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100% korrekt identifizierte COVID-19 Patienten und gesunde Probanden bei einem C_t-Wert von ≤ 30.

Der C_t-Wert gibt an wie viele Vermehrungszyklen bei einer Untersuchung mittels der quantitativen real-time PCR benötigt wurden, um ein eindeutiges Signal zu erhalten.

Die Abgrenzung, ob ein Patient ansteckend ist oder nicht liegt, den Regularien nach, bei einem C_t-Wert von <30. Oberhalb eines C_t-Werts von 30 gilt ein Patient nicht mehr als ansteckend, da die Viruslast zu niedrig ist.

Zusätzliche Informationen:

- Externe Validierungsstudie ESfEQA (Link)
- Studie Lanser L, Weiss G 2020 (Link)
- Internetauftritt RKI (Link)
- Internetauftritt CDC (Link)
- AESKU Flyer (Link)

Infection
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CORRESPONDENCE

Evaluating the clinical utility and sensitivity of SARS-CoV-2 antigen testing in relation to RT-PCR Ct values

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To the Editor,

Diagnosis of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in patients with suspected coronavirus disease 2019 (COVID-19) is most widely performed with real time polymerase chain reaction (RT-PCR) considered as gold standard [1]. RT-PCR is a highly sensitive diagnostic method for detecting viral ribonucleic acid (RNA) with the disadvantages of logistics for transport of samples to specific laboratories and the relative long duration of the diagnostic method. Positive SARS-CoV-2 RT-PCR also do not allow definitive conclusions whether the subject is still contagious or not. This can be partly attained by establishing the cycle threshold (Ct) value depicting the particular amount of viral RNA in the sample and thus allowing a conclusion on the viral load and infectivity [2]. However, because of the diagnostic effort and duration of the test, faster and less laborious tests attract interest which may help to rapidly identify and contain infected individuals. Therefore, point-of-care-testing with antigen tests, providing results in a couple of minutes, is currently evaluated for routine clinical use.

We compared the SARS-CoV-2 antigen detection in nasopharyngeal swab samples by the Panbio™ COVID-19 Ag Rapid test (Abbott, Chicago, Illionis) with the simultaneous routinely conducted RT-PCR analysis of SARS-CoV-2 orf1 RNA detection with the cobas® analyzer (Roche Diagnostics GmbH, Mannheim, Germany). The nasopharyngeal swab samples were collected from 53 patients with PCR-confirmed SARS-CoV-2 infection during their hospital stay in different stages of the disease. Panbio™ COVID-19 Ag Rapid test was performed right after nasopharyngeal swab sampling while RT-PCR was routinely performed in our central laboratory facility. RT-PCR was negative in two patients suggesting an already subsided infection; consistent with it the Panbio™ COVID-19 Ag Rapid test was also negative. Among 51 RT-PCR SARS-CoV-2 positive patients, the Panbio™ COVID-19 Ag Rapid test was positive in 31 subjects depicting a poor sensitivity of 60.8% (95% CI 46.1–74.2%), compared to 93.3% in the manufacturer's information. In the 14 patients with a Ct-value ≤ 25, being indicative for higher viral loads, the sensitivity for the Panbio™ COVID-19 Ag Rapid test was at a level of 85.7% (95% CI 57.2–98.2%, Table 1). Panbio™ COVID-19 Ag Rapid test was positive in 36.4% (95% CI 17.2–59.3%) of the patients with a Ct-value > 30 (Table 1). Of note, when we included subjects with a Ct value ≤ 30, which is considered to be a threshold for infectivity and currently recommended by the German Robert Koch Institute as an important cutoff to identify SARS-CoV2 contagious subjects, we found that the Ag rapid test correctly identified 79.3% of individuals. However, looking on the other site of the coin we found that subjects with a Ct-value > 30 were antigen positive in 36.4% of cases. The test is still positive in a considerable number of patients which are considered as being non-infectious according to the German Robert Koch Institute. Changing the cut-off value to Ct > 33 reduced the positive results of the Panbio™ COVID-19 Ag Rapid test to 16.7% (Table 1) whereas no positive Panbio™ COVID-19 Ag Rapid test result was achieved in subjects with RT-PCR Ct-values ≥ 35 ($n = 4$).

These results indicate a poor performance of the Panbio™ COVID-19 Ag Rapid test detecting SARS-CoV-2 antigen in patients with low virus load but a good performance in patients with high virus load. Viral load of SARS-CoV-2 was reported to be the highest around the time of symptom onset, and most probably become undetectable within approximately 2 weeks. Additionally, patients with more severe symptoms also seems to have a higher viral

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Table 1 Antigen test results stratified by different Ct value cut-offs

	Antigen test negative *n* (% within Ct value)	Antigen test positive *n* (% within Ct value)	Total *n* (% within total)
Ct value > 25	18 (48.6%)	19 [51.4% (95% CI 34.4–68.1)]	37 (72.5%)
Ct value ≤ 25	2 (14.3%)	12 [85.7% (95% CI 57.2–98.2)]	14 (27.5%)
Ct value > 30	14 (63.6%)	8 [36.4% (95% CI 17.2–59.3)]	22 (43.1%)
Ct value ≤ 30	6 (20.7%)	23 [79.3% (95% CI 60.3–92.0)]	29 (56.9%)
Ct value > 33	5 (83.3%)	1 [16.7% (95% CI 0.42–64.1)]	6 (11.8%)
Ct value ≤ 33	15 (33.3%)	30 [66.7% (95% CI 51.1–80.0)]	45 (88.2%)
Total	20 (39.2%)	31 [60.8% (95% CI 46.1–74.2)]	51 (100%)

loads [3, 4]. Therefore, antigen tests, like the one investigated herein, might be suitable and effective for rapidly identifying infectious subjects with symptoms compatible to a COVID-19 infection in a primary care setting given its sensitivity of around 80%. This is of relevance specifically in epidemic situations with numerous other circulating virus such as influenza but also for rapidly identifying SARS-CoV-2 positive patients for immediate initiation of containment and contact tracing strategies for better controlling the spread of the infection mainly during the cold season [5]. Moreover, the test may be of specific benefit in subjects with short onset of symptoms as viral loads are highest during the first days of infection and because the test has been shown herein to have an even higher sensitivity in patients with higher viral loads. However, one has to admit that not all subjects with a Ct-value ≤ 30 have been correctly identified as being SARS-CoV-2 infected. This would warrant the development of additional strategies to minimize the risk of false negative results. Such algorithms could include the performance of a RT-PCR test in subjects with symptoms compatible with COVID-19 but a negative antigen result. The discrepancy between the real sensitivity and that claimed by the manufacturer of SARS-CoV-2 Ag tests was already demonstrated recently [6]. Since these are CE-marked diagnostic devices this question the reliability of the European admission process.

The low number of positive antigen test results in subjects with higher Ct value > 33 which are considered to be not contagious (https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html) could have implications for follow up screening of initially antigen positive subjects to determine the time point when they are no longer contagious, which is specifically relevant for estimating the duration of quarantine measures. Whether or not this antigen test is suitable for public screening measures mostly of asymptomatic patients to identify undetected subjects with COVID-19 without generating a considerable number of false positive results remains to be shown. Although our results are quite encouraging regarding the use of antigen test as point-of-care diagnostic which may contribute to a better control of the pandemic, we need longitudinal studied which larger patient cohorts to corroborate our results and to develop algorithms or to identify those subjects who are contagious but not detected by that test.

Author contributions Conceptualization and methodology, GW, IT and RBW; Software and formal analysis, LL; Investigation and data curation, CWO, LH and RBW; resources, AG, GW, IT and RBW; Writing—original draft preparation, LL; Writing—review and editing, AG, CWO, GW, IT, LH and RBW; Supervision, GW. All authors have read and agreed to the final version of the manuscript.

Funding There was no funding source for this study.

Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

Ethics approval This study conformed to the principles outlined in the Declaration of Helsinki and was approved by ethics committee of the Innsbruck Medical University (ID of ethical vote: 1167/2020).

Consent to participate As the study was retrospective it was exempt from informed consent.

