.europa.eu/sites/default/files/documents/Options-use-of-rapid-antigen-tests-for-COVID- 19_0.pdf

4 areas of application

In the currently valid version of the Austrian test strategy, rapid antigen tests are used in the following three areas:

- Officially arranged tests,
- Specific screening programs and
- Population-wide screening programs

For further information on the tests mentioned above, reference is made to the document "Austrian Test Strategy SARS-CoV-2":
Austrian test strategy SARS-CoV-2

4.1 Antigen tests for personal use

Antigen tests for personal use (so-called self-tests) form a further addition to the Austrian test strategy as part of the population-wide screening programs. These are the same antigen tests, only the way in which the sample is taken differs. However, due to the decrease by laypeople as well as sampling types, which are associated with the extraction of lower amounts of virus, less reliable results may be obtained.

Legal Aspects: Up to now, in-vitro diagnostics for use by laypeople also had to be assessed by an independent third party (a so-called notified body). In the course of containing the pandemic, an exception was created which does not make this procedure with a notified body necessary for antigen tests for the limited period of the pandemic. Manufacturers, their authorized representatives or the person placing the product on the market must confirm by means of a declaration of self-commitment that a level of safety and performance is achieved that guarantees functionality and suitability for the intended purpose. The voluntary commitment is sent to the Federal Office for Health Safety (BASG). The list is

to be found on the BASG homepage under "Commitment to bring SARS-CoV-2 rapid tests to the market" BASG - Medical Devices COVID-19

5 sampling

A suitable and correctly carried out sampling is the basic requirement for a valid test result for every test method. Studies show that different amounts of virus material are obtained with different types of sampling under otherwise identical conditions. The gold standard with which the highest amount of virus material can usually be obtained before and at the onset of symptoms is the nasopharyngeal swab. This type of sampling should therefore also be preferred.

For further information on sampling, reference is made to the document "Austrian Test Strategy SARS-CoV-2":
Austrian test strategy SARS-CoV-2

6 Interpretation of results

The interpretation of an antigen test result depends on the above-described performance characteristics of the test used and the probability of the pre-test.

Rapid antigen tests produce the most reliable results in people with a high viral load. This corresponds to the period of the presymptomatic phase up to 5 days after the onset of symptoms. Particularly in a context with a low pre-test probability, positive antigen test results are confirmed by a molecular biological test (PCR or LAMP test). The result of an antigen test must always be put in context with the symptoms and the medical history as well as the pretest probability. Due to the high probability of pre-testing in symptomatic people and people who have had contact with an infected person, post-testing is not necessary in these cases.

With regard to the interpretation of the results, it is therefore recommended to see positive test results against the background of the pre-test probability:

Test result	Pre-test probability	Interpretation or approach
positive	Low	**Infection with SARS-CoV-2 possible; Confirmation of the test result by means of a test with higher sensitivity (e.g. PCR)**
positive	High	Infection with SARS-CoV-2 likely The interpretation of the test result should be carried out by appropriate specialist staff, who put the result in context with the symptoms and the patient's history as well as the probability of the pre-test.
negative	High Low	Infection with SARS-CoV-2 unlikely It should be noted, however, that every test for direct pathogen detection is only a snapshot and does not rule out any future infection.

* If the suspicion persists despite a negative antigen test result, an immediate molecular biological test (eg PCR) or a further antigen test should be carried out after 2–4 days. In general, the poorer performance of the antigen tests compared to molecular biological tests (eg PCR) can be compensated for by repeated testing.

7 obligation to notify

A positive antigen test triggers the reporting obligation in accordance with Section 2 of the Epidemic Act 1950. Persons who are required to report (especially doctors) or facilities (such as laboratories, pharmacies) must therefore report a positive antigen test to the responsible health authority.

