AVIS SUR L'UTILISATION D'AUTOTESTS – MISE À JOUR DÉCEMBRE 2021

RAG subgroup Testing – 21 Décembre 2021

Note : Les recommandations actuelles sont susceptibles d'être modifiées en fonction de nouvelles informations et/ou de l'évolution de l'épidémie.

Attention : Le RMG n'a pas suivi les recommandations du RAG concernant l'utilisation d'un autotest par les personnes présentant des symptômes légers ou à la fin de la période de quarantaine d'un contact à haut risque au septième jour.

Recommandations:

- Maintien des indications suivantes pour les autotests (voir Auto-tests | Coronavirus Covid-19 (sciensano.be)):
  - Par civilité, pour éviter d'infecter les autres avant d'avoir des contacts avec des personnes extérieures au foyer ;
  - Pour auto-détecter une possible infection à un stade précoce après un contact (qui n'a pas été déclaré formellement comme un contact à haut risque) où l'on craint d'avoir été infecté.
- Maintien de l'indication selon laquelle l'autotest peut être utilisé comme une stratégie possible pour le dépistage périodique au travail ou à l'école.
- Maintien de la recommandation selon laquelle les autotests ne peuvent pas être utilisés pour accéder à des événements (par exemple, pour obtenir un CST), tant qu'il y a une forte circulation de virus.
- Lorsque la situation épidémiologique est caractérisée par une incidence et un taux de positivité élevés, avec une capacité insuffisante pour obtenir un résultat rapide de RT-PCR ou de test Ag rapide réalisé par un prestataire de soins de santé, deux indications supplémentaires sont considérées comme acceptables :
  - Les personnes présentant des symptômes légers évocateurs de la COVID-19 ;
  - Pour mettre fin à la période de quarantaine d'un contact à haut risque au jour 7.
- Les autotests positifs chez les personnes testées pour ces deux dernières indications ne doivent pas être confirmés et elles sont immédiatement considérées comme cas COVID. Cependant, les autotests positifs pour les autres indications doivent toujours être confirmés par RT-PCR.
- Dans la mesure possible, tous les résultats des autotests devraient être signalés (par exemple via une plateforme en ligne).
- Maintien de la recommandation selon laquelle un autotest négatif n'exclut pas l'infection et ne dispense donc pas la personne testée de prendre toutes les mesures de précaution.
- Ne plus faire de distinction entre les personnes entièrement vaccinées et les personnes non entièrement vaccinées.
- Ne pas appliquer de limite d'âge pour l'autotest.
- **Renforcer la communication sur l'autotest, en soulignant l'importance d'une utilisation correcte et de la communication du résultat.**

Les personnes suivantes ont participé à cet avis :

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CONTEXT

The pressure on the testing capacity remains high and the delay in obtaining the test result is often long. There is anecdotal evidence that this leads to people using self-tests for purposes other than they are intended for, such as after a high risk contact. A request was therefore made to assess if the recommendations with regards to the use of self-tests, dating from May 2021, are still valid.

DISCUSSION

- The number of sold self-tests has sharply increased since end-October 2021. This roughly coincides with the start of the 4th wave, but no information is available on why people buy self-tests. There are indications that people use self-test also when having symptoms.
- Also the number of reported positive self-tests has increased. The ratio positive/sold self-tests is about 1%, but possibly not all positive self-tests are being reported.
- The performance of self-tests is depending on many factors, such as the brand used, how well they were stored, how well and in which conditions they were administered, ambient temperature, etc.
- From the few conducted studies we can conclude that compared to the standard PCR on a NPS they have on average a substantially lower sensitivity (roughly around 60%), even when viral load is high (around 80%), (which is lower than health professional-supervised rapid Ag tests). Like for HP-supervised rapid Ag tests, performance is much better during the first days after onset of symptoms. A recent study by NRC confirmed that the sensitivity is not equally distributed during an infection, and that the performance of a rapid Ag test is the lowest at the very early and late stages of the infection.
- Specificity, in contrast, appears to high, which is confirmed by the relatively high positive predictive value of the positive self-tests in Belgium.
- Several countries have recently expanded the indications for self-tests, mainly to relieve the pressure on the test capacity. Indications vary by country but some tendencies can be observed:
    - The main indications continue to be in a private setting to ensure one is not infected before visiting others and in a context of repetitive screenings;
    - Several countries now recommend it also for people presenting mild symptoms suggestive of COVID-19;

    - Some countries see a use of self-tests for high-risk contacts (for example the Netherlands in addition to the required test on day 5 to detect positive cases earlier; and the UK in fully vaccinated people in replacement of quarantine);
    - Some allow it for obtaining access to an event, if it is done on the spot under supervision.

