

Considerations on the use of self-tests for COVID-19 in the EU/EEA

17 March 2021

Key messages

Rapid antigen detection tests (RADTs) that can be used as self-tests to detect SARS-CoV-2 are becoming available in the European Union/European Economic Area (EU/EEA). These tests require individuals to collect a specimen, conduct a test and interpret the results by themselves.

At the time of writing this document, there were only a few RADTs available for self-testing for COVID-19. A list of RADTs with a CE-marking and which are available on the EU market in compliance with Directive 98/79/EC can be found on the JRC homepage (<https://covid-19-diagnostics.jrc.ec.europa.eu/>). This list includes RADTs for self-testing or at home-testing. The self-tests currently in use in some EU/EEA countries are regulated by each country's national regulatory system.

This document outlines the public health considerations for incorporating self-tests into national testing strategies by public health authorities in the EU/EEA.

From a public health perspective, self-tests can offer advantages when used to complement professionally administered RADTs or RT-PCR tests. They can improve the accessibility to testing. They allow individuals to obtain the result very quickly, which could support the early detection of infectious cases and reduce further community transmission.

Self-testing could therefore enhance disease control with prompt identification and isolation of cases. 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 contact tracing and quarantine of contacts even more challenging. Current indicators for monitoring the intensity and spread of the COVID-19 pandemic (testing rates, test positivity rates, and case notification rates) could be affected, and it could be difficult to monitor disease trends over time. An additional challenge is that samples from self-testing would not be available for sequencing and monitoring variants of concern.

In addition to the above, public health authorities looking to implement self-tests should take into account the population they are targeting, as well as the disease prevalence in that population.

Scope of this document

This document outlines the public health considerations for the use of self-tests to detect SARS-CoV-2 by public health authorities in the European Union/European Economic Area (EU/EEA). Only rapid antigen detection tests

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Erratum 26 April 2021: The following sentence was deleted 'there was no CE-marked RADT self-test placed on the EU market in compliance with Directive 98/79/EC' from page 1 and 3 and replaced with text that more accurately reflects the situation.

(RADTs) for self-testing for direct detection of SARS-CoV-2 virus particles in infectious individuals are considered within this document.

The public health considerations within this document do not apply to RADTs where the specimen is self-collected (also referred to as self-swabbing or self-sampling) and then fully processed at a laboratory or other healthcare setting by a trained person; these are presented in the ECDC guidance document [Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK](#).

This document is intended to assist EU/EEA Member States with decision making by providing scenarios and settings in which the use of SARS-CoV-2 RADTs for self-testing could be of support.

This document should be read in conjunction with the [Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK](#), which was published in November 2020 as well as the [COVID-19 testing strategies and objectives 2020](#).

Target audience

Public health authorities in EU/EEA Member States.

Glossary

A **self-test** requires an individual to collect a specimen from their nose/throat (can be a nose swab, throat swab, saliva or a combination of all), conduct the test and interpret the results according to the instructions provided. This is done using a single-use **self-test kit** that can be used at home (or in another setting) and without any specialised laboratory equipment or training.

Self-swabbing (or self-sampling) refers to an individual collecting their own swab, or specimen, for a SARS-CoV-2 test. This test could be performed using a self-test or could be performed in a laboratory (or other healthcare setting) by a trained person.

Rapid antigen diagnostic tests (RADTs) have been developed as both laboratory-based tests (requiring specialised equipment for analysis) as well as for 'near-patient' or 'point-of-care' use, for which the analysis is performed on a handheld cartridge with a visual readout. RADT results are usually generated 10 to 30 minutes after the start of the analysis. Further information about RADTs is available in [Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK](#).

Sensitivity is the probability of a **true positive**.

A **true positive** is when an infectious individual is correctly identified as a case (infectious) when tested using the particular test.

Specificity is the probability of a **true negative**.

A **true negative** is when a person without the infection is correctly identified as a non-case (non-infectious) when tested using the particular test.

A **false positive** is when a non-infectious individual (a non-case) is incorrectly identified as a case (infectious) when tested using the particular test.

A **false negative** is when an infectious individual (a case) is incorrectly identified as a non-case (non-infectious) when tested using the particular test.

Background

SARS-CoV-2 diagnostic self-tests require individuals to collect a specimen from their nose/throat (can be a nose swab, throat swab, saliva or a combination of all), conduct the test and interpret the results according to the instructions provided. Where required, individuals would also be responsible for reporting the results in accordance with instructions from public health authorities. These tests are rapid antigen detection tests (RADTs) that can be done at home, without the involvement of any health professionals or laboratory staff. The purpose of a self-test is to detect an active infection.

Instructions for the sampling and test procedures provided by the manufacturer and/or public health authorities should be well-designed, easy to read, locally adapted and user friendly. Instructions should clearly describe the environmental conditions, incubation times, time between sampling and reading, and correct interpretation of positive and negative results, in an illustrated way so that they can be easily followed by a lay person. Clear detailed instructions can significantly reduce errors in the performance of a rapid self-test, as described from existing experience of self-testing kits for other pathogens [1].

Self-tests allow individuals to obtain the result very quickly (within approximately 30 minutes), which may facilitate more timely isolation and may alleviate the bottlenecks for laboratory response identified in the recent *ECDC rapid assessment of laboratory practices and needs related to COVID-19* [2]. For the test result to be registered with the public health authorities, the individual would need to actively report the result.

Availability of self-tests

To place a diagnostic test on the EU market, the manufacturer must demonstrate compliance with the applicable legal requirements of EU Directive 98/79/EC for in vitro diagnostic medical devices [3]. This includes carrying out a performance evaluation of the device. Furthermore, for any devices intended for lay users, the manufacturer must also apply to a third-party body (called a notified body), which will examine the design aspects of the device and issue a corresponding certificate. Once the manufacturer has declared conformity of the device with the legal requirements, they may affix the 'CE' marking to the device and place it on the EU market [4].

A list of RADTs with a CE-marking and which are available on the EU market in compliance with Directive 98/79/EC can be found on the JRC homepage (<https://covid-19-diagnostics.jrc.ec.europa.eu/>). This list includes RADTs for self-testing or at home-testing. The self-tests currently in use in some EU/EEA countries are regulated by each country's national regulatory system.

For detailed information on the use of RADTs for professional use please refer to the ECDC Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK [4].

Clinical performance of self-testing compared with RT-PCR testing

The reliability of the test result depends on a few factors: the ability of the person taking the sample and performing the test to follow instructions, the viral load at the time of the sampling, and the disease prevalence in the population when the test is taken.