In the event of a positive result of a test for self-application, the health authority must be informed immediately, for example via the hotline 1450, or a re-test must be arranged independently by an authorized body in accordance with Section 3b of the 1950s Epidemic Act.

credentials

The Federal Ministry for Social Affairs, Health, Care and Consumer Protection (BMSGPK) offers specialist information, recommendations for action and general information on the coronavirus on its website. BMSGPK - specialist information https://www.sozi

Further information on statistical key figures (e.g. positive and negative predictive value) of a diagnostic test can be found in the Lexicon of Medical Laboratory Diagnostics and on the website of the Austrian Society for Laboratory Medicine and Clinical Chemistry (ÖGLMKC). https://www.oeglmkc.at/corona.html

The Vienna Health Association, together with the MA15 Health Service, has published a guideline on the rational use of SARS-CoV-2 rapid antigen tests. A clinically oriented decision-making aid for the use of AG rapid tests is intended to support affected facilities in containing outbreaks.
https://www.aekwien.at/documents/263869/449604/201016_MA15_CoV_Update_AT_Teststrategy_Schnelltests.pdf / 53e83a01-c5eb-f0de-f597-1e220689414d? t = 1603097066806

The German Robert Koch Institute (RKI) provides extensive information on testing patients for SARS-CoV-2 infection. RKI - Testing SARS-CoV-2

https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Vorl_Testung_nCoV.html

The German Federal Institute for Drugs and Medical Devices (BFARM) publishes a regularly updated list of antigen tests for the direct detection of SARS-CoV-2 pathogens. The published data correspond to the information provided by the manufacturer; Only the information in the respective instructions for use is binding): BFARM - antigen tests

https://antigentest.bfarm.de/ords/f?p=101:100:17196373534932:::::&tz=1:00

The database of the Joint Research Center of the European Commission collects scientific articles on various test methods, including antigen tests: https://covid19-diagnostics.jrc.ec.e

The World Health Organization (WHO) publishes regularly updated recommendations for action for the use of antigen tests to detect SARS-CoV-2 infections: https://www.who.int/publicatio

The non-profit organization "Foundation for innovative new Diagnostics" (FIND) offers on its website an overview of examinations of performance characteristics of diagnostic tests for the detection of SARS-CoV-2, which were carried out by independent institutions. This information can be called up in the form of standardized reports (FIND reports or - once prepared - in a dashboard (FIND dashboard).

https://www.finddx.org/covid-19/sarscov2-eval/

Literature (selection)

The use of commercial antigen tests has been investigated in various studies that have been published in peer-reviewed journals:

Cerutti, F., Burdino, E., Milia, MG, Allice, T., Gregori, G., Bruzzone, B., and Ghisetti, V. (2020). Urgent need of rapid tests for SARS CoV-2 antigen detection: Evaluation of the SD biosensor antigen test for SARS-CoV-2. DOI: 10.1016 / j.jcv.2020.104654 https://www.sciencedirect.com/science/article/pii/S1386653220303966

Diao, B., Wen, K., Chen, J., Liu, Y., Yuan, Z., Han, C., Chen, J., Pan, Y., Chen, L., Dan, Y., et al. (2020). Diagnosis of Acute Respiratory Syndrome Coronavirus 2 Infection by Detection of Nucleocapsid Protein. DOI: 10.1101 / 2020.03.07.20032524 https://www.medrxiv.org/content/10.1101/2020.03.07.20032524v2

Krueger, LJ, Gaeddert, M., Koeppel, L., Bruemmer, L., Gottschalk, C., Miranda, IB, Schnitzler, P., Kraeusslich, H.-G., Lindner, A., Nikolai, O. , et al. (2020). Evaluation of the accuracy, ease of use and limit of detection of novel, rapid, antigen-detecting point-ofcare diagnostics for SARS-CoV 2. DOI: 10.1101 / 2020.10.01.20203836 https://www.medrxiv.org/content/10.1101/2020.10.01.20203836v1