- In most countries the rules for self-testing now apply both to fully vaccinated and non-fully vaccinated individuals.
- Most countries warn for a false sense of security and recommend people to still adhere to all preventive measures in the case of a negative test. All countries require positive self-tests to be confirmed with RT-PCR.
- The most commonly mentioned advantages of self-tests are that they improve accessibility and allow individuals to quickly obtain some indication about their infectiousness. The disadvantages are the lower sensitivity and the risk of underreporting of positive cases, making response measures such as contract tracing and quarantine even more challenging.
- Because of waning immunity and reduced protection against Omicron, it is no longer adequate to make a distinction between fully vaccinated and non-fully vaccinated people with regards to self-test indications.
- There was agreement that there should be no age limit for self-tests.
- Indications for self-testing should vary in function of the epidemiological context. When incidence and positivity rate are high, self-tests can help to reduce the pressure on the testing capacity. However, when incidence and positivity rate are low, PCR or rapid Ag tests performed by a professional might for some situations be better options.
- When the positivity rate is high, self-tests have a better predictive value (sufficient to confirm infection if positive). However, when positivity rate is low, the risk of false positive results increases, so that RT-PCR confirmation is required in case of positivity to avoid unnecessary contact tracing and quarantine.
- In the current epidemiological context of high viral circulation, self-tests can therefore be used in case of patients with mild symptoms suggestive of COVID-19 and a positive result is sufficient to confirm infection. In such cased, it is of utmost importance that all positive results be reported to keep an accurate view on the epidemic. Ideally, a system has to be put in place whereby citizens can report their self-test results (both negative and positive) online.
- A second situation for which self-testing is an acceptable indication is in high-risk contacts who have to respect a 10-day quarantine that can be ended on day 7 under the condition of a negative test (currently this applies to non-fully vaccinated high-risk contacts >=12 years old and children <12 years who had a high-risk contact within the household). Currently a RT-PCR test is required but this could, in the current epidemiological context, be replaced by a self-test.

- The RAG Testing agreed that in the current situation of waning immunity/ reduced protection against Omicron, the rules with regards to quarantine of high-risk contacts need to be discussed (in a broader RAG meeting).

RECOMMENDATIONS

The RAG Testing recommends:

- To maintain the current indications with regards to self-testing in the private sphere (see current procedures for more detail: Zelftesten | Coronavirus Covid-19 (sciensano.be) or Auto-tests | Coronavirus Covid-19 (sciensano.be))
    - Out of courtesy, to prevent infecting others, before having contact with people outside the household;
    - To early detect a possible infection in oneself after an at risk situation, that doesn't classify as a formal high-risk contact.
- To maintain the current recommendation that self-testing can be used as a possible strategy for repetitive testing in the workplace or schools.
- To maintain the current recommendation that self-tests cannot be used to obtain access to events (for example to obtain a CST) as long as the virus circulation remains high.
- To add, as long as the current epidemiological situation of high incidence and positivity rate with insufficient capacity to timely provide a PCR or professional-administered rapid Ag test result continues, two situations in which a self-test is an acceptable alternative:
    - People with mild symptoms suggestive of COVID-19;
    - To end the quarantine period of high-risk contacts on day 7.
- In these two situations, a positive self-test does not need to be confirmed by RT-PCR and isolation and contact tracing should start immediately. All positive self-tests for other indications, however, need to be confirmed by RT-PCR.
- Efforts should be made to put a system in place to report all self-test results (including negative results) and at least all positive self-test results have to be reported (for example through an online platform).
- To maintain the recommendation that a negative self-test results does not exclude infection and does not dismiss the person of respecting all preventive measures.
- To no longer distinguish between fully vaccinated and non-fully vaccinated people with regards to indications for self-testing.
- To apply no age limit for self-testing.
- To reinforce the communication with regards to self-testing with a focus on the importance of correct use (according manufacturer' recommendations) and of reporting the result.