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Flexibel

Unsere Tests sind vorgesehen für Abstriche aus dem vorderen Nasenraum – 1,5 bis 3 cm tief ab Naseneingang. Dafür sind die Tests auch extern validiert worden. Sie liefern aber auch valide Ergebnisse, wenn die Abstriche aus dem Rachen oder Nasen-Rachen-Raum entnommen werden..

Eine durch AESKU beauftragte externe Studie bei der DAkkS-akkreditierten European Society for External Quality Assessment (ESfEQA) ergab, dass die Abstrich-Ergebnisse aus dem vorderen Nasenraum bzw. aus dem Rachen und Nasen-Rachen-Raum bei identifizierten COVID-19 Patienten und gesunden Probanden übereinstimmten.

Zusätzliche Informationen:

- Studie Lindner A K, Drosten C, Denkinger C M 2020 (Link)
- Externe Validierungsstudie ESfEQA (Link)
- AESKU Flyer (Link)

ESfEQA
European Society for
External Quality Assessment

Evaluation of the AESKU SARS-CoV-2 Antigen Rapid Test

Purpose of the Study

The objective of this performance study is to establish the diagnostic sensitivity and diagnostic specificity of the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit (REF: 840001) and to provide data to demonstrate the product is effective for its intended use.

Product Information

Manufacturer	AESKU.DIAGNOSTICS GmbH & Co. KG Mikroforum Ring 2 55234 Wendelsheim Germany Tel.: +49 6734 9622 0, info@aesku.com, www.aesku.com
Test Name	AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit (REF: 840001)
Detection Method	Immunochromatographic Test using a colored polymer-labeled novel coronavirus monoclonal antibody
Intended Use	Qualitative Detection of the N protein antigen from SARS-CoV-2 in human nasal swab specimen
Specimen	human nasal swab
Content of Testkit	AESKU.RAPID SARS-CoV-2 antigen test cassette Specimen processing tube Specimen sampling swab
Storage Condition	4-30°C
Lot number	P202010005 (exp date 09.04.2020), P202011003 (exp date 09.05.2020)

Study Management

Sample Collection

Biomex GmbH, Siemensstr. 38, 69123 Heidelberg, Germany

Investigation

Hannes Deisel, Biomex GmbH, Siemensstr. 38, 69123 Heidelberg, Germany
Sabine Szczesny, Biomex GmbH, Siemensstr. 38, 69123 Heidelberg, Germany
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Study Coordinator and Author

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Testing Site

Biomex GmbH, Siemensstr. 38, 69123 Heidelberg, Germany

Timelines

The Study was performed in November and December 2020

Study Design

Samples

- 148 nasal swabs and 19 throat swabs from donors with known SARS-CoV-2 infection. Sex, age and symptoms of the donors as well as date of onset of symptoms were known. The date of infection was presumed from indications by the donor. Date of swab collections were documented. Samples were collected within 7 days after onset of symptoms.
- 164 nasal swabs and 50 throat swabs from healthy donors: Sex, age and date of sample collection were known (see annex "Comparison study SARS COV-2_AESKU Rapid Test and PCR Test").

The nasal and throat swabs were collected between October 26th and December 12th and were stored at or below -20°C before they were analyzed.

Analytical investigation

The study was performed on three separate days. Each sample was analyzed with the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test kit and immediately afterwards with the R-Biopharm (Darmstadt, Germany) real-time RT-PCR kit (see below). Identical sample preparations were used for both analytical methods.

Sample swabs were extracted in the AESKU.RAPID SARS-CoV-2 specimen processing tube as described in the IFU of the rapid test. Three drops of the specimen (approximately 145 µL) were added to the sample well of the test cassette. Results obtained with the rapid test device were visually read-out by two operators between 15 and 20 minutes after the sample had been applied onto the test cassette. Digital images were taken from used rapid test cassettes after visual read-out.

Total RNA was extracted from 300 µL of the remaining liquid using the R-Biopharm RIDA Xtract (REF:PGZ001) lot QL2000033 and lot QL200009, expiry date April 2022, and analyzed with the R-Biopharm RIDA Gene SARS-CoV-2 RUO real-time PCR kit (REF:PG6815 RUO) lot 24110N, expiry date March 2022, lot 26160N, expiry date April 2022, and RIDA Gene SARS-CoV-2 real time PCR kit (REF:PG6815) lot 24450N, expiry date November 2022. The instructions of the real-time RT-PCR kit manufacturer were followed with the exception that 300 µl instead of 400 µl of the solution was used for the extraction due to the limited volume in the specimen processing tube.

Real-time RT-PCR analysis was performed in duplicate analysis for all samples that were collected from infected donors and conducted using a CFX96 Touch Real-Time PCR Detection System from Bio-Rad Laboratories (Hercules, USA). The real-time RT-PCR results were obtained as Ct values. Samples with a Ct value above 36 (mean of the two replicates) were excluded from any statistical evaluation in this study.

Results

In total 381 samples were tested in parallel with the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test and the R-Biopharm real-time RT-PCR assay and included in this study.

Definitions

True positive sample: sample that was determined positive both using the AESKU.RAPID SARS-CoV-2 Antigen test and by RT-PCR.

False positive sample: sample that was determined positive using the AESKU.RAPID SARS-CoV-2 Antigen test, but negative by RT-PCR.

True negative sample: sample that was determined negative both using the AESKU.RAPID SARS-CoV-2 Antigen test and by RT-PCR.

False negative sample: sample that was determined negative using the AESKU.RAPID SARS-CoV-2 Antigen test but positive by RT-PCR.

Specificity (%): # true negative samples/(# true negative samples + # false positive samples) x 100

Sensitivity (%): # true positive samples/(# true positive samples + # false negative samples) x 100

Analytical Results for all samples with PCR result either negative or positive with a Ct value of less than 32:

		RT-PCR	
		positive	negative
AESKU.RAPID SARS-CoV-2 Antigen test	positive	105	4
	negative	4	218

Specificity of AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit: 98% (218/222), CI: 95-99%
Sensitivity of AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit (Ct < 32): 96% (105/109), CI: 91-99%

Analytical Results with correlation to Ct-values of the samples:

Ct value	Number of Samples	Number of true positive Rapid Test Samples	Number of false negative Rapid Test Samples	Sensitivity of AESKU.RAPID SARS-CoV-2 Antigen test (CI)
< 30	77	77	0	100 % (95-100)
< 32	105	101	4	96 % (91-99)
< 34	136	123	13	90 % (84-94)
< 36	157	133	24	85 % (78-90)

The correlation between the Ct-values of the analyzed samples and the sensitivity reveals a sensitivity of 100% for samples with a Ct-value of up to 30. Samples with a higher Ct value in the real-time RT-PCR and consequently less viral RNA copies as well as viral antigen in the samples result in lower

sensitivity values for the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test. This is in line with expectations regarding viral detection by antigen rapid testing compared to PCR analysis.

Conclusion

The specificity and sensitivity of the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit was evaluated in this study with 381 samples collected as nasal or throat swabs. All samples were tested in parallel with the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit and a real-time RT-PCR assay. Samples with a Ct value below 32 were selected for the calculation of the sensitivity of the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit.

The specificity of the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit calculated from results of all samples was 98%, the sensitivity calculated from results of samples with a Ct-value less than 32 (105 samples) was 96% (95% CI: 91-99%). As expected, the sensitivity decreases by including samples with higher Ct value. Thus, by including all samples with a Ct value of or below 36 (157 samples) the sensitivity is calculated as 85% (95% CI: 78-90%).

In conclusion, the results from this study confirm that the AESKU RAPID SARS-CoV-2 Antigen Rapid Test Kit can be used for the qualitative detection of antigen from SARS-CoV-2 in human nasal swab and throat swab specimens.

Approval

This study complements version 002 of the 'Evaluation of the AESKU SARS-CoV-2 Antigen Rapid Test' by including a larger number of samples.

Version 003 of the Evaluation Study Aesku Diagnostics SARS-CoV-2 Antigen Test was created and approved in December 2020 by the following persons:

Do-it-yourself

Leicht verständliche Anleitung und Probeentnahme aus der Nase.

Eine selbsterklärende, reichbebilderte Anleitung zur Probenentnahme aus der Nase in Anlehnung an das Schema der CDC (Centers for Disease Control and Prevention = Behörde des US-amerikanischen Gesundheitsministeriums) . Unsere Anleitung führt Sie in wenigen einfachen Schritten zu ihrem Testergebnis nach nur 15 Minuten.