Lindner, AK, Nikolai, O, Kausch, F., Wintel, M., Hommes, F., Gertler, M., Krüger, LJ, Gaeddert, M., Tobian, F., Lainati, F., Köppel, L ., Seybold, J., Corman, VM, Christian Drosten, C., Hofmann, J., Sacks, JA, Mockenhaupt, FP, Denkinger, CM (2020) Head-to-head comparison of SARS-CoV-2 antigen-detecting rapid test with self-collected anterior nasal swab versus professional-collected nasopharyngeal swab. DOI: 10.1183 / 13993003.039612020 https://www.medrxiv.org/co

Mak, GC, Cheng, PK, Lau, SS, Wong, KK, Lau, CS, Lam, ET, Chan, RC, and Tsang, DN (2020). Evaluation of rapid antigen test for detection of SARS-CoV-2 virus DOI: 10.1016 / j.jcv.2020.104500 https://www.sciencedirect.com/science/article/pii/S1386653220302420

Nagura-Ikeda, M., Imai, K., Tabata, S., Miyoshi, K., Murahara, N., Mizuno, T., Horiuchi, M., Kato, K., Imoto, Y., Iwata, M. ., et al. (2020). Clinical Evaluation of Self-Collected Saliva by

Quantitative Reverse Transcription-PCR (RT-qPCR), Direct RT-qPCR, Reverse TranscriptionLoop-Mediated Isothermal Amplification, and a Rapid Antigen Test To Diagnose COVID-19. DOI: 10.1128 / JCM.01438-20 https://jcm.asm.org/content/58/9/e01438-20.abstract

Porte L, Legarraga P, Vollrath V, Aguilera X, Munita JM, Araos R, et al. Evaluation of novel antigen-based rapid detection test for the diagnosis of SARS-CoV-2 in respiratory sample DOI: 10.1016 / j.ijid.2020.05.098; https://www.sciencedirect.com/science/article/pii/S1201971220304057

Stohr, JJJM, Zwart, VF, Goderski, G., Meijer, A., Nagel-Imming, CRS, Kluytmans-van den Bergh, MFQ, Pas, SD, van den Oetelaar, F., Hellwich, M., Gan, KH Rietveld, A .; Verweij, JJ, Murk, JL, van den Bijllaardt, W., Kluytmans, JAJW (2021) Self-testing for the detection of SARS-CoV-2 infection with rapid antigen tests DOI: 10.1101 / 2021.02.21.21252153, https://www.medrxiv.org/content/10.1101/2021.02.21.21252153v1.article-info

Weitzel T, Legarraga P, Iruretagoyena M, Pizarro G, Vollrath V, Araos R, et al. Head-tohead comparison of four antigen-based rapid detection tests for the diagnosis of SARSCoV-2 in respiratory samples; DOI: 10.1101 / 2020.05.27.119255 https://www.biorxiv.org/content/10.1101/2020.05.27.119255v1.abstract

In addition to the publications mentioned, the Cochrane Collaboration has produced a review on the evidence of the diagnostic accuracy of antigen tests: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013705/full

Annex I: Overview of the results of studies on performance features of antigen test

The table below provides information on the results of studies on the performance of antigen tests. The compilation is based on information that has been published or made known to the Ministry in the form of application documentation by users in Austria. This compilation is not an exhaustive list: Further developments as well as feedback on application documentation using reporting templates are continuously added.

The footnotes listed in the table refer to the respective table column.

Table 3: Overview of results of examinations of the performance characteristics of Antigen-Test