BACKGROUND

Current indications

The recommendations of the May 2021 RAG advise and the current procedures with regards to the use of self-tests are available on the Sciensano website: 20210510 Advice RAG Indications for self-testing NL.pdf (sciensano.be) or 20210510 Advice RAG Indications for self-testing FR.pdf (sciensano.be); and Zelftesten | Coronavirus Covid-19 (sciensano.be) or Auto-tests | Coronavirus Covid-19 (sciensano.be).

In brief, self-tests are **currently never intended to be used in replacement of existing test indications** such as when having suspicious symptoms, having been identified as a high-risk contact or testing after travel.

Self-tests are mainly intended in two situations: (1) out of courtesy towards people with whom you will be in close contact, to ensure that you will not infect them; (2) to reassure that you were not infected after a situation that doesn't classify you as a high-risk contact but in which you fear you might have been infected.

Self-tests can never be used to obtain access to events (for example to obtain a CST).

Self-tests can also be used in a context of **repetitive screening**. With regards to repetitive screening at the workplace, both self-tests under supervision at the workplace and self-tests performed at home were accepted as strategy (see: 20210323 Advice RAG Repetitive screening in the workplace NL.pdf (sciensano.be) or 20210323 Advice RAG Repetitive screening in the workplace FR.pdf (sciensano.be)).

Self-tests are currently not recommended for fully-vaccinated people, except after an at risk contact.

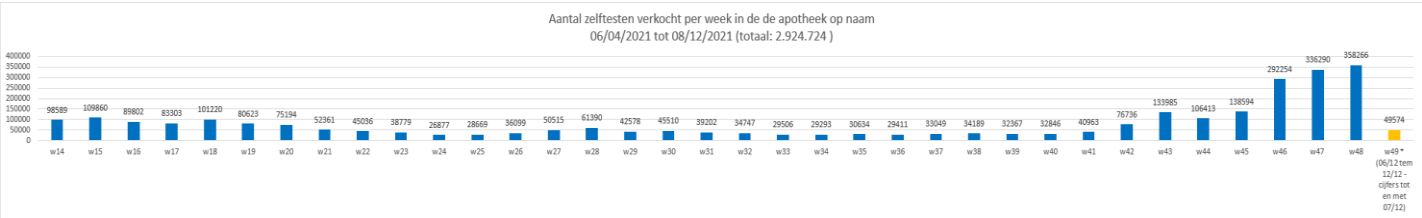
A **negative self-test** can **never** be **a justification to no longer respect the preventive measures** in place. The only **exception** is the recently decided rule that **fully vaccinated high-risk contacts**, who have to perform a PCR test between 3-6 days after the last contact, can lift quarantine before reception of the test result if they haven't received this yet by day 4 and under the condition of daily performing a self-test.

A **positive self-test always need to be confirmed with a PCR** (see: 20210323 Advice RAG Interpretation of self-test results NL.pdf (sciensano.be) or 20210323 Advice RAG Interpretation of self-test results FR.pdf (sciensano.be)).