Impact of self-swabbing and viral load on test results

In a study performed by Linder et al. [5], the agreement of results between a self-test and a test performed by health professionals was assessed. It was concluded that when people swabbed their own noses and completed an unnamed rapid test approved by the World Health Organization (WHO), the sensitivities were very similar to those achieved by antigen testing performed by professionals, despite the fact that the individuals often deviated from the instructions. The positive percent agreement between the results of self-testing and professional testing using RADT was 91.4% (95%CI 77.6-97.0), while the negative percent agreement was 99.1% (95%CI 95.0-100). Although deviations in sampling and testing (e.g. incomplete self-sampling or extraction procedure, or imprecise volume applied on the test device) were observed in more than half of the positive samples, they conclude that results of self-administered testing can be comparable to those obtained by professionals.

A few studies have reported on the quality of specimens taken by lay persons versus trained healthcare professionals, as well as the overall performance of a self-test compared with the gold standard SARS-CoV-2 detection method, which is RT-PCR. The effect of the person performing the RADT on samples from RT-PCR-positive cases was investigated in a study by Peto et al. [6] using the Innova LFD (RADT). They found that the RADT test was more sensitive when used by a laboratory specialist (78.8%, 95%CI: 72.4-84.3%), compared with a trained healthcare worker (70.0%, 95%CI: 63.5-75.9%) and a self-trained member of the public (57.5%, 95%CI: 52.3-62.6%).

In a study by Stohr et al. [7], a clinical testing situation was compared with an at home-testing situation. A total of 3 215 participants received the self-testing kits BD Veritor System RADT or the RADT by Roche Diagnostics, and used them on self-collected specimens from nasal swabs. Sensitivity of self-testing was compared with the gold standard method (RT-PCR), which involved a specimen being collected by a healthcare worker and sent to a laboratory for testing. The sensitivity was found to be 75.5% (95%CI: 66.6-82.6) for the BD RADT and 80.1% (95%CI: 72.7-86.0) for the Roche RADT. Both RADTs demonstrated very high specificity >99% (BD RADT: 99.7% (95%CI: 99.2-99.9); Roche RADT: 99.1% (95%CI: 98.5-99.5)). The study by Stohr et al. identified determinants independently associated with false-negative self-testing results, including higher age, low viral load, and finding the self-testing procedure difficult. Of note, the sensitivity and specificity identified in the study did not meet the minimum performance requirements of $\geq 90\%$ and $\geq 97\%$ suggested by ECDC as being appropriate for SARS-CoV-2 RADTs [4]. However, the overall conclusion from Stohr et al. was that self-testing, using commercially available RADTs, proved to be feasible for testing and delivered reliable results, particularly to detect individuals with a high viral load and therefore a higher probability of infectiousness.

Impact of population disease prevalence on test results

The positive predictive value (PPV) of a test decreases with decreasing prevalence in the population where the test is being used (see section *General consideration for inclusion of self-tests into testing strategies* below). A test with 80% sensitivity and 99% specificity has a PPV of 44.7% and 7.4% respectively in populations with a 1% and 0.1% true point prevalence of SARS-CoV-2. This suggests that only a minority of cases testing positive in a self-test (and other RADTs) in a low prevalence setting would be positive if tested with RT-PCR. Therefore, a confirmatory test with RT-PCR is recommended in such low-prevalence settings [4]. The negative predictive value (NPV) is generally high (>98%), even in higher prevalence settings, but there will still be individuals who obtain false negative results. The impact on transmission of false negative results should be considered, as individuals may demonstrate lower adherence to non-pharmaceutical measures or participate in social mixing believing that they tested negative. Please also refer to section below (General considerations for inclusion of self-tests into testing strategies).

Frequency of self-testing

A recent modelling study by Larremore et al. [8] proposed that for effective COVID-19 screening, the frequency of testing as well as the timeliness of reporting were more important than the sensitivity of the tests used. Test accessibility, frequency of testing, and sample-to-answer time are priority areas that can make self-testing a very effective tool to minimise spread of COVID-19. Bootsma et al. [9] had a similar finding from their modelling study, which estimated that a test with 80% sensitivity performed by at least 70% of the population once a week would reduce the effective reproduction number (Rt) from 1.5 to below 1.0, and also proposed that the frequency of testing should be more important than the sensitivity of the test itself. However, these considerations are theoretical and should be confirmed in real-life settings.

Current use of self-tests

To date, where they have been introduced, self-tests for COVID-19 have largely been used in occupational settings where there is a high risk of exposure (such as health care facilities) or where large numbers of individuals are mixing (such as in schools), as well as in research settings.

At the time of developing this report, there was still limited information about the use of self-tests, with only a small number of countries in the early stages of introducing them. The self-tests currently in use in some EU/EEA countries are regulated by each country's national regulatory systems, as no self-test for COVID-19 has yet been CE-marked. A summary of the use of self-tests in these countries is provided in Annex 1.

Some differences in implementation across these countries include:

- How the self-tests are provided or accessed by individuals (including number of test kits provided), i.e. free from pharmacies (with or without prescription), provided in school or occupational settings, provided at testing centres, or for purchase in stores (private market);
- Whether self-tests are used for screening the whole population or within targeted settings (such as occupational or school settings);
- Whether self-tests results are reported, and if so, how this is done (such as through the use of mobile apps, online forms, or phone 'hotlines');
- Whether confirmatory testing using laboratory-based methods is recommended for individuals with positive self-test results.

Impact of self-tests from a public health perspective

Introduction of self-tests into routine use for detection of infectious people needs to be well-planned and carefully implemented. As mentioned above, this document complements the [Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK](#) and the [COVID-19 testing strategies and objectives 2020](#), and the reader should therefore refer to these resources as well [4,10]. As for any diagnostic approach, when introducing self-tests, considerations include the performance of the test, timeliness of test results, scalability, simplicity of use, overall logistical arrangements for distribution and costs, reporting arrangements, and epidemiological situation [4].

General considerations for inclusion of self-tests in testing strategies

Based on the guidance document *COVID-19 testing strategies and objectives 2020*, using RADTs in a non-clinical setting (i.e. self-tests) may be beneficial for controlling transmission through early detection of infectious cases, rapid commencement of contact tracing, or population-wide testing, and to identify clusters or outbreaks in specific settings, again facilitating early detection and isolation. In these situations, using self-tests may offer an advantage over RT-PCR in terms of bringing testing closer to persons needing testing, and improving the timeliness of results [4]. A summary of the general advantages and disadvantages of self-tests is presented in Table 1.