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
Panbio ™ COVID Abbott **19 Ag Rapid Test** ***(Test by WHO recommended)***		NP	T (n = 535)	85.5		96.8	89.7 5)		100	FindDX Link
		NP	T (n = 1108)	86.8		95.8	88.3 5)		99.9	Nat.Unders. (CH)
		np	T (n = 50)	n / A		96.7	45.2	0	ka	HSC
		NP	S (n = 412) ER (n = 387) KI (n = 85)	79.6		100			100	ECDC / Nat.Unters. (IT)
		NP	S (n = 208)	81			98 4)		100	ECDC / Nat.Unters. (AW)
		NP	T (n = 240) S (n = 185) A (n = 55)	73.3		100	87.5 / 25 6)		100	ECDC / Nat.Unters. (CHL)
		NP	T (n = 3991) S (n = 199) A (n = 47)	73.3		100	83.8		99.92	Nat.Unders. (NO)
		NP	n / a	93.3					99.4	common list HSC (BE)
		n / a	n / a	86.5					100	Nat. Under (IT)
		n / a	n / a	82.1					99.1	Nat. Under (BRA)
		NP		91.4					99.8	PEI, BAG ***
		NP + AS	T (n = 281) S (n = 279)	86.4 / 90.9		96.8 / 96.8	90.5 5) / 92.9 5)		99.2 / 99.2	FindDX Link (DE)
		n / a	MS (n = 7187)	72.6 (69.1-75.8)					100 (99.9-100)	11 studies in Nat. Unt. (NL)
		NP	AS (n = 2390)	66.7					100	Nat. Unt. (NL)
		NP + OP	S (n = 1130)	53.7					100	Nat. Unt. (NL)

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
Standard® Q Covid-19 Ag *(Test by WHO recommended)*	SD organic sensor F. Hoff-man-La Roche LTD	NP	T (n = 400) S (n = 397) A (n = 3)	88.7		95.9	91.9 5)		97.6	FindDX Link (BRA)
		NP + OP	S (n = 2417)	76.6		100		62.1 1)	99.3	FindDX Link (DE)
		NP	S (n = 529)	89		97.2	91.8 5)		99.7	FindDX Link (CH) Nat.Unders. (CH)
		np	T (n = 50)	n / A		94.4	54.4 1)	5.5	n / A	HSC
		NP	T (n = 330) S (n = 185) TR (n = 145)	70.6		95	100 3)	9.1 3)	100	ECDC / Nat. Under (IT)
		NP	na (n = 359)	47.1					98.4	ECDC / Nat. Under (IT)
		NP	n / a	96.5					99.7	common list HSC (BE, SI)
		n / a	T (n = 546)	71					94	Nat. Under (FR)
		AS + NP	S (n = 179)	80.5, 73.2		100, 95.5	87.5 5), 84.4 5)		99.3, 99.3	FindDX Link (DE)
		np	T (n = 50)	n / A		97.2	55.4 1)	11.1	n / A	HSC
		n / a	MS (n = 3697)	80.2 (76.6-83.4)					99.7 (99.5-99.9)	9 studies in Nat. Unt. (NL)
		n / a	S (n = 309)	55.6 (41.4-68)					95.7 (92.4-97.6)	3 studies in Nat. Unt. (NL)
				96.52					99.68	PEI, BAG ***

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
Standard® F Covid-19 AG	SD organic sensor F. Hoff-man-La Roche LTD	NP	T (n = 453) S (n = 450) A (n = 3)	77.5		87.9	80.9 5)		97.9	FindDX Link (BRA)
		np	T (n = 50)	n / A		100	45.7 1)	0	n / A	HSC
		n / A	na (n = 359)	47	100 1)	95 1)		42 2)	98.43	ECDC / Nat. Under (F)
		NP	n / a	96.5					99.7	common list HSC (BE)
		n / a	MS (n = 722)	78.1 (70.4-84.2)					99.3 (98.3-99.7)	2 studies in Nat. Unt. (NL)
		NP		96.36					100	PEI, BAG ***
RapiGEN Biocredit AG	RapiGEN Inc.	NP	S (n = 476)	74.4		90.9	82.5 5)		98.95	FindDX Link (BRA)
		NP	S (n = 111)	62		84.9		15.4 1)	100	ECDC / Nat. Under (CHL)
		n / a	n / a	29					87	Nat. Under (DE)
		n / a	n / a	32					n / a	Nat. Under (CN)