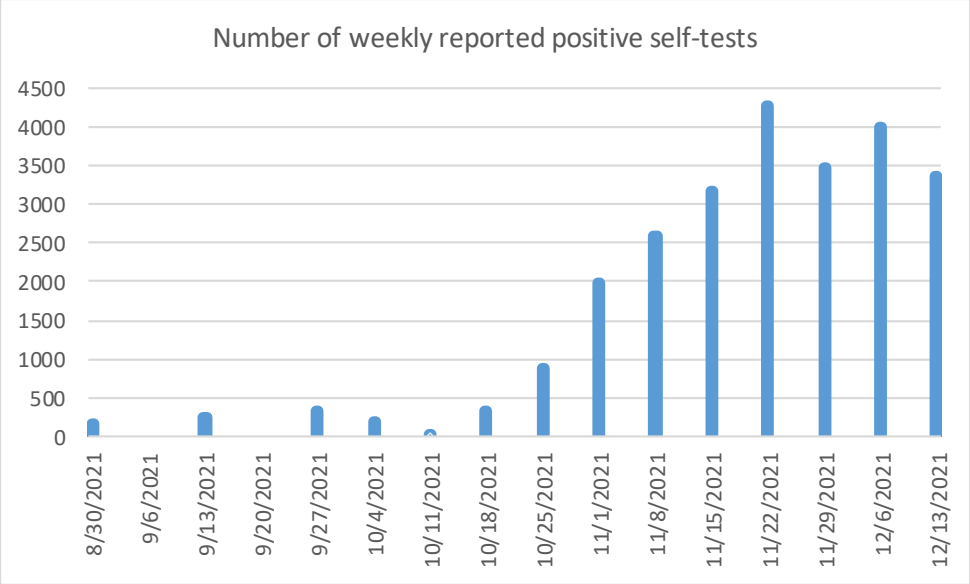
Data on self-testing in Belgium

The Belgian federal agency for medicines and medical products (FAGG/AFMPS) has till now approved 16 rapid Ag self-test kits, among which 3 rapid Ag tests that are approved for self-test use (see: Belgian validation CE autotest 20211217.xlsx (live.com) and Belgian validation autotest.xlsx (live.com)).

Self-test kits can be purchased at pharmacies and since July 2021 also in supermarkets. There are data on the number of self-tests sold at pharmacies, but not at supermarkets. The evolution of the number sold at pharmacies is presented in the figures below. The number remained quite stable until October 2021, but since end-October a sharp increase is observed. In the week of 29 November – 5 December 2021, a total of 358,266 self-test kits were sold. Considering that in the same period (30/11-6/12) 748,959 tests by professionals were reported, we can conclude that self-tests currently comprise an important proportion of all SARS-CoV-2 tests performed.



Results of self-tests do not have to be reported and there are therefore no data on the number of self-tests effectively performed. Positive results have to be confirmed with a PCR test. The figure below presents the number of positive self-tests for which a PCR is requested per week. The same trend is observed with a sharp increase since end October. By 13 December 2021, a total of 36,041 positive self-tests had been reported and 34,635 confirmatory PCR tests had been performed. 31,303 of these (90.4%) had a positive PCR result, indicating a high positive predictive value. In the week of 7-13 December 2724 confirmed positive self-tests were reported, out of a total of 94,308 reported positive SARS-CoV-2 tests. The reported positive self-tests therefore only comprise a small proportion (about 3%) of all positive tests. The ratio of reported positive tests by number of sold tests was in the week of 29 November – 5 December 1.1%. This could indicate a low positivity rate, but care has to be taken because many positive self-tests might not have been reported.



In the latest online Great Corona Survey by the University Antwerp (December 2021), more than half of the respondents answered that they ever used a self-test. When asked why they never used it, 61% reported that it is because they never had symptoms, which appears to indicate that many are not aware that self-tests should not be used when having symptoms. About 40% reported that they plan to use a self-test on New Year's eve (21% plans do to a self-test and 19% expects that all present will have done a self-test).

Scientific literature

Performance of rapid Ag tests

Several studies validating the performance of specific rapid Ag tests have been published by now, including systematic reviews and meta-analyses of these studies.

Already last year, a Cochrane review was done including 8 evaluations in 5 studies on four commercial tests (1). Sensitivity varied considerably across studies (from 0% to 94%) and was on average 56.2%. Specificity was on average 99.5%. The review concluded that the evidence was is not yet strong enough to determine how useful rapid Ag tests are in clinical practice.

Since then, more extensive reviews and meta-analyses have been published.

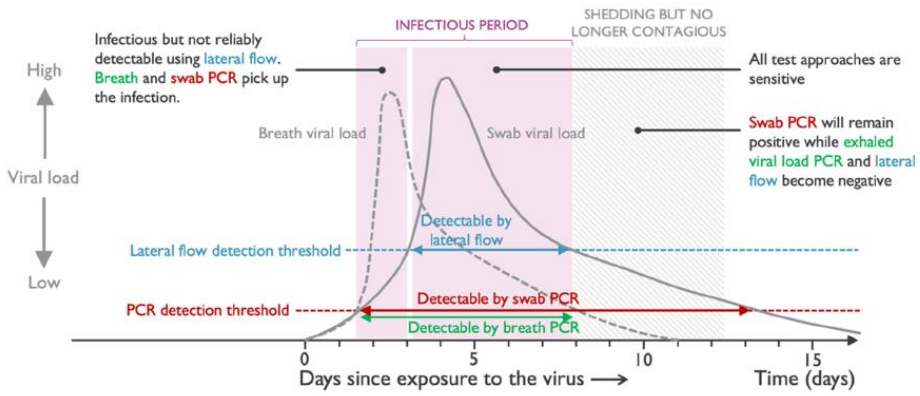
Brümmer et al. reviewed 133 analytical and clinical studies resulting in 214 clinical accuracy datasets (2). A total of 61 different Ag-RDTs were evaluated. The pooled Ag-RDT sensitivity and specificity were **71.2%** (95% CI 68.2% to 74.0%) and **98.9%** (95% CI 98.6% to 99.1%), respectively. Sensitivity increased to **76.3%** (95% CI 73.1% to 79.2%) if analysis was restricted to studies that followed the Ag-RDT manufacturers' instructions. Sensitivity among samples with Ct values <20 was 96.5% (95% CI 92.6% to 98.4%) and **Ct<25 95.8%** (95% CI 92.3% to 97.8%). Testing in the **first week from symptom onset** resulted in substantially higher sensitivity (**83.8%**, 95% CI 76.3% to 89.2%) compared to testing after 1 week (61.5%, 95% CI 52.2% to 70.0%).