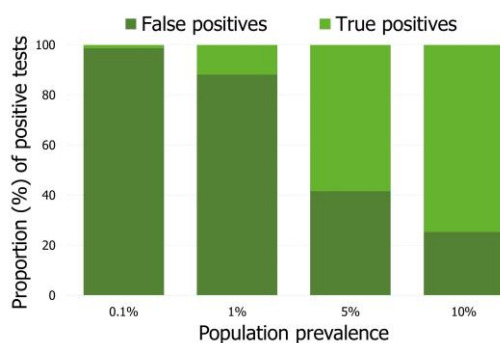
Table 1. Summary of self-testing advantages and disadvantages

Advantages	<ul style="list-style-type: none"> • Reduced risk of transmission associated with travelling to see a healthcare worker (HCW) or attend a testing clinic. • Convenience of collecting the sample at any time, including before entering specific settings where transmission to others may occur. • Reduced burden on HCW/testing clinic staff to collect specimens and run analysis and reduced occupational exposures to HCWs. • Results available in less than an hour. • More timely self-isolation and a subsequent reduction in transmission. • Cheaper compared with laboratory-based testing (when factoring in HCW and/laboratory staff time, laboratory consumables, etc.). • Reduction of equipment and person/machine time needed and reduced pressure on healthcare system.
Disadvantages	<ul style="list-style-type: none"> • Might lead to sub-optimal sample quality, affecting reliability of results. • Management of the entire testing process left to the individual, including the interpretation of results. • Lack of immediate professional support/counselling following test result. • Requires self-reporting of results to HCW or public health authority, which has implications for surveillance and public health response. • May require confirmatory testing (if positive result), which may cause increased burden on healthcare system and laboratories. • False positive results may lead to unnecessary self-isolation and increase the burden on PH authorities and laboratories. • False negative results might convey an inappropriate sense of safety and result in increased transmission (e.g. contacts of cases who stop self-isolating earlier than recommended based on a negative self-test result).

The value of the RADTs used for self-testing depends on the test characteristics (sensitivity and specificity) in combination with the prevalence of the disease in the population tested. The specificity of currently available tests is very high, but when used in asymptomatic individuals in a low prevalence setting, the positive predictive value remains low. The performance of self-tests needs to be balanced against the potential benefits of self-testing.

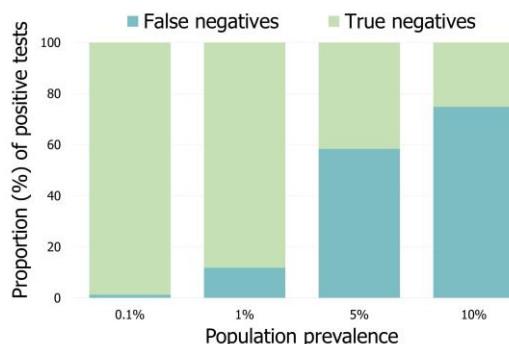
As self-tests tend to have a low PPV, if the self-test is positive, individuals with positive results should self-isolate, and arrange confirmatory testing using a laboratory-based test (i.e. RT-PCR), as there is a definite possibility that the result was false positive (Figures 1).

Figure 1. Proportion of false and true positive test results per 10 000 tests performed, for prevalence between 0.1% and 10%, for ECDC recommended minimum test requirements (sensitivity 80%, specificity 97%) [4,6,11,12]



Self-tests perform well to rule out positivity (the certainty is high that a negative result is truly negative) in scenarios with low prevalence (~99% negative predictive value) (Figure 2). Therefore, in a scenario with low prevalence, if the self-test is negative, and no other clinical signs/symptoms are present, no additional confirmatory testing would be needed. However, in scenarios with very high prevalence (i.e. outbreaks), due to the higher likelihood of false negative results, laboratory-based tests (i.e. RT-PCR) would be needed to confirm a negative result.

Figure 2. Proportion of false and true negative test results per 10 000 tests performed, for prevalence between 0.1% and 10%, for ECDC recommended minimum test requirements (sensitivity 80%, specificity 97%) [4,6,11,12]



Annex 2 presents the potential public health impact of implementing self-tests in two scenarios, based on two levels of COVID-19 prevalence within that (sub-) population. The scenarios are:

- Population-level screening, broad screening of a whole population (i.e. healthy people that are non-symptomatic, not contacts of cases, and not in specific risk groups) and/or screening individuals attending specific public settings (i.e. prior to access to indoor/outdoor settings with a high number of individuals mixing) (Annex 2: Figure 3).
- Within targeted settings, which could include (but are not limited to) settings with high risk of transmission to vulnerable people (e.g. healthcare settings, long-term care facilities, prisons, migration centres, accommodation for vulnerable persons) and settings with a high number of children and adolescents mixing (e.g. schools) (Annex 2: Figure 4).

Impact on prevention and control measures

Self-tests can contribute to overall COVID-19 testing capacity by supporting the early detection of infectious cases and reducing further community transmission by allowing the rapid isolation of infectious cases. As described below and in the annexes, prior to implementing self-tests, public health authorities need to consider:

- The scenario in which they will be used (i.e. for screening the general population or for screening targeted settings or groups) as well as the disease prevalence, taking into account that:
 - The lower the prevalence in the population to be tested, the higher the proportion of false positive results.
 - The higher the prevalence in the population to be tested, the higher the proportion of false negative results.
- The public health as well as the surveillance implications of their introduction.

There are few studies on self-testing as a tool for controlling COVID-19. A modelling study from the US concluded that “high-frequency home testing for SARS-CoV-2 using an inexpensive, imperfect test could contribute to pandemic control at justifiable cost and warrants consideration as part of a national containment strategy” [13]. Mina et al. [14], also refer to a strategy for containment with a frequent use of cheap, simple, rapid tests that can effectively complement control measures and improve the overall control of SARS-CoV-2, even if their analytic sensitivities are vastly inferior to those of benchmark tests.

Prior to implementing self-testing, public health authorities should take the impact on self-isolation, contact tracing, community measures, and the issuing of certificates (and other official documents) into account.

Self-isolation

One of the drivers of the pandemic is the significant number of undiagnosed and therefore underreported asymptomatic or mild cases. The availability of self-testing could allow individuals to test themselves early, when having mild or atypical symptoms, or when they are asymptomatic. An individual's threshold for testing would be expected to be lower if self-tests were easily available and the process was simpler compared with being tested at a testing facility (especially if this requires an appointment). In a US survey, respondents indicated that they would prefer using tests with rapid turn-around and performed at home over tests with longer turn-around time performed at a healthcare provider's office [15].

At an individual level, earlier detection of infection allows more timely self-isolation [16] and as such, is likely to lead to fewer exposed contacts and reduce further transmission. Ideally, self-test kits should include clear instructions and recommendations on what to do if the test is positive, negative or unclear/invalid, as well as accessible healthcare contact points if further information is needed. Including information about what to do if the test result is negative or unclear/invalid will be crucial, as there is a risk that individuals could gain a false sense of security following a negative result and may, for example, come out of self-isolation earlier than recommended.