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
COVID-19 Ag Respi-Strip	SD organic sensor F. Hoff-man-La Roche NP LTD	NP	T (n = 453) S (n = 450) A (n = 3)	77.5		87.9	80.9 5)		97.9	FindDX Link (BRA)
		NP + OP	S (n = 328)	57.6		73.9			99.5	ECDC / Nat. Under (BE)
			S (n = 56)	30th					100	ECDC / Nat. Under (BE)
		NP	na (n = 148)	30.2		100	70.6 / 40.9 6)		100	ECDC / Nat. Under (BE)
		NP	na (n = 138)	50		82.2			100	ECDC / Nat. Under (F)
		NP	S (n = 45)	29		87			100	ECDC / Nat. Under (F)
		n / a	T (n = 1032)	43					100	3 studies in Nat. Under (FR)
NowCheck COVID-19 Ag test	Bionote, Inc.	NP	T (n = 400) S (n = 392) A (n = 8)	89.2		94.8	91.4		97.3	FindDX Link (BRA)
		np	T (n = 50)	n / A		100	67.4 1)	5.5	n / A	HSC
		NP, AS		89.2					97.6	PEI, BAG ***

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
CLINITEST COVID-19 Rapid test	Siemens Healthcare Diagnostics GmbH	np	T (n = 50)	n / A		100	71.7 1)	16.6	n / A	HSC
			MS (n = 796)	80.6 (72.7-86.6)					99.7 (98.9-99.9)	4 studies in Nat. Unt. (NL)
		NP	n / a	98.32					99.6	common list HSC (BE)
		AP + NP	n / a	96.7					99.2	common list HSC (SI)
		NP		96.72					99.22	PEI ***
Antigen test SARS-CoV-2 (Prototype)	Dräger	np	T (n = 50)	n / A		80.6	15.2 1)	0	n / A	HSC
Rida®Quick SARS-CoV-2 antigen	R-Biopharm AG	np	T (n = 50)	n / A		98.2	71 1)	7.4	n / A	HSC
		NP		95					100	PEI ***
Sofia SARS Antigen FIA	Quidel	NP	MS (n = 733)	84	91.8	93.5	79.2		99	ECDC / Nat. Under (NL)
				96.7					100	PEI, BAG ***
		AS + NP	n / a	97.7					100	common list HSC (BE, SI)
		n / a	n / a	≥ 80%					> 99%	Nat. Under (UNITED STATES)
		n / a	209	97					100	Nat. Unters (FR)

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
Bioeasy 2019-nCoV Ag Rapid Test kit	Shenzhen Bioeasy Organic technology Co., Ltd	NP + OP	S (n = 727)	66.7		88.9		33.3 1)	93.1	FindDX Link (CH)
		NP + OP	S (n = 127)	93.9		100				ECDC / Nat. Under (CHL)
		NP + OP	S (n = 111)	85		100		54 1)	100	ECDC / Nat. Under (CHL)
		n / a	n / a	68					100	Nat. Under (CN)
		n / a	n / a	94					100	Nat. Under (CN)
BD Veritor ™ system	Becton Dickinson GmbH	NP + OP	S (n = 251)	76.3					99.5	ECDC / Nat. Under (UNITED STATES)
		n / a	n / a	≥ 80					> 99	Nat. Under (UNITED STATES)
		NP + OP	MS (n = 1330)	80.9 (74.4-86.0)					99.8 (99.4-100)	2 studies in Nat. Unt. (NL) 100
		NP		84						PEI ***
LUMIPULSE SARS CoV-2 Ag kit	Fujirebio	NP	na (n = 313)	55.2					99.6	ECDC / Nat. Under (JP)
NADAL Covid-19 AG rapid test	Nal from Minden GmbH	np	T (n = 50)	n / A		77.8	6.5 1)	0	n / A	HSC
		NP + OP	n / a	97.6					99.9	common list HSC (SI, BE)
		NP + OP		97.6					99.9	PEI ***
Wondfo 2019-nCoV antigen test	Guang-zhou Wondfo Biotech Co., Ltd	NP	T (n = 328) S (n = 56)	85.7		100	92.2 5)		100	FindDX Link (CH)
		NP		96.18					99.72	PEI, BAG ***