Die Einfachheit der selbstdurchgeführten Probenentnahme wurde in einer externen Anwendbarkeitsstudie an 16 bis 84jährigen Probanden durch das ESfEQA bescheinigt

Zusätzliche Informationen:

- CDC-Schema (Link)
- Studie Lindner A K, Drosten C, Denkinger C M 2020 (Link)
- Externe Anwendbarkeitsstudie ESfEQA (Link)
- AESKU Flyer (Link)

Head-to-head comparison of SARS-CoV-2 antigen-detecting rapid test with self-collected anterior nasal swab versus professional-collected nasopharyngeal swab

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Abstract

Background: Two antigen-detecting rapid diagnostic tests (Ag-RDTs) are now approved through the WHO Emergency Use Listing procedure and can be performed at the point-of-care. However, both tests use nasopharyngeal (NP) swab samples. NP swab samples must be collected by trained healthcare personnel with protective equipment and are frequently perceived as uncomfortable by patients.

Methods: This was a manufacturer-independent, prospective diagnostic accuracy study with comparison of a supervised, self-collected anterior nose (AN) swab sample with a professional-collected NP swab sample, using a WHO-listed SARS-CoV-2 Ag-RDT, STANDARD Q COVID-19 Ag Test (SD Biosensor), which is also being distributed by Roche. The reference standard was RT-PCR from an oro-/nasopharyngeal swab sample. Percent positive and negative agreement as well as sensitivity and specificity were calculated.

Results: Among the 289 participants, 39 (13.5%) tested positive for SARS-CoV-2 by RT-PCR. The positive percent agreement of the two different sampling techniques for the Ag-RDT was 90.6% (CI 75.8-96.8). The negative percent agreement was 99.2% (CI 97.2-99.8). The Ag-RDT with AN sampling showed a sensitivity of 74.4% (29/39 PCR positives detected; CI 58.9-85.4) and specificity of 99.2% (CI 97.1-99.8) compared to RT-PCR. The sensitivity with NP sampling was 79.5% (31/39 PCR positives detected; CI 64.5-89.2) and specificity was 99.6% (CI 97.8-100). In patients with high viral load (>7.0 $\log_{10}$ RNA SARS-CoV2/swab), the sensitivity of the Ag-RDT with AN sampling was 96% and 100% with NP sampling.

Conclusion: Supervised self-sampling from the anterior nose is a reliable alternative to professional nasopharyngeal sampling using a WHO-listed SARS-CoV-2 Ag-RDT. Considering the ease-of-use of Ag-RDTs, self-sampling and potentially patient self-testing at home may be a future use case.

To the Editor:

A number of antigen-detecting rapid diagnostic tests (Ag-RDTs) for SARS-CoV-2 are now commercially available and can result in rapid decisions on patient care, isolation and contact tracing at the point-of-care [1]. Two Ag-RDTs using nasopharyngeal (NP) swab samples meet WHO targets and are now approved through the WHO Emergency Use Listing procedure [2-4].

NP swab samples are frequently perceived as uncomfortable by patients and must be collected by trained healthcare personnel with protective equipment. Evidence supports the use of alternative sampling methods for RT-PCR, including anterior nasal (AN) swabs collected by patients and some tests have received regulatory approval with AN samples [5, 6]. Considering the ease-of-use of Ag-RDTs, a reliable simple sampling method would not only allow self-sampling, but may also pave the way for self-testing.

The primary objective of this prospective diagnostic accuracy study was a head-to-head comparison (positive and negative percent agreement) of a supervised, self-collected AN swab sample with a health care worker (professional)-collected NP swab sample, using a WHO-listed SARS-CoV-2 Ag-RDT against the reference standard RT-PCR collected from a NP/oropharyngeal (OP) swab. The secondary objective was to assess sensitivity and specificity for different sampling techniques with Ag-RDT. The study was continued until at least 30 positive NP swab samples according to Ag-RDT were obtained. This manufacturer-independent study was conducted in partnership with the Foundation of Innovative New Diagnostics (FIND), the WHO collaborating centre for COVID-19 diagnostics.

The study protocol was approved by the ethical review committee at Heidelberg University Hospital for the study site in Berlin (registration number S-180/2020). The study took place at the ambulatory SARS-CoV-2 testing facility of Charité University Hospital (Charité-Universitätsmedizin Berlin, Germany) from 23 September to 14 October 2020. The study enrolled adults at high risk for SARS-CoV-2 infection according to clinical suspicion. Participants were excluded if either of the swabs for the Ag-RDT or the RT-PCR reference standard could not be collected.

Participants underwent first an instructed, self-collected bilateral AN swab for the Ag-RDT. Verbal instruction was given to insert the swab horizontally 2-3 cm into the nostril and rotate it for 15 seconds against the nasal walls on each side. Deviations from the instructed technique were recorded. Subsequently, a combined OP/NP swab (eSwab from Copan) as per institutional recommendations for RT-PCR, and a separate NP swab for the Ag-RDT were taken from different sides of the nose. The samples for the Ag-RDTs were collected using the swab provided by the manufacturer within the test kit.

The Ag-RDT evaluated in this study was the STANDARD Q COVID-19 Ag Test (SD Biosensor, Inc. Gyeonggi-do, Korea; henceforth called STANDARD Q) [7], which is also being distributed by Roche [8]. The test uses the lateral flow assay principle in a cassette-based format with a visual read-out after 15-30 minutes. The manufacturer's instructions for use were followed. The Ag-RDTs were performed directly after sampling (within 60 minutes) at point-of-care by study physicians. The Ag-RDT results were interpreted by two operators, each blinded to the result of the other. The second reader was also blinded to the second Ag-RDT results of individual patients. The visual read out of the Ag-RDT test band was categorized on a semi-quantitative scale as negative, weak positive, positive and strong positive.

The Roche Cobas SARS-CoV-2 assay (Pleasanton, CA United States) or the SARS-CoV-2 E-gene assay from TibMolbiol (Berlin, Germany) were performed for RT-PCR according to routine procedures at the central laboratory. Viral RNA concentrations were calculated using assay specific CT-values, based on external calibrations curves [9, 10]. Staff performing the Ag-RDTs were blinded to results of RT-PCR tests and vice versa.

Of 303 patients invited, 289 (95.4%) consented to participate. Two patients were excluded as both swabs for the Ag-RDT could not be obtained. The average age of participants was 34.7 years (Standard Deviation [SD] 11.0) with 42.9% female and 19.0% having comorbidities. On the day of testing, 97.6% of participants had one or more symptoms consistent with COVID-19. Duration of symptoms at the time of presentation on average was 4.4 days (SD 2.7). Among the 289 participants, 39 (13.5%) tested positive for SARS-CoV-2 by RT-PCR (Table 1).

No invalid tests were observed on either AN or NP samples. Two patients were detected by NP but not by AN sampling. No patient was detected by AN sampling only. The positive percent agreement was 90.6% (CI 75.8-96.8; including 2 false positive results with AN and 1 with NP). The negative percent agreement was 99.2% (CI 97.2-99.8). Inter-rater reliability was near perfect with kappa of 0.98 for AN and 1.0 for NP samples. The semi-quantitative read-out was more often higher for the NP samples (9 higher on NP, 4 higher on AN). Of the two patients detected by NP but not by AN sampling, one patient collected the AN swab only with gentle rotation, the second presented 10 days post symptom onset with a low viral load (Table 1).

The STANDARD Q Ag-RDT with AN sampling showed a sensitivity of 74.4% (29/39 PCR positives detected; CI 58.9-85.4) and specificity of 99.2% (CI 97.1-99.8) compared to RT-PCR. The sensitivity with NP sampling was 79.5% (31/39 PCR positives detected; CI 64.5-89.2) and specificity was 99.6% (CI 97.8-100). In patients with high viral load (>7.0 $\log_{10}$ RNA SARS-CoV2/swab), the sensitivity of the Ag-RDT with AN sampling was 96% (24/25 PCR positives detected; CI 80.5-99.8) and 100% (25/25 PCR positives detected; CI 86.7-100) with NP sampling. In contrast, the Ag-RDT frequently did not detect patients with lower viral load or with symptoms >7 days (Table 1). For most patients, the application of the

flexible swab (meant for NP swab collection) in the anterior nose appeared unpleasant due to a tickling sensation and led to frequent sneezing.