False positive results could also occur, making an individual self-isolate when they do not need to. However, if individuals with positive self-test results are confirmed using laboratory-based methods, then the likelihood of unnecessary self-isolation is reduced.

Contact tracing

Contact tracing efforts will be reliant on individuals reporting their results to public health authorities, and ideally, the tests should contain clear instructions on how to report these results. Modification of mobile apps, such as those already in use for contact tracing, to report self-test results may facilitate both notification to the health authorities as well as contact tracing. There is a risk that positive tests go unreported which could have a negative effect on contact tracing and control efforts.

On the other hand, if the availability of self-tests means that individuals are tested more frequently, obtain more timely results, and report their results, the impact on contact tracing may be positive. Even if individuals do not report their result to public health authorities, they may still go ahead and inform their contacts which may have a positive impact on control.

Self-testing could also increase the speed at which contact tracing is initiated which could be highly beneficial as contacts can be quarantined earlier. Given that the positive predictive value of a positive self-test is low in situations of low prevalence, contact tracing would be initiated for many cases that are false positive which may over-stretch resources. While a solution could be to wait for a confirmatory test following the self-test to start contact tracing, the advantage of speed is lost. Please refer to the ECDC guidance on contact tracing [17] for specific information on use of antigen tests for testing of contact persons.

Community measures

There is a paucity of studies which evaluate self-testing as a tool to complement non-pharmaceutical interventions (NPIs), such as physical distancing.

A study of repeated at-home self-testing among 602 teachers in Germany, identified five confirmed cases, one of which was pre-symptomatic and four had mild symptoms [18]. Sixteen false-positive cases were identified out of 10 836 tests (0.15% of all tests), and false positives were more common when the incidence in the general population was low. Furthermore, four false-negative results were reported by the self-test, where a RT-PCR had detected a SARS-CoV-2 infection.

Self-tests may contribute to decreasing the risk of transmission when used by asymptomatic individuals prior to social interactions, such as visits to family/friends, appointments, travel and participation in events, as the self-test would identify infectious cases at the time of testing. They may also contribute to decreased transmission risk when frequent testing is done in workplaces with high risk of occupational exposure (such as in healthcare settings), and those with large numbers of close interactions between individuals (such as educational settings). By using self-tests frequently to ensure individuals are negative prior to their attendance at, school, the workplace, or a social event, together with the continued use of NPIs, the risk of transmission is further decreased.

It is unknown to what extent the use of self-tests would change behaviour or lower the adherence of individuals to general advice regarding physical distancing. Individuals may change their behaviour following a negative result (for example, believing that they are 'clear') or following a positive result (for example, if they consider themselves immune and no longer at risk). Given their low sensitivity in an asymptomatic population, and the possibility of false negatives and false positives, this may carry a risk of increased overall transmission. As such, it is important to note that even where frequent testing is implemented, clear communication on the importance of withholding the non-pharmaceutical interventions to mitigate the risk of ongoing transmission should be ensured [19].

There is potential for misuse of self-testing if required for social interactions, through falsification of results and/or personal data. Measures should be in place to minimise this risk. However, it can be expected that such cases would be a minority and would not significantly influence the overall positive effect of using self-tests.

The self-tests covered in this document are RADTs and as outlined in the [Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK](#) report, RADTs per se could be used for screening asymptomatic individuals in high prevalence settings and/or for recurrent screening of asymptomatic individuals in high prevalence settings. However, it is important to note that RADTs perform best in individuals with COVID-19 compatible symptoms (i.e. due to higher viral shedding), particularly around the onset of symptoms [4], so the self-test result can be used to aid early diagnosis, in all settings and irrespective of community prevalence [4].

In summary, in the current stage of the pandemic and based on the current knowledge, self-tests should not be used to replace NPIs and/or to exempt individuals from following NPIs such as physical distancing.

Certification

Formal certification of testing and/or recovery cannot be based solely on the results of a self-test.

Impact on surveillance

Self-testing could enhance disease control with prompt identification and isolation of cases. However, the responsibility of reporting test results to public health authorities shifts from traditional reporters (healthcare professionals, laboratories, and other trained professionals) to the individual. Relying on the public to voluntarily report their self-test results will likely lead to an under-reporting of all test results (and likely biased towards higher under-reporting of negative or invalid test results). Integration with existing technology to report results, for example using mobile apps (as is done in the UK), would support public health authorities to collect results with minimal administrative burden. No reporting, or significant under-reporting, of positive self-test results would also impact the ability of local public health authorities to monitor activity, commence contact tracing, and provide advice.

The current [EU case definition for coronavirus disease 2019 \(COVID-19\)](#) could be interpreted as including positive test results from self-tests as they meet the laboratory criteria of 'detection of SARS-COV-2 nucleic acid or antigen in a clinical specimen'. Presently, RADT results for tests performed outside of laboratories (but by trained healthcare personnel) are considered confirmed cases.

If widely used, self-tests have the potential to significantly affect the available surveillance data. Without a mechanism for incorporating the self-test results into traditional public health surveillance systems, current indicators for monitoring the intensity and spread of the COVID-19 pandemic (testing rates, test positivity rates, and case notification rates) will be affected and it will be difficult to monitor disease trends over time. Specific scenarios considering the availability of self-testing data and their impact on surveillance are provided in Annex 3.

Again, if widely used, large increases in testing volumes will have an impact on the algorithms used for the [Council recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic](#). The change in testing rates and test positivity rates would require a reassessment and/or adjustment of the current thresholds, especially if there are different approaches across EU/EEA Member States on how self-tests are used and what data are collected.

Another surveillance consideration is the monitoring and detection of variants of concern (VOCs). An important drawback of RADTs, which would also mean for self-tests, is that the specimens cannot be further characterised or sequenced. As long as self-tests complement, and do not replace, laboratory-based RT-PCR testing and countries continue to sequence the minimum number of samples suggested [20], it will still be possible to monitor VOCs. It will be important however, that public health authorities ensure that there are no marked differences (or biases) in the subset of individuals who are tested using laboratory-based RT-PCR methods compared with those who only self-test, if self-tests are introduced.

It will be integral to ensure that self-test results can be reported (in some way) by the individual and incorporated into the public health surveillance system to facilitate interaction with PH authorities. This could require the establishment of a simple mechanism to allow cases to interact with their healthcare provider or public health authority to report the result, get the appropriate advice on self-isolation, and enable contact tracing to begin. Where no mechanism is provided, there will be the risk of cases not following public health recommendations, and public health authorities may be blinded to the true nature of disease transmission within the population.