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
JOYSBIO SARS-CoV-2 antigen Rapid test kits	Joysbio (Tianjin) Biotechnology Co., Ltd.	AS	T (n = 265) S (n = 44)	70.5		91.3	78.3 5)		99.1	FindDX Link (CH)
iChroma COVID-19 Ag test	Boditech Medical, Inc.	NP	T (n = 232) S (n = 41)	74.4		95.5	83.3		100	FindDX Link (CH)
		n / a	MS (n = 722)	78.1 (70.4-84.2)					99.3 (98.3-99.7)	2 studies in Nat. Unt. (NL)
BIOSYNEX COVID-19 Ag BSS	BIOSYNEX SWISS SA	NP	n / a							common list HSC (FR)
		NP		96					100	PEI, BAG ***
		NP + OP	MS (n = 838)	69.6 (56.2-80.1)					100 (99.5-100)	2 studies in Nat. Unt. (NL)
BIOSYNEX COVID-19 Ag + BSS	BIOSYNEX SWISS SA	NP		97.5					100	BAG ***
MEDsan® SARS CoV-2 antigen Rapid test	MEDsan GmbH	NP		92.5					99.8	PEI, BAG ***

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
Fluorecare SARS-CoV-2 Spike protein Test kit	Shenzhen NP Micro profit organic tech Co., Ltd.			89.68					100	PEI ***
TestNOW® - COVID-19 antigen	Affimedix NP			93.7					99.2	PEI ***
Coronavirus Ag Rapid test Cassette (swab)	Zhejiang Orient Genes bio tech Co., Ltd	AS, NP		96.72					99.22	PEI, BAG ***
ESPLINE® SARS-CoV-2	Fujirebio NP Inc. (mast Diagnostics GmbH)			80.6					100	PEI ***
GenBody COVID-19 Ag	Gene body Inc.	NP + OP		96.83					99.18	PEI ***
		OP	MS (n = 436)	89.1			96.7 / 94.9 4)		100	Nat. Under (NL)
		NP		93.8					98.8	PEI, BAG ***
Exdia COVID-19 Ag test	Precision Biosensor Inc. (Axon Lab AG)	NP		93.88					98	PEI, BAG ***

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
WANTAI SARS-CoV-2 Ag Rapid Test (FIA)	Beijing Wantai Biological Pharmacy Enterprise Co Ltd	NP		96.6					96.9	PEI ***
		NP	MS (n = 72)	66.7			96.7		100	Nat. Under (NL)
Medicovid AG SARS-CoV-2 antigen Rapid test	Xiamen Boson Biotech Co.	NP + OP		96.49			97.1		99.5	PEI, BAG ***
Rapid SARS CoV-2 antigen Test card	Xiamen Boson Biotech Co., Ldt.	NP	n / a	93.8					100	common list HSC (BE, SI)
		NP		96.36					100	PEI, BAG ***
Biotime SARS CoV 2 antigen Rapid Qualitative Test kit	Xiamen Biotime Organic technology Co., Ltd.	n / a	T (n = 295)	96					100	Nat. Unters (FR)
COVID-19 Antigen Rapid test	Joinstar Biomedical Technology	NP		96.1					98.10	PEI ***
mö-screen Corona antigen test	Mölab GmbH	NP		97.3					99.9	PEI ***

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
Rapid SARS CoV-2 antigen Test card	MP Bio medicals Germany GmbH	NP		96.4					99.3	PEI, BAG ***
Clungene COVID-19 Ag Rapid test kit	Hangzhou AS Clongenes Biotech Co., Ltd.			91.4					99.4	PEI, BAG ***
ALLTest COVID 19 antigen Rapid test	Hangzhou ALL test Biotech Co. Ltd.,	NP		96.4					99.0	BAG ***
		AT		92.9					99.9	BAG ***
LYSUN Covid 19 Antigen Rapid Test device	Hangzhou Lysun Organic technology Co	NP	ka	96.3					100	PEI, BAG ***
Lyher Novel Coronavirus (COVID-19) antigen Test kit (Colloidal Gold)	Hangzhou Laihe Organic tech Co., Ltd. (Lissner Qi GmbH)	NP		96.16					99.70	PEI ***
AMP Rapid Test SARS-CoV-2 Ag	AMEDA Laboratory-diagnostics GmbH	NP	n / a	97.3					100	common list HSC (BE, SI)
		NP	n / a	97.3					100	PEI, BAG ***
		NP + OP	MS (n = 99)	85			94.4		100	Nat. Unt. (NL)