Lee et al. identified 24 studies. The overall pooled sensitivity was 68% (95%CI, 59% – 76%) and the specificity 99% (95%CI, 99% – 100%)(3). The pooled sensitivity was significantly increased in subjects with viral load of Ct-value ≤25 or in those within 5 days after symptom onset than it was in subjects with lower viral loads or longer symptom duration.

Hawthorne et al. focused on studies assessing performance in real-life situations and reviewed 87 studies evaluating 27 Ag tests (4). They found the performance of tests in clinical practice to be markedly different from the manufacturers reported performance and laboratory-only evaluations in the majority of scenarios. They did not conduct a meta-analysis, but conclude in the discussion that there is a strong tendency of antigen tests to be less accurate than NAAT in field clinical trials. They pointed out that for a same test reported performance varied substantially among studies. For instance, the sensitivity of the SD Biosensor test ranged from 28% to 92%, and the sensitivity of the PANBIO test from 38 to 90%. A contributing factor is inappropriate testing kits transport and storage, which in several studies resulted in a substantial reduction of sensitivity.

Several countries have conducted evaluations of a large number of commercial rapid Ag tests. Germany **compared the sensitivity of 122 CE-marked rapid Ag tests** (5). For acceptable Ag RDT performance, they defined a minimum sensitivity of 75% in samples with high viral load (Cq≤25). Of the 122 evaluated tests, only 96 fulfilled this criterion. In the UK, 45 out of 64 tests didn't pass the phase 2 evaluation and didn't perform at a level in accordance with the "prioritization criteria" (6). Five tests had a kit failure rate above the pre-specified threshold for exclusion (>10%), 17 kits had a false-positive rate below the pre-defined specificity threshold (<97%) and 28 kits a false-negative rate below the LOD threshold (<60% at 102 pfu/m). Three tests did not pass the phase 3a evaluation and of the eight tests that passed four have so far shown desirable performance characteristics (viral antigen detection of >90% at 100,000 RNA copies/ml), while the other four are still under evaluation.

A recent study by the NRC, comparing the performance of a breath test with PCR and rapid Ag tests on NPS, prospectively followed high-risk contacts from an early phase onwards and found that rapid Ag tests performed poorly in the early and late stages of infection (7). During the 2 days prior to onset of symptoms, rapid antigen tests only detected half of the positive patients.



Source: Adapted from FT and Michael Mina et al., "Rethinking Covid-19 test Sensitivity – A Strategy for Containment", N Engl J Med 2020; 383:e120
Note: lateral flow test = rapid antigen test

Performance of self-administered rapid Ag tests (self-tests)

Studies evaluating the performance of rapid Ag test when self-administered by the user are still rare. The most comprehensive data come from studies in the Netherlands that found an **overall sensitivity ranging between 49% and 69%** (using nasal swabs) and a sensitivity **between 76% and 84% in samples with high viral load**. Two studies compared Ag-RDT self-testing by a lay person with Ag-RDT testing by a professional and found a lower sensitivity when done by a lay person.