Conclusions

Self-tests offer many advantages from a public health perspective when used to complement professionally administered RADTs or RT-PCR tests. They lower the threshold to get tested, and if accompanied with clear public health instructions, offer the possibility to isolate infectious individuals early and thereby reducing further transmission.

Several factors need to be considered before introducing self-tests and are summarised here.

The value of the RADTs used for self-testing depends on the test characteristics (sensitivity and specificity) in combination with the prevalence of the disease in the population tested. The specificity of currently available tests is very high, but when used in asymptomatic individuals in a low prevalence setting, the positive predictive value remains low. The lower sensitivity of available tests compared with RT-PCR partly reflects the high-sensitivity of RT-PCR in detecting SARS-CoV-2, including non-viable virus particles, and the ability of the individual to follow instructions of the self-test process. However, the lower performance of self-tests needs to be balanced against the potential benefits of self-testing.

Self-tests can complement but not replace other sampling and testing methods to improve accessibility to testing, expedite diagnosis, and facilitate the timely isolation of cases and quarantine of contacts. Self-tests may provide advantages in occupational and educational settings.

In times of high prevalence and high pressure on the healthcare system and laboratories, the benefits of self-testing and subsequent identification and isolation of positive cases may outweigh the disadvantages related to under-reporting and false positive results.

If self-testing is made available, individuals should be provided with clear instructions for performing, interpreting and reporting their results to the local public health authority. This will ensure authorities can incorporate positive cases into the surveillance systems, provide advice for isolation and other preventive measures, commence contact tracing, and arrange retesting using laboratory-based methods. Local public health authorities may need to be additionally resourced to manage the potential increased workload due to the increased number of cases being detected.

The examples from countries' experiences can provide guidance about how self-testing could be an integrated component of the local public health authority's testing strategy.

For integration with public health response and surveillance, self-testing should ideally include the following components:

- Self-tests are ordered from the local public health authority (or a central source) to allow incorporation of local public health advice, ensure approved self-test kits are used, make it easier for members of the public to order/access the tests, and to track, if possible, the number of tests distributed/used;
- Self-testing should be accessible, affordable (if not free) and distributed equitably;
- Self-tests should include clear, illustrated, and simple instructions on:
 - how to collect the sample and perform the test;
 - how to interpret the result;
 - what to do based on the result, whether it is positive, negative or unclear/invalid (such as informing public health authorities, isolation guidelines, informing contacts, seeking follow-up laboratory confirmation of the test result, etc.);
 - how to report the results (ideally from positive and negative);
 - who to contact to seek professional advice and support.
- Public health authorities should have a system in place to collect the reported results (mobile app, cloud platform, dedicated hotline, or via healthcare workers, etc.) and to arrange for confirmatory testing (if applicable);
- Results should be incorporated into the national surveillance system with data fields to separate these results from laboratory-based results and prompt secondary actions (whether confirmatory testing, contact tracing, and/or other public health response measures);
- Ideally, all results (positive, negative, and unclear/invalid) should be reported to monitor distribution, usage and performance of these tests.

Contributing ECDC experts (in alphabetical order)

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Disclaimer

All data published in this document are correct to the best of our knowledge at the time of publication.

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Annex 1. Self-test use and reporting practices as of 14 March 2021

Examples of self-test practices in countries identified through literature and/or countries' official websites can be found below.

In Austria, self-tests have become available under a special national regulatory process [21] and are being incorporated into the testing strategy of the Ministry of Health [22]. From the beginning of March, self-tests have been distributed by pharmacies to individuals with registered national health insurance with a maximum of five tests provided per person per month for free [22]. Instructions on what to do if the test result is positive (including self-isolation and notification to the authorities) are available on the Austrian Ministry of Health website [22]. All positive results from self-administered tests must be reported to the official health hotline and will be confirmed by authorities using a laboratory-based test (usually RT-PCR) [22].

In Germany, a number of self-tests recently became available for purchase in supermarkets, pharmacies, corner stores and on the internet. These self-tests are introduced following issuing of national derogations from Directive 98/79/EC [23]. It is anticipated that self-tests will be utilised to provide reassurance to individuals prior to 'everyday situations', like before visiting someone or going to the theatre/cinema [24]. There is currently no statutory obligation to report a positive-test result to local health authorities, however individuals with positive self-test results are requested to arrange a laboratory-based test for confirmation [24].

The UK has implemented self-testing into their national COVID-19 testing programme to complement the existing laboratory-based testing services. In England, as schools are reopening, self-test kits are provided to allow twice-weekly testing of asymptomatic secondary school students, staff of primary and secondary schools, and household contacts of students and school staff [25].

Also across England, self-test kits are being distributed to residential aged care facilities for testing of staff and visitors [26], and some local councils are offering free self-tests to asymptomatic individuals and are encouraging twice weekly testing for essential workers, those who cannot work from home, household contacts of school staff or students, and adults working in the wider school community (for example, bus drivers and school club leaders) [27]. Every result (positive or negative) can be reported through the [NHS Track and Trace app, online](#), or by calling an information line [25]. Symptomatic individuals will continue to be offered RT-PCR testing under the national COVID-19 testing programme.

The first self-test kit was authorised for use in the US in November 2020 [28]. The US Centers for Disease Control and Prevention (CDC) have issued guidance for self-testing, including how to collect a specimen, perform the test, as well as how to interpret and report the result. They recommend that individuals communicate their result to their healthcare provider who is responsible for reporting the result to the state health department [29]. Some self-test kits may be accompanied by mobile apps which can collect and report the results to the state health department [29].

Annex 2. Scenarios of self-test use and possible impact from a public health perspective

This annex lists possible impacts of using self-tests on the public health response, if implemented in four different (sub-) population scenarios. For each scenario, the impact is described for two levels of COVID-19 prevalence (very low to low and high to very high). For setting one, prevalence of 0.1% to 1% ('very low to low') is compared to prevalence of 5% to 10% ('high to very high'). For settings two to four, prevalence of 0.1% to 5% ('very low to low') is compared to prevalence of 10% to 20% ('high to very high').