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
GensureTM COVID-19 Antigen Rapid Test kit	GenSure Biotech Inc.	NP		96.86					100	PEI ***
SARS-CoV-2 Antigen Rapid Test kit	Beijing Lepu Medical Technology Co., Ltd	NP		92					99.26	PEI ***
SARS-CoV-2 antigen Rapid test	Qingdao High top Biotech Co Ltd.	NP		95					99.75	PEI ***
Safecare COVID 19 Ag Rapid Test kit (swab)	Safecare Biotech Hangzhou Co., Ltd.	AS		97.27					99.42	PEI ***
NOVA test SARS-CoV-2 Antigen Rapid Test kit	Atlas Link Technology Co., Ltd.,	NP		97.6					99.2	BAG ***
EBS SARS-CoV-2 Ag Rapid Test	Eurobio Scientific, Les Ulis	NP		95.7					99.1	BAG ***

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
Biozek SARS-CoV-2 Rapid Test cassette	Inzek International Trading BV	NP		93.33					100	BAG ***
		NP	MS (n = 294)	81.8			91.9		99.6	Nat. Under (NL)
Willi Fox COVID 19 antigen test	Willi Fox GmbH, Basel	NP + OP		97.6					98.9	BAG ***
COVID-VIRO® Rapid antigen test COVID-19	AAZ-LMB	NP	n / a	96.6					100	common list HSC (BE, FR)
		NP		96.6					100	BAG ***
SARS-CoV-2 Antigen Rapid test	Liming Bio-Products	n / a	n / a	0					90	Nat. Under (CHL)
ESPLINE® SARS-CoV-2	Fujirebio Inc.	n / a	n / a	12th					n / a	Nat. Under (JP)
		n / a	n / a	81					100	Nat. Under (JP)
		n / a	T (n = 313)	55					100	Nat. Under (FR)
Huakai SARS-CoV-2 N protein Detection kit	Beijing Savant Biotechnology Co., Ltd	n / a	T (n = 104)	17th		21	8th		100	Nat. Under (CHL)

Surname	providers	Type of sample extraction (OP, NP *)	information to the whole sample (T, S, A, MS, na, ER., KI **)	sensitivity Total sample	sensitivity Ct value <20 or <18 1)	sensitivity Ct value <25 or 18-25 1)	Sensitivity Ct value <30 or 25-30 1) or 20-30 2) or <28 3) or <32 4) or <33 5) or <35 6)	sensitivity Ct value> 30 > 25 1) or 25-35 2) or> 34 3)	Specificity	source
				in %	in %	in %	in %	in %	in %	
Healgen Rapid COVID-19 Antigen test	Seaweed Scientific, LLC	n / a	MS (n = 796)	80.6 (72.7-86.6)					99.7 (98.9-99.9)	4 studies in Nat. sub. (NL)
Gene body COVID-19 Ag	Meridian Bioscience, Inc.	NP + OP	MS (n = 83)	100					100	Nat. Under (NL)
Romed SARS-CoV-2 antigen Rapid test Cassette	Van Oostveen Medical BV	NP + OP	MS (n = 600)	81.3 (74.3- 86.8)					99.8 (98.8-100)	2 studies in Nat. sub. (NL)
		NP + OP	S (n = 300)	65.3			90.6		100	Nat. Under (NL)
Liaison SARS CoV-2 Ag	Diasorin	n / a	MS (n = 1064)	84.5 (76.7-90.0)					99.2 (98.5-99.6)	3 studies in Nat. Under (NL)
Detection kit for 2019 novel Coronavirus antigen	Diano	NO + OP	MS (n = 1399)	66.9			79.5		99.6	Nat. Under (NL)
AFIAS COVID-19 Ag	Boditech Medical, Inc. OP		MS (n = 427)	81.1			96.4 / 89.4 4)		100	Nat. Under (NL)