Table: Sensitivity and specificity of self-administered rapid Ag tests, compared to RT-PCR on NPS

Study	Type and place of test	Population	N positive	Sensitivity	Specificity	PPV
Schuit et al.	At-home saliva self-test	Test center attendees	183	46.7%	99.0%	76.6%
		High viral load	143	**54.9%**	98.8%	70.9%
	At home nasal self-test (SD Biosensor)	Test center attendees	183	68.9%	99.5%	91.2%
		High viral load	143	**83.9%**	99.5%	90.2%
		Symptomatic	149	78.5%	99.5%	92.1%
		Asymptomatic	31	22.6%	99.6%	77.8%
		Symptomatic and high viral load	125	90.4%	-	-
		Asymptomatic and high viral load	18	38.9%	-	-
		No prior COVID infection	161	72.7%	99.6%	92.9%
		No prior infection and high viral load	126	83.1%	-	-
Stohr et al.	At-home BD Veritor RDT on mid-turbinate swab	Test center attendees	179	49.1%	99.9%	-
		High viral load	-	**76.1%**	99.7%	-
		Compared to composite index for infectiousness	-	**75.9%**	99.9%	-
	At-home Roche-RDT on mid-turbinate swab	Test center attendees	198	61.5%	99.7%	-
		High viral load	-	**80.1%**	99.1%	-
		Compared to composite index for infectiousness	-	**78.8%**	99.7%	-
Lindner et al.	SD-Biosensor RDT at OPD	Symptomatic patients	40	82.5%	100%	-

Lindner et al compared the results of a self-administered rapid Ag test (SD Biosensor) on a self-collected nasal mid-turbinate sample in **146 symptomatic patients consulting a hospital out-patient department** with a HCP-administered rapid Ag test on a HCP-collected naso-pharyngeal sample and a RT-PCR on a HCP-collected naso-pharyngeal sample (8). Of the 40 participants who tested positive with the RT-PCR, 33 (82.5%) had tested positive with the self-testing and 34 (85.0%) with the HCP-administered rapid Ag test on a NPS. All negative RT-PCR results had been negative with the self-administered rapid Ag tests, and there was one false positive among the HCP-administered rapid Ag tests (specificity=100% and 99.1%, respectively). In patients with high viral load (≥7.0 log10 copies/ml) the sensitivity was 96.6% (28/29; 95% CI 82.8-99.8) for both self-testing and professional testing. One patient with a positive self-test had falsely interpreted his result as negative. 80.9% of participants stated

that the test was rather easy to perform, 16.3% medium easy/difficult, and 2.8% rather difficult.

Hoehl et al. piloted **at-home self-testing of teachers** with a rapid Ag test on a self-collected anterior nasal swab (9). On a total of 10,836 tests among 602 teachers, 21 tested positive, but only 5 of these were confirmed by the RT-PCR performed on the same sample (resulting in a positive predictive value of only 23.8%). Negative results were not verified with RT-PCR and a calculation of the sensitivity was therefore not possible. However, for four teachers, a false negative result in the antigen test was assumed, as they reported to have received a positive PCR test result, in another context, during the period of self-testing.

Stohr et al. assessed the performance of **at-home self-testing** with a rapid Ag test (BD Veritor and Roche) on a mid-turbinate nasal sample among visitors of a testing center (10). Specificity was 99.9% and 99.7% for the BD Veritor and Roche test, respectively. Sensitivity was 49.1% for the BD Veritor and 61.5% for the Roche test. Sensitivity among samples with a high viral load (Ct value by LDA<=23; Ct value by AA<=24.5) was 76.1% and 80.1%, respectively. Determinants independently associated with a false-negative self-testing result were: higher age, low viral load and finding self-testing difficult.

The most extensive evaluation was done by Schuit et al. who assessed the validity of an **at-home saliva Ag-RDT self-test** (Hangzhou AllTest) **and a nasal Ag-RDT self-test** (SD Biosensor) among 2819 people, >= 16 years old, attending test sites in the Netherlands (11). Of the 183 who tested positive by PCR on a nasopharyngeal swab, 46.7% (95%CI 39.3%-54.2%) tested positive with the saliva self-test and 68.9% (95%CI 61.6%-75.6%) with the nasal self-test at home, within a few hours without knowledge of their molecular test result. When viral load was high (≥5.2 log10 SARS-CoV-2 E-gene copies/mL; N=143), sensitivities increased to 54.9% (46.4%-63.3%) for the saliva self-test and 83.9% (76.9%-89.5%) for the nasal self-test. For the nasal self-test, sensitivities were 78.5% (71.1%-84.8%) and 22.6% (9.6%-41.1%) in those with and without symptoms, which increased to 90.4% (83.8%-94.9%) and 38.9% (17.3%-64.3%) after applying the viral load cut-off. In those with and without prior confirmed SARS-CoV-2, sensitivities were 36.8% (16.3%-61.6%) and 72.7% (65.1%-79.4%), which increased to 100% (59.0%-100%) and 83.1% (75.7%-89.0%) after applying the viral load cutoff. Specificities were >99%, positive predictive values >70% and negative predictive values >95%, for the saliva self-test, and >99%, >90%, and >95% for the nasal self-test, respectively, in most analyses. The authors concluded that the **saliva self-test was not reliable** for SARS-CoV-2 infection detection, and that the **SD Biosensor self-test had high sensitivity in individuals with symptoms and in those without a prior SARS-CoV-2 infection**.