The strengths of the study are the rigorous methods, including standardized sampling, two independent blinded readers and an additional semi-quantitative assessment of Ag-RDT results. The cohort was representative, judging from the comparable sensitivity observed in the recent independent validation study of STANDARD Q (sensitivity 76.6%; CI 62.8-86.4) [4]. The study is limited as it was performed in a single centre. Also, the NP swab was usually rotated against the nasopharyngeal wall for less time than recommended by the manufacturer, which may have a negative impact on the sensitivity of the Ag-RDT with NP sampling, but also reflects the difficulty of collection of this sample type.

In conclusion, this study demonstrates that supervised self-sampling from the anterior nose is a reliable alternative to professional nasopharyngeal sampling with STANDARD Q. The data will contribute to WHO recommendations for use of this test. Considering the ease-of-use of Ag-RDTs, self-sampling and potentially patient self-testing at home may be a future use case. If such testing could be repeated frequently and immediately ahead of situations when transmissions are likely to occur, self-testing with Ag-RDTs may have a significant impact on the pandemic. Further implementation studies on optimized self-sampling techniques and swabs (e.g. less flexible sponge swab) and the correct performance/interpretation of the test by patients themselves, are urgently needed to drive self-testing to scale.

TABLE 1 Antigen-detecting RDT results with a supervised self-collected anterior nasal (AN) swab and with a professional-collected nasopharyngeal (NP) swab in RT-PCR positive patients from combined oro-/nasopharyngeal swab. CT-values and viral load (in descending order) of the paired RT-PCR samples are shown, as well as the duration of symptoms per patient. The positive percent agreement between AN and NP samples on Ag-RDT, as well as the respective sensitivities compared to RT-PCR are shown.

No.	AN swab self-collected SD Q Ag-RDT	NP swab prof.-collected SD Q Ag-RDT	OP/NP swab RT-PCR		Symptom duration (days)
			CT value	Viral load[3]	
1	pos (+++)	pos (+++)	17.33[1]	9.92	2
2	pos (++)	pos (+++)	17.86[1]	9.76	1
3	pos (+++)	pos (+++)	18.01[1]	9.71	1
4	pos (++)	pos (+++)	18.31[1]	9.62	3
5	pos (+++)	pos (+++)	18.40[1]	9.60	3
6	pos (+++)	pos (+++)	18.76[1]	9.49	4
7	pos (+++)	pos (+++)	18.77[1]	9.49	5
8	pos (+++)	pos (+++)	18.78[1]	9.49	5
9	pos (+++)	pos (+++)	19.05[1]	9.41	3
10	pos. (+++)	pos. (+++)	19.40[1]	9.30	2
11	neg.	pos (+++)	19.66[1]	9.23	1
12	pos (+++)	pos (+++)	20.32[1]	9.03	3
13	pos (++)	pos (+++)	20.44[1]	9.00	2
14	pos (++)	pos (++)	20.54[1]	8.96	5
15	pos (+++)	pos (+++)	17.81[2]	8.86	4
16	pos (+++)	pos (+++)	21.09[1]	8.80	4
17	pos (+++)	pos (+)	18.62[2]	8.62	4
18	pos (+)	pos (++)	21.87[1]	8.57	7
19	pos (++)	pos (+++)	22.05[1]	8.52	2
20	pos (++)	pos (+++)	19.34[2]	8.41	5
21	pos (+++)	pos (+++)	19.47[2]	8.37	6
22	pos (+++)	pos (+++)	22.60[1]	8.36	6
23	pos (+++)	pos (++)	23.66[1]	8.04	6
24	pos (+)	pos (++)	26.42[1]	7.23	5
25	pos (+++)	pos (+++)	26.77[1]	7.12	5
26	neg.	neg.	24.25[2]	6.96	10
27	pos (++)	pos (+++)	24.77[2]	6.80	4
28	pos (+++)	pos (++)	25.29[2]	6.64	2
29	pos (+)	pos (++)	29.33[1]	6.36	5
30	neg.	neg.	29.56[1]	6.30	3
31	neg.	neg.	29.95[1]	6.18	3
32	pos (+)	pos (+)	30.25[1]	6.09	4
33	neg.	neg.	27.81[2]	5.90	8
34	pos (++)	pos (+)	31.20[1]	5.81	8
35	neg.	pos (+)	31.61[1]	5.69	10
36	neg.	neg.	32.58[1]	5.40	10
37	neg.	neg.	32.86[1]	5.32	2
38	neg.	neg.	34.62[1]	4.80	7
39	neg.	neg.	35.53[1]	4.53	14
	Sensitivity 29/39 (74.4%)	**Sensitivity** 31/39 (79.5%)			
	Positive percent agreement[4] 90.6% (CI 75.8-96.8)				

[1] Roche Cobas SARS-CoV-2 assay (E-gene, T2 target)
[2] TibMolbiol assay, E-gene target.
[3] $\log_{10}$ RNA SARS-CoV2/swab
[4] including 2 false positives on AN and 1 on NP

Abbreviations: No., patient number; SD Q, STANDARD Q COVID-19 Ag Test (SD Biosensor); Ag-RDT, antigen-detecting rapid diagnostic test; AN, anterior nasal; NP, nasopharyngeal; OP, oropharyngeal; CT, cycle threshold; RT-PCR, reverse transcription-polymerase chain reaction; neg., negative; pos (+), weak positive; pos. (++), positive; pos. (+++), strong positive.

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Author contributions: AKL, LJK, FL and CMD designed the study and developed standard operating procedures. AKL and ON implemented the study design, enrolled patients, performed laboratory work and led the writing of the manuscript. FPM and JS coordinated and supervised the study site. FK, MW, FH enrolled patients. MGe coordinated the testing facility. MGa, LK and FT led the data analysis. VC, JH and CD were responsible for PCR testing and contributed to the interpretation of the data. JAS supported the study design setup and the interpretation of the data. CMD was the principle investigator of the study. All authors have reviewed the manuscript.

Data availability: All raw data and analysis code are available upon a request to the corresponding author.

Conflict of interest: None declared.

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Komfortabel

Probenentnahme in der Nase, in nur 2,5cm Tiefe.

Die *Centers for Disease Control and Prevention* (CDC) in den USA und eine Studie der Charité mit der Universität Heidelberg , dem DZIF, dem Labor Berlin und der Foundation for Innovative New Diagnostics (Schweiz) zeigen, dass eine Probenentnahme im vorderen Bereich der Nase (zwischen 1,5 und 3cm) gleiche Ergebnisse liefert wie die Probenentnahme aus dem Rachen oder dem Nasen-Rachen-Raum.

Zusätzliche Informationen:

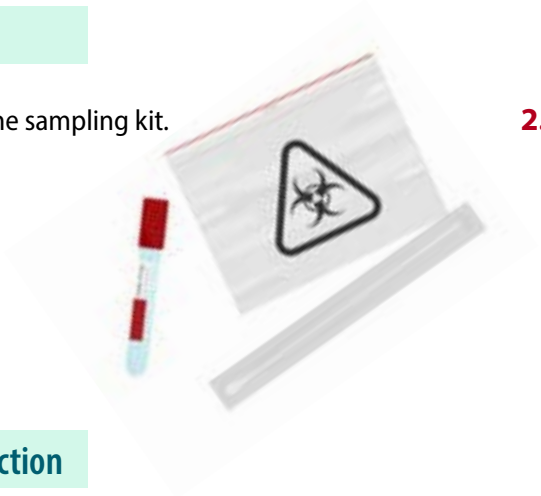
- CDC-Schema (Link)
- Studie Lindner A K, Drosten C, Denkinger C M 2020 (Link)
- Externe Validierungsstudie ESfEQA (Link)
- Externe Anwendbarkeitsstudie ESfEQA (Link)
- AESKU Flyer (Link)

HOW TO COLLECT YOUR ANTERIOR NASAL SWAB SAMPLE FOR COVID-19 TESTING

Follow the instructions included with your sample kit. Use **only** materials provided in your kit to collect and store your sample, unless the kit says to do otherwise. Use **only** an approved sample collection kit given to you by your healthcare provider or personnel at the testing center.