* nasal swabs / nasopharyngeal swabs = NP, orophalopharyngeal swabs / oropharynx swabs = OP, anterior nares sample / smear in the anterior nasal area =

* * AS total = T, symptomatic = S, asymptomatic = A, mildly symptomatic = MS, adults = ER, child = KI,

* * * "The named institution carries out a comparative evaluation of SARS-CoV-2 antigen tests, the aim of which is to assess whether the respective test kits correspond to the state of the art. There are no detailed results for the test kits, but it is assumed that the manufacturer's specifications were achieved under the conditions specified by the manufacturer."

Disclaimer: List "Information on the assessment of the suitability assessment":

This list of the BMSGPK on information for the assessment of the suitability assessment of antigen tests in order to be able to differentiate the currently high quality from less good specimens was created as a service. It does not claim to be complete and does not represent a recommendation by the BMSGPK for the use of a specific test based on the suitability assessment test. The criteria for inclusion in the list "Information for assessing the suitability assessment" were that the test and an independent Study on the quality of the test brought to the attention of BMSGPK. This study must be suitable for a suitability assessment and comparability with other studies (whether this is also unpublished or provided by valid sources such as WHO or ECDC). This list is not permanent.

Annex II: Negative and positive predictive value below different parameters

Table 2: Negative and positive predictive value with different assumptions about the prevalence of COVID-19 or the sensitivity and specificity of the test used

Exemplary Prevalence	sensitivity	Specificity	More negative Predictive value	More positive Predictive Value	Correct Positive	Not correct Positive	Correct Negatives	Not correct Negatives	number sick people	number more positive Test results
50/100 000	0.8	0.98	1,000	0.020	40	1999	97,951	10	50	2,039
50/100 000	0.98	0.999	1,000	0.329	49	100	99,850	1	50	149
100/100 000	0.8	0.98	1,000	0.038	80	1.998	97.902	20th	100	2,078
100/100 000	0.98	0.999	1,000	0.495	98	100	99,800	2	100	198
500/100 000	0.8	0.98	0.999	0.167	400	1,990	97,510	100	500	2,390
500/100 000	0.98	0.999	1,000	0.831	490	100	99,401	10	500	590
1,000/100,000	0.8	0.98	0.998	0.288	800	1,980	97.020	200	1,000	2,780
1,000/100,000	0.98	0.999	1,000	0.908	980	99	98.901	20th	1,000	1,079
5,000/100,000	0.8	0.98	0.989	0.678	4,000	1,900	93,100	1,000	5,000	5,900
5,000/100,000	0.98	0.999	0.999	0.981	4900	95	94.905	100	5,000	4,995
10,000/100,000	0.8	0.98	0.978	0.816	8,000	1,800	88,200	2,000	10,000	9,800

Exemplary Prevalence	sensitivity	Specificity	More negative Predictive value	More positive Predictive Value	Correct Positive	Not correct Positive	Correct Negatives	Not correct Negatives	number sick people	number more positive Test results
10,000/100,000	0.98	0.999	0.998	0.991	9,800	90	89.910	200	10,000	9,890
20,000/100,000	0.8	0.98	0.951	0.909	16,000	1,600	78,400	4,000	20,000	17,600
20,000/100,000	0.98	0.999	0.995	0.996	19,600	80	79,920	400	20,000	19,680
50,000/100,000	0.8	0.98	0.831	0.976	40,000	1,000	49,000	10,000	50,000	41,000
50,000/100,000	0.98	0.999	0.980	0.999	49,000	50	49,950	1,000	50,000	49,050

ECDC (2020). Options for the use of rapid antigen tests for COVID-19 in the EU / EEA and the UK. https://www.ecdc.europa.eu/en/publications-data/options-use-rapidantigen-tests-covid-19-eueea-and-uk , accessed on December 1st, 2020

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