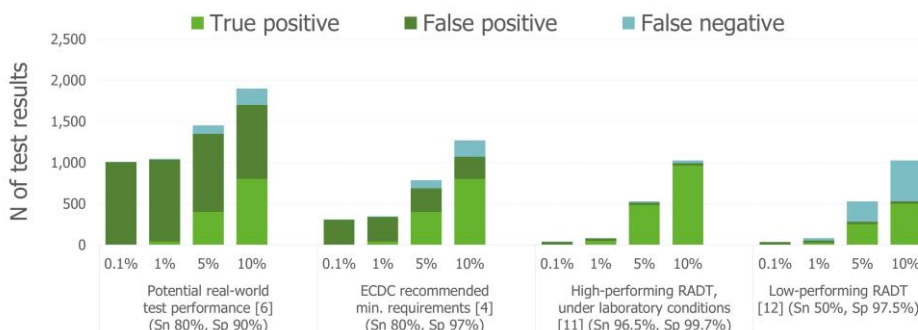
If the prevalence is unknown, public health authorities may consider which scenario is applicable based on the available local indicators including incidence, test positivity, rates of absenteeism, known outbreaks, and rates of hospitalisation and death.

The scenarios are:

- Population-level screening, broad screening of a whole population (i.e. healthy people that are non-symptomatic, not contacts of cases, and not in specific risk groups) and/or screening individuals attending specific public settings (i.e. prior to access to indoor/outdoor settings with a high number of individuals mixing) (Figure 3);
- Within targeted settings, which could include (but are not limited to) settings with high risk of transmission to vulnerable people (e.g. healthcare settings, long-term care facilities, prisons, migration centres, accommodation for vulnerable persons) and settings with a high number of children and adolescents mixing (e.g. schools) (Figure 4).

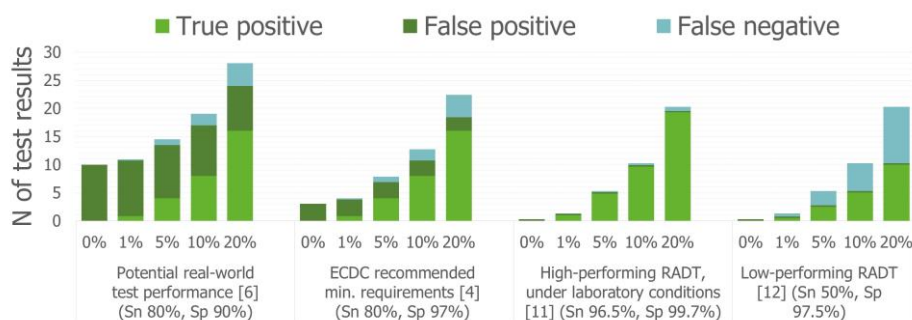
To aid interpretation of the provided considerations for each of these scenarios, figures 3 and 4 present the mathematical relationship between prevalence of a disease, and the resulting rates of true or false positive and negative test results, based on the number of tests and test performance categories. The four categories are based on RADTs available at the time of writing this report [4,6,11,12].

Figure 3. Test results following screening of 10 000 population, for prevalence between 0.1% and 10%, for four test performance categories [4,6,11,12]



Key: RADT – rapid antigen detection test; Sn – sensitivity; Sp - specificity; the remaining category of test result (true negative) is not presented in the figure.

Figure 4. Test results following targeted screening of 100 persons, for prevalence between 0% and 20%, for four different test performance categories [4,6,11,12]



Key: RADT – rapid antigen detection test; Sn – sensitivity; Sp - specificity; the remaining category of test result (true negative) is not presented in the figure.

SCENARIO 1. Use of self-tests for population-level screening (please refer to Figure 3)

Population-level screening can utilise self-tests to:

- Broadly screen a whole population (e.g. healthy people that are non-symptomatic, not contacts of cases, and not in specific risk groups)
- Screen individuals attending specific public settings, such as prior to access to indoor/outdoor settings with a high number of individuals mixing.

It is important to consider that settings may differ in prevalence, transmission dynamics, and the proportion of asymptomatic cases (i.e. possibly higher in settings or areas with more children).

In all scenarios, self-tests should not be used to replace NPIs and/or exempt individuals from following NPIs such as physical distancing.

Main considerations for this scenario common to both low and high-prevalence levels

Advantages:

- Self-tests can help reduce further transmission through early detection of infectious cases, thereby enabling rapid isolation.
- Likely to have higher acceptability at population level, due to relative convenience compared to tests that require scheduling, travel and/or inter-personal contact.
- Reduced pressure on testing centres and laboratories to process tests, except confirmatory tests.
- Screening asymptomatic individuals, with rapid results, will allow larger proportion of cases to self-isolate at an early stage of infection.
- Contact tracing and subsequent quarantine may be initiated earlier, if there is higher population-level uptake of this test type and rapid RT-PCR confirmation of positive test results.

Disadvantages

- More challenging for public health authorities to acquire the self-test results and follow-up with individuals with positive results. It will therefore be more difficult to form appropriate situational awareness of compliance with self-isolation of the individuals with positive test results according to PH guidelines.
- Population-level screening will result in large numbers of false positive cases, who are requested to self-isolate unnecessarily. In countries in lockdown this would have impact on those in shared households.
- Where tests are used in specific settings, and there will need to be consideration of what to do with individuals who had been mixing with others while waiting for the result.

Required:

- Clear procedures for reporting to authorities, e.g. via web apps.
- Clear recommendations for individuals reading a positive result, i.e. self-isolation and test confirmation.
- Mechanisms to incentivise individuals with positive test results to self-isolate and retest.
- Clear risk communication, particularly in low prevalence scenarios, regarding the PPV of self-tests, i.e. that a positive result from a self-test implies the need to self-isolate and follow the requirement for a confirmatory test, rather than the acquisition of natural immunity.