Initial set-up

1. Open the sampling kit.

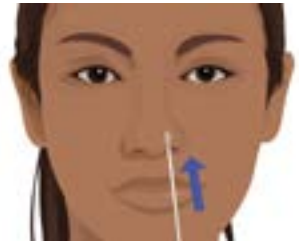


2. Apply hand sanitizer with at least 60% alcohol. Cover all surfaces of your hands and rub them together until they feel dry.

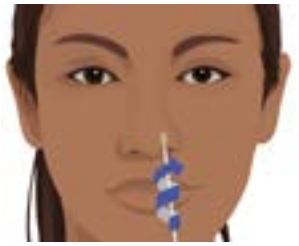
Sample collection

3. Remove the swab from the container, being careful not to touch the soft end, which is the absorbent tip.

4. Insert the entire absorbent tip of the swab into your nostril, but do not insert the swab more than ¾ of an inch (1.5 cm) into your nose.



5. Slowly rotate the swab in a circular path against the inside of your nostril at least 4 times for a total of 15 seconds. Be sure to collect any nasal drainage that may be present on the swab.



6. Gently remove the swab.

7. Using the same swab, repeat steps 4-6 in your other nostril.

cdc.gov/coronavirus

CS 317702-C 11/13/2020

Preparation of sample for return

8. Place the swab in the sterile tube and snap off the end of the swab at the break line. Place the cap on the tube.

9. Re-apply hand sanitizer.

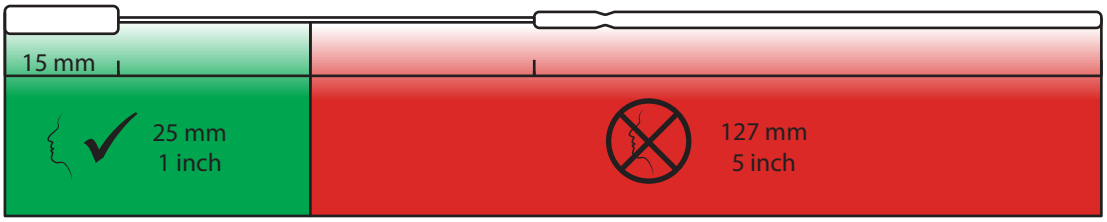
10. Place the tube containing the swab in the biohazard bag provided and seal the bag.

Returning the sample and clean-up

11. Give the bag with the swab to testing personnel.

12. Throw away the remaining sample kit items.

13. Re-apply hand sanitizer.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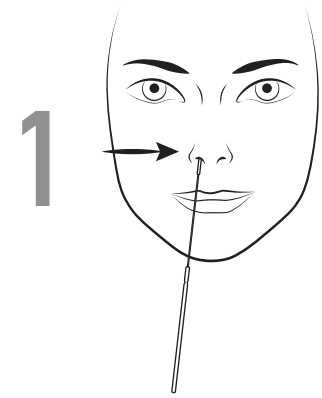
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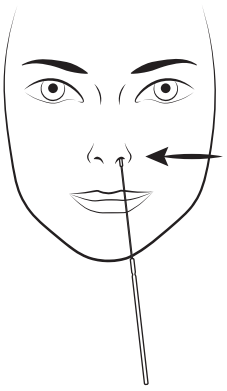
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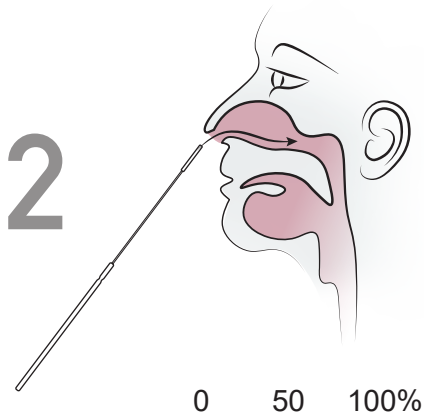
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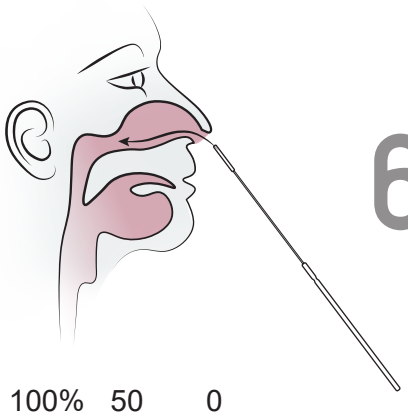
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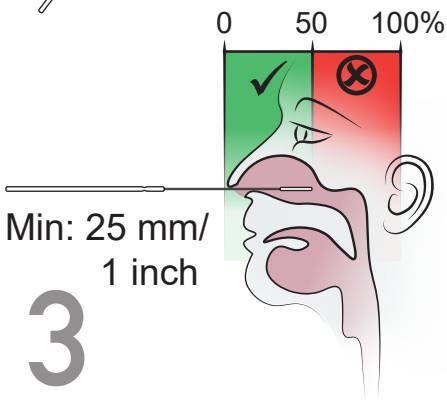
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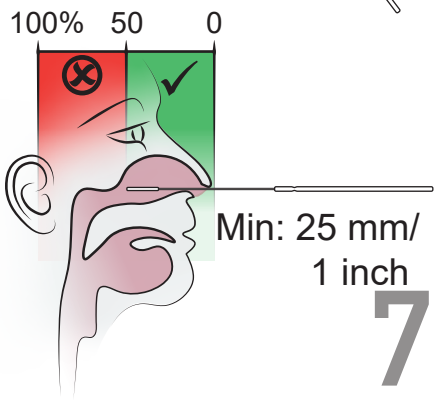
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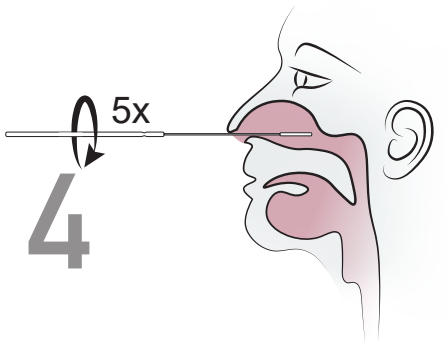
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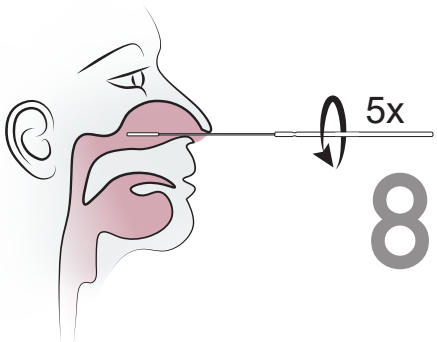
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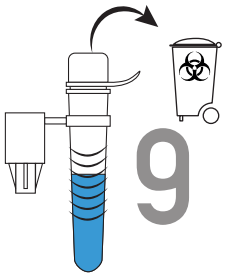
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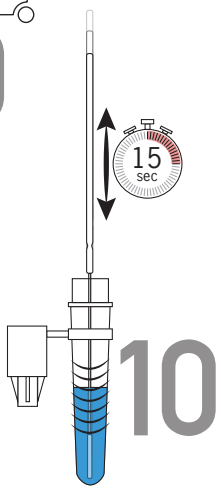
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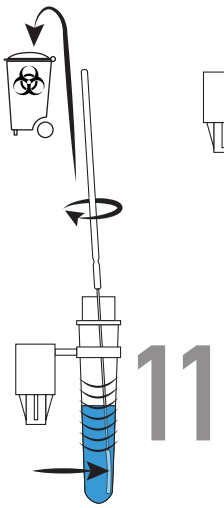
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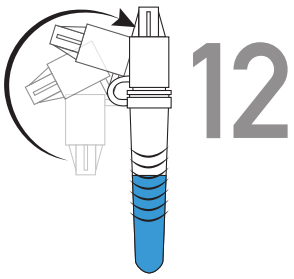
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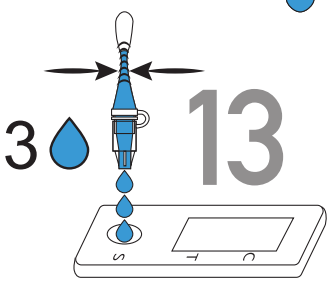
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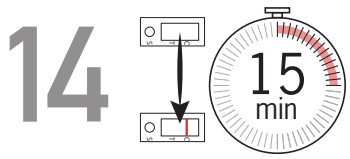
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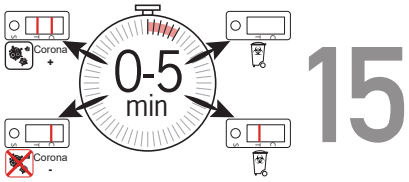
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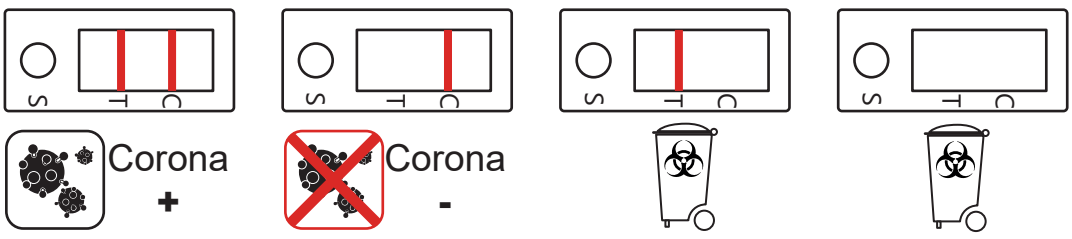
Corona
+
Corona
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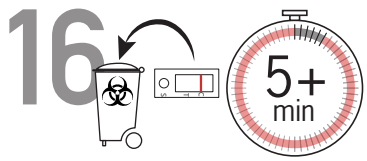
16
5+
min