Although not assessing self-testing as such, another study of interest is by Peto et al. As part of a national systematic evaluation of rapid Ag tests in the UK, they evaluated performance of the Innova test by type of operator (12). Performance was optimal when used by laboratory scientists (sensitivity: 78.8%, 95% CI: 72.4-84.3%) relative to trained healthcare workers (70.0%, 95% CI: 63.5-75.9%) and self-trained members of the public given a protocol (57.5%, 95% CI: 52.3-62.6%; p<0.0001).

International guidelines

Current indications for self-testing by some international agencies and countries are summarized in the table below, and more extensively described further on. In brief, the most common recommendation is still the use in the private sphere, for example before joining with others. Almost all countries also approve self-testing in a context of repetitive screenings at the workplace or in schools. Germany also allows it for accessing a place where a COVID Safe Ticket is required, under the condition that the test is performed on the spot and under supervision. More countries are now also recommending it for people with mild symptoms. Very recently, the Netherlands and the UK allow it also for high-risk contacts. In the Netherlands this is in addition to the other required tests and a negative test does not lift quarantine. In the UK it only applies to fully vaccinated people and children<18.5 years old, who do not need to go into quarantine.

Agency/ country	Private use	Repetitive screenings	When having symptoms	Other
ECDC	Yes	Yes	No	-
CDC	Yes	-	Yes	-
Netherlands	Yes	Yes	Yes	High-risk contacts
France	Yes	Yes	Yes	-
UK	Yes	Yes	No	High-risk contacts
Germany	Yes	Yes	No	Access to events, if under supervision

WHO

In its latest guidance on national SARS-CoV-2 testing strategies (June 2021), WHO briefly addresses self-testing. It states that applications of self-testing are being explored, such as home testing of symptomatic individuals, and may be complementary to national testing strategies, but that at the present time there is not sufficient evidence to make recommendations. The potential benefits and harms of self-testing with Ag-RDTs would be addressed in a separate guidance document, but no such document has been issued yet.

ECDC

In its latest update on the use of rapid Ag tests (October 2021) ECDC repeats its earlier recommendations on the use of self-tests. They state that self-tests can offer advantages when used to complement professionally administered RADTs or NAAT tests as they can improve the accessibility to testing. They **allow individuals to obtain the result quickly, which could support the early detection and subsequent isolation of infectious cases** and hence reduce further community transmission. **However**, shifting the responsibility of reporting test results from health professionals and laboratories to individuals **could lead to underreporting, and make response measures such as contract tracing and quarantine of contacts and monitoring of disease trends over time even more challenging**. While self-sampling under supervision and subsequent RADT performed at the laboratory can be an

acceptable solution for a certified test, RADTs performed by untrained individuals **should not be used for issuing of any formal certificate**.

In May 2021, ECDC issued recommendations on the use of self-tests in the workplace. They state that **in occupational settings**, the self-test RADTs **could allow an even more rapid identification of infectious individuals as compared to RADTs**, allowing rapid isolation of cases, quarantine of their contacts and prevention of further transmission in the targeted setting provided results are communicated properly and in a timely fashion to public health authorities. The pout out that the **reliability of the self-test RADTs depends on the ability of the person** taking the sample, how good the instructions are, how well the individual can follow instructions, the viral load at the time of the sample collection and the disease prevalence at the time the test is performed. This in turn needs to be considered together with any occupational health regulations there may be for the use of self-tests in the workplace.

CDC

The latest update by CDC with regards to self-testing dates 6 December 2021. It doesn't list specific indications but states that a self-test can be considered **before joining indoor gatherings with others who are not in your household,** especially before gathering with unvaccinated children, older individuals, those who are immunocompromised, or individuals at risk of severe disease. In addition, self-tests may also be used **if one has COVID-19 symptoms or has been exposed or potentially exposed to an individual with COVID-19**. Self-tests can be used **regardless of vaccination status**.