<p>Very low and low prevalence (0.1%—1%)</p>	<p><i>In addition to the main considerations for this scenario, for low-prevalence:</i></p> <p><i>Main conclusions/considerations:</i></p> <ul style="list-style-type: none"> • The use of self-tests alone for population screening is unlikely to provide a public health advantage in this context, due the large number of false positive results from the very low PPV (<5%; Figure 1). However, it is likely to be useful as a screening step, with a positive test result requiring laboratory confirmation, i.e. RT-PCR. For example, in a population with 0.1%-1% prevalence, if self-tests with a specificity of 90%-95% are performed on 10 000 people, then 500—1 000 people will require laboratory confirmation. <p><i>Advantages:</i></p> <ul style="list-style-type: none"> • If used as a screening step prior to laboratory confirmation: useful. • Self-tests may be more feasible and acceptable for population-wide screening, and thereby lead to earlier identification of cases than for other testing technologies. <p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> • At the time of a rapid test result, false positive cases cannot be distinguished from true positive cases. • Even if there are no cases, there will be false positive cases, requiring self-isolation and contact tracing until confirmatory laboratory test results are available. This may result in societal impacts and/or inefficient use of public health resources. • Cannot necessarily be used to identify clusters/outbreaks, if there are a small proportion of positive cases, in case they are all false positive, until laboratory confirmation, i.e. RT-PCR.
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	<ul style="list-style-type: none"> • Not useful for public health purposes, if self-tests are used as the only test to identify cases in the community. • Insufficient risk communication of the meaning of a positive test result could lead to false belief that individuals have natural immunity.
<p>High prevalence (5 to 10%)</p>	<p><i>In addition to the main considerations for this scenario, for high-prevalence:</i></p> <p><i>Main conclusions/considerations:</i></p> <ul style="list-style-type: none"> • Higher number of cases detected using self-tests may increase pressure on public health authorities for surveillance and response activities. • Assuming that self-test positive test results are accurate without confirmation will decrease pressure on public health laboratory resources. • In areas with high population prevalence, it is plausible that there will be sub-populations or groups with very high prevalence, such as sub-populations with more risk-taking behaviours. Self-tests are not recommended for targeted use in these sub-populations or groups, as the possibility for false negative test results reduces the possibility to exclude true cases and may result in increased transmission. <p><i>Advantages:</i></p> <ul style="list-style-type: none"> • Potential to detect faster a high proportion of cases. • A larger number of cases will have the opportunity to self-isolate at an early stage of infection, which can make an impact on local transmission. • May increase the speed of contact tracing initiation. <p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> • 1-2% of the tests will be false negatives (for tests with 80% sensitivity, see Figure 2). <ul style="list-style-type: none"> • The contact tracing resource requirements would be large, but should still continue if feasible. • Requires laboratory capacity to process confirmation tests.

SCENARIO 2. Use of self-tests within targeted settings (please refer to Figure 4)

Settings

Targeted settings can include, but are not limited to:

- settings with high risk of transmission to vulnerable people (e.g. healthcare settings, long-term care facilities, prisons, migration centres, accommodation for vulnerable persons)
- settings with a high number of children and adolescents mixing (e.g. schools, sports activities).

It is important to consider that settings may differ in prevalence, transmission dynamics, and the proportion of asymptomatic cases (i.e. possibly higher in children and/or school settings).

In all settings, self-tests should not be used to replace NPIs and/or exempt individuals from following NPIs such as physical distancing.

Main considerations for use of self-tests in targeted settings, common to both low and high-prevalence levels:

- Self-tests can help reduce further transmission through early detection of infectious cases, thereby enabling rapid isolation.
- Even if there are no cases, there will be false positive cases, requiring self-isolation and contact tracing until confirmatory laboratory test results are available (Figure 2).
- Compared to the population setting, it may be easier to collect results and follow-up positive cases in targeted settings (with known/defined individuals).
- Self-tests may be more feasible and acceptable for setting-wide screening than RT-PCR, which is likely to lead to earlier identification of cases.
- The consequences of false negative results are significant, particularly in high-risk settings, and therefore self-tests should not be used for confirmation of being non-infectious in these settings.
- In settings with younger age groups, for example school settings where students are tested, the use of self-tests is likely to be useful, as children are more likely to be asymptomatic/pre-symptomatic and less likely to seek a test for COVID-19 in a testing facility etc.
- Compared to population-level screening, this targeted approach has lower absolute numbers of positive results to laboratory-confirm.
- Contact tracing should always be undertaken, whenever feasible.

Zero to low prevalence (0%–5%)	<p><i>In addition to the main considerations for this scenario, for low-prevalence:</i></p> <ul style="list-style-type: none"> • Cannot necessarily be used to identify clusters/outbreaks, if there are a small proportion of positive cases, in case they are all false positive, until laboratory confirmation, i.e. RT-PCR.
High to very high prevalence (10% to 20%)	<p><i>In addition to the main considerations for this scenario, for high-prevalence:</i></p> <ul style="list-style-type: none"> • A test to define the extent of an outbreak is useful for its control, e.g. allowing for isolation of potentially infectious people. • Due to the possibility for false negative test results, they should not be used for confirmation of being non-infectious in these settings.

Annex 3. Scenarios of self-test use and possible impact on surveillance

The below flow chart and the associated impacts on surveillance are based on the assumption that self-tests are implemented at a population-level and that they are uniformly accessible to all individuals within that population/area. In other words, we do not consider the specific impacts on population-level surveillance where self-tests are used in very limited targeted settings (e.g. only in schools in one small regional area), however some of the implications may apply. It is important to note that where different scenarios are implemented within one population, the surveillance implications will be very complex. As such, it is highly recommended that PH authorities implement a uniform approach to the implementation of self-tests at all local and regional levels.

Irrespective of which scenario is implemented, communication from PH authorities will be critical to ensure the negative impacts on surveillance are minimised. A robust communication strategy should include information about how to perform the self-test and interpret the result, as well as what the individual needs to upon reading their test results, including how to report the result, what the recommendations are for self-isolation, the process for organising a confirmatory test using a laboratory-based method, and the process for liaising with public health authorities for contact tracing.

To minimise under-reporting of self-test results, it will be essential that the reporting process is kept very simple. Existing COVID-19 digital reporting solutions/processes could be adapted to accommodate this (e.g. adapting contract tracing apps or including it as an option when calling a central phone line).