Usability Study of the AESKU SARS-CoV-2 Antigen Rapid Test

Purpose of the Study

The objective of this usability study is to evaluate the usability of the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit (REF: 840001) and to provide data to demonstrate that the product can be used safely by professional and laypersons.

Product Information

Manufacturer	AESKU.DIAGNOSTICS GmbH & Co. KG Mikroforum Ring 2 55234 Wendelsheim Germany Tel.: +49 6734 9622 0, info@aesku.com, www.aesku.com
Test Name	AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit (REF: 840001)
Detection Method	Immunochromatographic Test using a colored polymer-labeled novel coronavirus monoclonal antibody
Intended Use	Qualitative Detection of the N protein antigen from SARS-CoV-2 in human nasal swab specimen
Specimen	human nasal swab
Content of Testkit	AESKU.RAPID SARS-CoV-2 antigen test cassette Specimen processing tube Specimen sampling swab
Storage Condition	4-30°C
Lot number	P202010005
Expiration Date	09.04.2022

Study Management

Questionnaire

A questionnaire for the usability evaluation of the AESKU.RAPID SARS-CoV-2 Antigen test was developed by ESfEQA GmbH, Siemensstr. 38, 69123 Heidelberg, Germany

Study Coordinator

ESfEQA GmbH, Siemensstr. 38. 69123 Heidelberg, Germany
Tel.: 06221 89466971, groche@esfeqa.eu

Timelines

The Study was performed in November 2020

Study Design

Test persons

Professionals experienced in IvD testing as well as laypersons were involved in this study.

Items provided to the test persons

- AESKU.RAPID SARS-CoV-2 Antigen test, consisting of AESKU.RAPID SARS-CoV-2 antigen test cassette, specimen processing tube and specimen sampling swabs
- Gebrauchsanweisung AESKU.RAPID SARS-CoV-2 Rapid Test (in German language), Version 001 (Draft)
- Illustration of sample collection and test procedure (see annex)
- Questionnaire 'Fragebogen zum Usability-Test AESKU.Rapid SARS-CoV-2 Rapid Test' (in German language), Version 1, November 2020 (see annex)

Results

Eleven individuals of the age between 16 and 84 years (5 female, 6 male) were selected for this usability study. The participants represent a wide range of age groups. Among them were 3 persons trained for performing in-vitro-diagnostic test. All participants were German-native speakers or at least fluent in German language.

The questionnaire addresses questions about the comprehension of the test procedure as well as the practical application of the test device. The individual questions (17 in total) could be answered in 5 different grades from very easy/perfect to very difficult/need of improvement.

All questions of the questionnaire were answered predominantly by the two highest grades (very easy/easy and perfect/almost perfect). The illustrations in the Instruction for Use ('Gebrauchs-anweisung') and the description for the interpretation of test results were rated once as 'rather difficult'.

Several participants of this study (laypersons) missed the description of the sample collection in the chapter 'test execution' since they regard the sample collection as part of it. Instead, the sample collection is described in the IFU in the separate chapter 'sample material'. The separation of the description of the sample collection and testing procedure in the 1st version of the IFU may be reconsidered.

One participant of the study missed instructions in the IFU for the interpretation of a faint test line.

Conclusion

The usability of the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit (REF: 840001) was evaluated in this study. The participants of this study, professionals in IvD testing as well as laypersons, have rated the comprehensibility as well as the practical test procedure predominantly as very easy to easy. Participants recommended to reconsider the separation of sample collection and test execution in two separate chapters in the IFU.

In conclusion, based on the predominantly positive feedback of the participants, the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit is evaluated as easy to use.

Approval

Usability study of the AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit, Version 001 November 2020

Studie zur Validität des AESKU SARS-CoV-2 Antigen Rapid Test bei 2-8°C

Ziel der Studie

Das Ziel dieser Studie ist die Überprüfung der Validität des AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit (REF: 840001) bei Anwendung unter niedrigen Umgebungstemperaturen (2-8°C).

Produkt Information

Hersteller	AESKU.DIAGNOSTICS GmbH & Co. KG Mikroforum Ring 2 55234 Wendelsheim Germany Tel.: +49 6734 9622 0, info@aesku.com, www.aesku.com
Testname	AESKU.RAPID SARS-CoV-2 Antigen Rapid Test Kit
Nachweismethode	Immunochromatographischer Test mit einem farbigen polymermarkiertem monoklonalen Coronavirus-Anitkörper
Verwendungszweck	Qualitativer Nachweis des N-Protein-Antigens von SARS-CoV-2 in humanen Nasenabstrich-Proben
Untersuchungsmaterial	Humane Nasenabstrich- und Rachenabstrich-Proben
Test-Komponenten	COVID-19 Antigen-Test-Kassette Probenröhrchen mit Extraktionspuffer Probentupfer
Lagerungsbedingungen	4-30°C
Chargen-Nummer	P202011003
Verfallsdatum	2022-05

Studiendesign

Teilnehmer

An der Studie haben 14 Testpersonen teilgenommen, die keine Symptome einer Corona-Infektion zeigten.

Durchführung

Hannes Deisel, Biomex GmbH, Siemensstr. 38, 69123 Heidelberg, Germany
Dr. Heike Lukhaup, Biomex GmbH, Siemensstr. 38, 69123 Heidelberg, Germany

Ort der Durchführung

Lager der Biomex GmbH, Temperatur: 2-8°C

Probenmaterial

14 Nasenabstriche und 14 Rachenabstriche von gesunden Spendern: Geschlecht, Alter und Datum der Probenentnahme sind bekannt.

Ergebnisse

An der Studie haben 14 Personen (3 weiblich, 11 männlich) im Alter zwischen 19 und 63 Jahren teilgenommen. Von jedem Teilnehmer wurde jeweils 1 Nasen- und 1 Rachenabstrich getestet.

Die Tests wurden bei einer Temperatur von 2-8°C durchgeführt, das Testmaterial wurde direkt aus der Kühlzelle (2-8°C) entnommen und nicht auf die vorgeschriebene Raumtemperatur aufgewärmt. Ziel war es die Validität des Tests auch bei niedrigen Umgebungstemperaturen zu überprüfen und falsch positive Ergebnisse auszuschließen.

Alle 28 getesteten Proben waren wie erwartet negativ, d.h. es wurde eine Spezifität von 100% erreicht.