CDC warns that **a negative self-test result** means that the test did not detect the virus, but it **does not rule out infection**. Repeating the test within a few days, with at least 24 hours between tests, will increase the confidence that the person is not infected.

The Netherlands

The latest guidance on self-testing by the Dutch National Health Institute (RIVM) dates 3 December 2021. It states that, in addition to the previous indications of April 2021, it is since 3 December possible to use a self-test **when having mild symptoms** suggestive of COVID-19. **Positive tests need to be confirmed** by a test center. **Self-tests cannot be used to lift quarantine measures**, and are **not recommended in vulnerable people** and people who work with or have contact with vulnerable people. RIVM also warns that self-tests are less accurate than a test administered by a professional and that it is **still important to follow the basic preventive measures if testing negative**.

The Dutch government lists the current possible indications for self-tests:

- When having symptoms
- When having been in contact with someone with COVID-19
- When returning from travel
- Before visiting someone or before receiving visits
- Before going to work
- As a pupil, before going to school

- Regularly when you are a student
- Regularly when home-work is not possible

Self-tests are **also recommended for fully vaccinated people**.

Indications for which self-tests cannot be used include:

- When having an increased risk of a serious COVID-19, or if in contact with those people
- When in quarantine - The only way to end the quarantine is to go to a testing center for testing on day 5
- When at work coming into contact with people with an increased risk of serious COVID-19

Self-tests need to be paid for by the user, but the Dutch government is providing free self-tests in certain contexts, such as for schools and people with a vulnerable health.

France

In March 2021 the Haute Autorité de Santé issued guidance on the use of self-tests. Self-tests were recommended in two situations: (1) in **repetitive screening programs**; and (2) **in the private sphere**, for example before a meeting with relatives). Initially the recommendation was only for people >=15 years old but was broadened to all ages in August 2021, in particular to allow repetitive screening with self-tests in schools.

On 8 December 2021, the French Scientific Council issued an advice with regards to the upcoming holiday season. In it, it recommended to self-test before private meetings on the same day, and broadened the indications to include self-testing **in case of symptoms** (what still had been strongly discouraged in the March advise).

Positive self-tests need to be confirmed with a PCR test, and in case of a negative test it is imperative that **the person continues to respect the measures**.

Self-tests are at the cost of the user, except in certain contexts in which they are provided for free by the government, such as in professional care of the elderly and disabled, and in repetitive screenings.

United Kingdom

In the United Kingdom self-tests are not recommended when having symptoms. Generally, they are recommended on days when a person is more likely to catch or spread COVID-19. Examples are **before mixing with people** in crowded indoor places or **before visiting someone who is at higher risk** of getting seriously ill from COVID-19. Self-tests can be picked up from pharmacies, ordered online or picked up from a community collection point. In addition, self-tests are recommended for children >=11 years and staff if attending or working **at a school, college or nursery** in which case it is advised to test **twice a week**.

Since 12 December 2021, in response the emergence of Omicron, England is also recommending self-testing for **high-risk contacts** aged 5 years and over **who do not need to self-isolate** (fully vaccinated people and children<18.5 years old). They are strongly advised to self-test **every day for 7 days** or until 10 days since their last contact with the person who

tested positive for COVID-19 if this is earlier. For HRC who live in the same household as the index, the period is 7 days, or until the household member who has COVID-19 reaches the end of their self-isolation period if this is earlier.

Positive self-tests need to be confirmed with a PCR test, and in the event of a negative test it is still advised to respect basic preventive measures, such as limiting close contacts with other people outside the household, especially in crowded, enclosed or poorly ventilated spaces, working from home, etc.

Germany

Since beginning November 2021, every German citizen is again entitled to a free rapid antigen test at least once a week. The German Ministry of Health advises them in concrete situations in everyday life – for example, during a **private visit** or in the future before a visit to the theatre or cinema. They can also be used **in schools and day-care centers** as part of the test strategies of the federal states.

Negative self-tests cannot be used **to obtain a COVID free pass** (3G measure), unless the testing takes place **at the site of the 3G measure** and is **done under supervision** of the person who is subject to the respective protective measure. Before a visit to a restaurant, for example, a self-test can be carried out under the supervision of a restaurant employee and, if the test result is negative, the restaurant can be visited. Other contexts where self-tests can used in this manner are.

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