Zusammenfassung

In dieser Studie wurde die Validität des AESKU.RAPID SARS-CoV-2 Antigen Rapid auch bei niedrigen Umgebungstemperaturen überprüft. Da alle 28 getesteten Proben ein eindeutig negatives Ergebnis ergaben, ist die Durchführung des Tests auch bei niedrigen Umgebungstemperaturen möglich und es werden valide Ergebnisse erhalten.


Gewissheit in 15 min
AESKU.RAPID
SARS-CoV-2 Rapid Test
Extern evaluiert durch
ESfEQA
European Society for
External Quality Assessment
AESKU.RAPID
20 Tests
SARS-CoV-2 Rapid Test
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5 Tests
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AESKU.RAPID

SARS-CoV-2 Rapid Test

Der ***AESKU.RAPID*** SARS-CoV-2 Schnelltest basiert auf immunchromatographischer Polymertechnologie kombiniert mit dem Sandwich-Prinzip zum qualitativen Nachweis des Nukleokapsid-Protein-Antigens in humanen Nasenabstrich-Proben. Die Probe wird hierbei in der Probenvertiefung der Testkassette mit farbigem polymermarkiertem monoklonalem SARS-CoV-2-Antikörper 1 gemischt und entlang der Nitrozellulosemembran chromatographiert. Liegen SARS-CoV-2-Antigene in der Probe vor, binden diese an den SARS-CoV-2-Antikörper 1. Das Gemisch bindet im Anschluss an den immobilisierten SARS-CoV-2-Antikörper 2 auf der Nitrozellulosemembran. Der so entstandene Komplex aus Antikörper 1, Antigen und Antikörper 2 bildet die farbige Testlinie. Die Kontrolllinie der Testkassette ist mit sekundären Antikörpern beschichtet, wodurch sich bei normalem Testablauf ein farbiger Streifen abzeichnet.

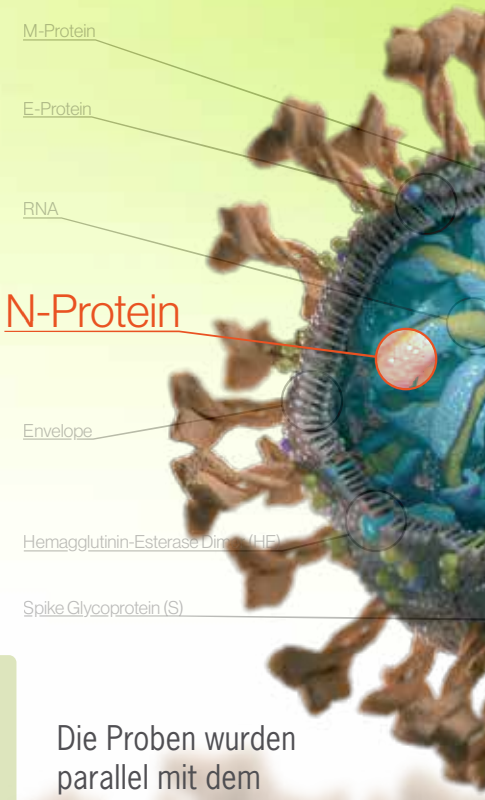
ESfEQA Evaluation Study: AESKU SARS-CoV-2 Antigen Rapid Test

Version 003, Dezember 2020

AESKU.RAPID

Sensitivität	**100% C_t-Wert ≤ 30,0 (95% CI 95%-100%)**
Spezifität	**98% (95% CI 95%-99%)**

	RT-PCR		
	Positiv	Negativ	Total
Positiv	105	4	109
Negativ	4	218	222
Total	109	222	331

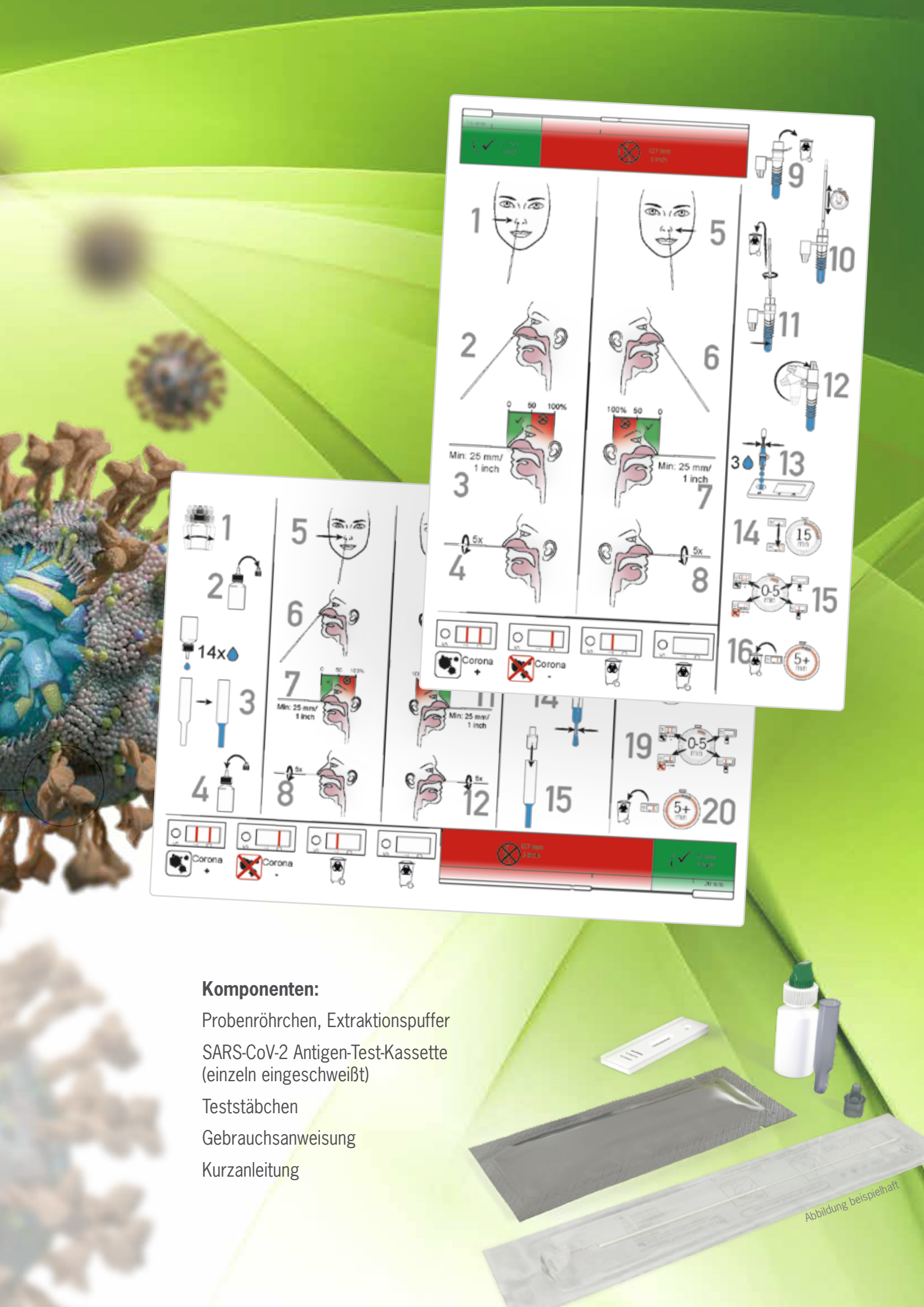


Die Proben wurden parallel mit dem RT-PCR Test eines führenden Europäischen Herstellers getestet.

Extern evaluiert durch ESfEQA
European Society for External Quality Assessment

„…, die Ergebnisse zeigen eine herausragende Sensitivität des AESKU.RAPID SARS-CoV-2-Antigen-Schnelltestkits im Vergleich zu anderen kommerziellen SARS-CoV-2-Antigen-Tests."

Positive Testergebnisse bestätigen das Vorhandensein viraler Antigene.
Negative Testergebnisse schließen COVID-19 nicht vollkommen aus.
Eine klinische Anamnese des Patienten ist jedoch weiterhin notwendig, um den Infektionsstatus zu bestimmen.



Komponenten:

Probenröhrchen, Extraktionspuffer

SARS-CoV-2 Antigen-Test-Kassette (einzeln eingeschweißt)

Teststäbchen

Gebrauchsanweisung

Kurzanleitung

Produktdetails

Antigen-Schnelltest zum direkten Nachweis von SARS-CoV-2 NP Antigen

Schnelles Testergebnis nach 15 Minuten

Lateral-Flow-Prinzip basierend

Testmaterial: minimalinvasiver Nasenabstrich (2,5 cm Tiefe)

Sehr hohe Sensitivität:

100% C_t-Wert ≤ 30,0 (95% CI 95%-100%)

Sehr große Spezifität 98% (95% CI 95%-99%)

Detektionslimit von 50 $TCID_{50}$/ml

Keine Kreuzreaktivitäten festgestellt

Der Antigen-Schnelltest ist bei 4-30°C bis zu 18 Monate haltbar

Testdurchführung bei Raumtemperatur (15-30°C)

Testmaterial bitte vorher auf Raumtemperatur bringen

Jeder Test einzeln im verschweißten Folienbeutel

Packungsgrößen:

5 Tests, inkl. Verbrauchsmaterialien

20 Tests, inkl. Verbrauchsmaterialien

CE zertifiziert

Bestellinformation

REF.	Produkt:	Format:	Beschreibung:
840003	***AESKU.****RAPID* SARS-CoV-2	5 Tests	***AESKU.****RAPID* SARS-CoV-2 ist ein patientennaher Antigen-Schnelltest zum direkten Nachweis von SARS-CoV-2 NP-Antigen in humanen Nasenabstrich-Proben.
840001	***AESKU.****RAPID* SARS-CoV-2	20 Tests	***AESKU.****RAPID* SARS-CoV-2 ist ein patientennaher Antigen-Schnelltest zum direkten Nachweis von SARS-CoV-2 NP-Antigen in humanen Nasenabstrich-Proben.

VERSION 008: 2021-01-11-DE

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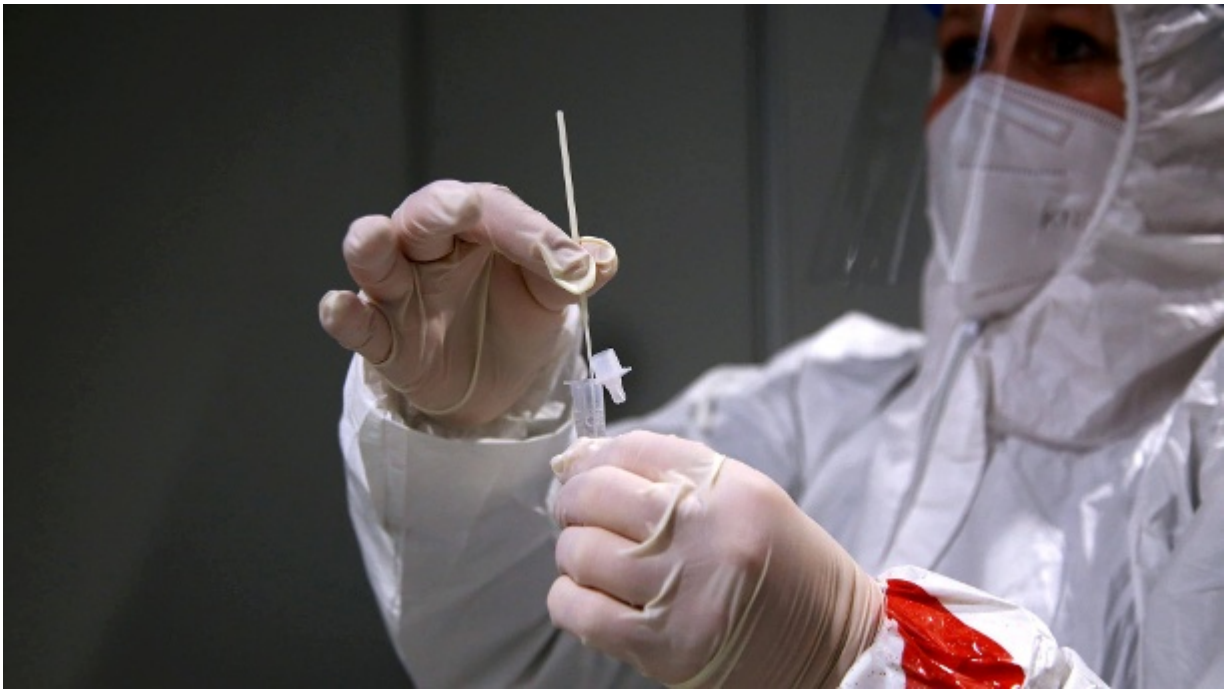
Bei geringsten Symptomen

Grüne fordern Corona-Tests für den Heimgebrauch

04.01.2021, 20:34 Uhr | Annika Leister



Ein Corona-Test: Die Grünen fordern die Erlaubnis, sich zu Hause selber auf das Virus zu testen. (Symbolbild) (Quelle: imago images)

Bisher darf nur geschultes Personal Antigen-Tests machen. Die Grünen wollen das ändern: Sie fordern die Erlaubnis für jedermann. Die Tests liefern schnellere Ergebnisse – sind aber auch unsicherer.

Sich im eigenen Badezimmer in wenigen Minuten auf Corona testen – das soll nach Plänen der Grünen in Zukunft für alle Bürger möglich sein. In einem Antrag, der t-online exklusiv vorliegt, fordert die Fraktion, die Abgabe von Antigen-Schnelltests in Apotheken an Privatpersonen zu erlauben – zur "regelmäßigen Selbstanwendung". Die Bundesregierung solle hierfür "unverzüglich" durch eine Änderung der Abgabeverordnung für Medizinprodukte sorgen, heißt es in dem Antrag, den die Fraktion noch in dieser Woche einbringen will.

"Es darf keine Barrieren mehr geben, der Erwerb und die Anwendung von Schnelltests muss erlaubt werden für Laien", sagte der Grünen-Abgeordnete Janosch Dahmen, Arzt und Mitglied des Gesundheitsausschusses, zu t-online. Neben dem Einsatz in Krankenhäusern und Pflegeheimen sollen sich nach Vorstellung der Grünen zunächst Berufsgruppen mit vielen Kontakten regelmäßig selbst testen können – im Antrag werden unter anderem Lehrkräfte, Erzieher, Verkäufer und Polizisten genannt.

Selbsttest schon bei geringsten Symptomen

Ziel sei es, die Verfügbarkeit der Tests so zu steigern, dass jeder Mensch den Test schon bei geringsten Symptomen zuhause erledigen könne. "Die Gesundheitsämter sind in Zeiten hoher

Infektionszahlen oft überfordert mit der Kontaktnachverfolgung, die Schnelltests könnten gerade in dieser Phase für die rasche Isolation von Infizierten sorgen", so Dahmen.

Auch die Berliner Grünen-Fraktionschefin Silke Gebel dringt auf den Masseneinsatz von Schnelltests. In Berlin solle die Bildungsverwaltung die Tests zuerst zügig für Lehrer zur Verfügung stellen, damit die sich mehrfach in der Woche selbst testen könnten, sagte Gebel. Außerdem sollten auch Tests für Schüler folgen.

Vorteile der Schnelltests: Sie liefern das Ergebnis sehr viel zügiger als PCR-Tests, gelten vor allem bei hoher Viruslast als zuverlässig und sind günstig in der Produktion. Ein Team um Charité-Virologe Christian Drosten veröffentlichte Mitte November eine Preprint-Studie, die Schnelltests Potential in der Pandemiebekämpfung bescheinigt: "Die unmittelbare Verfügbarkeit von Testergebnissen könnte neuartige Gesundheitskonzepte ermöglichen, bei denen die Entscheidung über eine Isolation auf dem Testen der Infektiosität und nicht der Infektion basieren."

Niedergelassene Ärzte warnen vor "trügerischer Sicherheit"

Auch das Bundesgesundheitsministerium lehnt Selbsttests bisher deutlich ab: Man wolle den Fokus beim Testen wie bisher auf den medizinischen Bereich legen, teilte ein Sprecher t-online am Montag auf Nachfrage mit. Testen ohne begründeten Verdacht erhöhe das Risiko falsch-positiver Tests und belaste die Kapazitäten.

zum Artikel