Figure 3. Reporting of self-test results and possible impact on surveillance

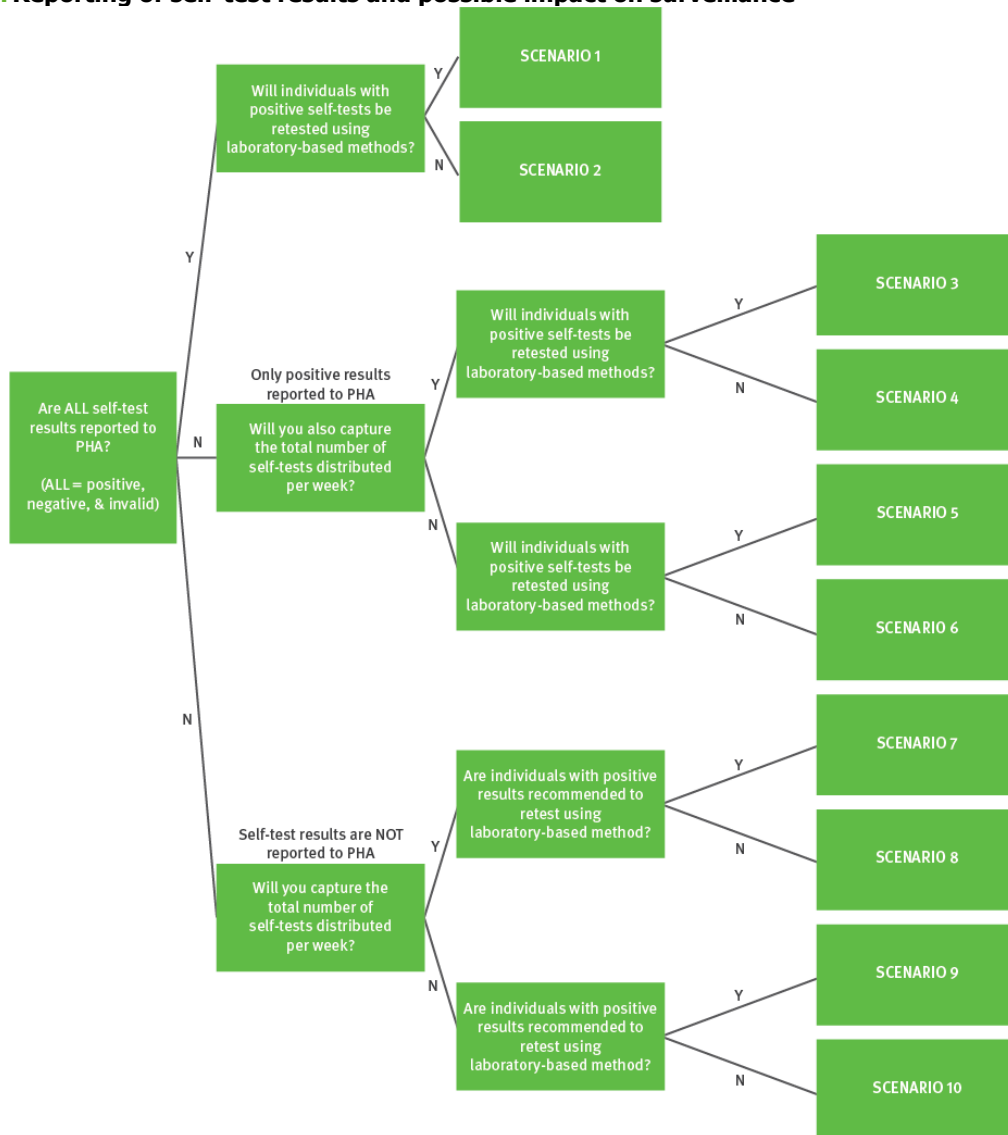


Table 3. Scenarios of self-test use and possible impact on surveillance

<p>Scenario 1:</p> <p>All self-test results are reported to public health authority</p> <p>Known testing denominator to calculate true test positivity</p> <p>Individuals with positive self-tests are recommended to retest using laboratory-based method</p>	<p>Common surveillance impacts for scenario 1 and 2:</p> <p>It will be possible to calculate the case notification rate, testing rate, and test positivity rate based on self-testing and laboratory-based data, either individually or by combining these datasets.</p> <p>The possible under-reporting of self-test results could bias any/all of these indicators depending on local circumstances, and as such under-reporting would need to be carefully monitored.</p> <ul style="list-style-type: none"> • Uniform under-reporting of all self-test results would lead to under-estimation of the notification rate, however the testing rate and test positivity would still be reflective of the true situation. • Under-reporting of only positive results would lead to under-estimation of all three indicators (notification rate, testing rate, test positivity). • Under-reporting of only negative results would not impact the notification rate, however the testing rate and test positivity rate would be higher than the true situation (as it would impact the denominator for those calculations). 	<p>Additional surveillance impacts specifically for scenario 1:</p> <p>Where it is recommended that individuals with positive self-test results are retested using laboratory-based methods, there are additional impacts on surveillance:</p> <ul style="list-style-type: none"> • Risk of double counting positive cases if public health authorities don't have ability to link positive results to individual cases. • If not possible to link results to individuals it may not be beneficial to utilise both self-test and laboratory-based results (or alternatively, individuals with positive self-test results should not be encouraged to retest using laboratory-based methods). • To prevent inflating test positivity rates, only the first positive test result (self-test or confirmatory laboratory test) should be reported per individual.
<p>Scenario 2:</p> <p>All self-test results are reported to public health authority.</p> <p>Known testing denominator to calculate true test positivity</p> <p>Individuals with positive self-tests NOT encouraged to retest using laboratory-based method.</p>	<p>To estimate the level of under-reporting of all self-test results, PH authorities could monitor the number of self-tests distributed or sold.</p> <p>Public health response activities (such as contact tracing) based on self-test results are enhanced provided positive test results are reported.</p> <p>Laboratory confirmation testing might be strained depending on the volume of positive self-test reports.</p>	<p>Additional surveillance impacts specifically for scenario 2:</p> <p>If individuals with positive self-test results are not recommended to confirm using laboratory-based methods, the implications are as follows:</p> <ul style="list-style-type: none"> • Reduced risk of double counting cases. • Reduction of testing pressure on laboratory systems and resources. • Linkage of results will still need to be considered by public health authorities, even if they are not recommending retesting, as there may be incentives for individuals to get retested to obtain a positive laboratory-based result (e.g. for a certificate). • A widespread shift away from laboratory-based testing could impact public health's ability to monitor, or identify, variants of concern if there are fewer samples available for sequencing.

<p>Scenario 3:</p> <p>Only positive self-test results are reported to public health authority.</p> <p>Have proxy self-test testing denominator (based on e.g. distribution data).</p> <p>Individuals with positive self-tests encouraged to retest using laboratory-based method.</p>	<p>Same surveillance impacts as scenario 1 and 2</p>	<p>Same additional surveillance impacts as scenario 1 with additional impacts:</p> <ul style="list-style-type: none"> • Testing rates and testing positivity rates using the proxy denominator data may not be accurate if individuals can obtain multiple self-test kits at a time. • Under-reporting of positive results will lead to under-estimation of test positivity. <p>It would be possible to undertake public health response activities (such as contact tracing) based on self-test results, however under-reporting of positive results by individuals could undermine efforts.</p>
<p>Scenario 4:</p> <p>Only positive self-test results are reported to public health authority.</p> <p>Have proxy self-test testing denominator (based on e.g. distribution data).</p> <p>Individuals with positive self-tests NOT encouraged to retest using laboratory-based method.</p>		<p>Same as scenario 2</p>
<p>Scenario 5:</p> <p>Only positive self-test results are reported to public health authority.</p> <p>NO proxy self-test testing denominator.</p> <p>Individuals with positive self-tests encouraged to retest using laboratory-based method.</p>	<p>Same surveillance impacts as scenario 1 and 2 with additional impacts:</p> <ul style="list-style-type: none"> • Not possible to estimate the testing rate or test positivity rates as no self-test denominator data are available. • If public health authorities incorporated both self-test positive results and laboratory-based positive results in the surveillance data but only calculated the number of laboratory-based tests conducted as the denominator the testing rate is underestimated whereas, the test positivity rate is overestimated. 	<p>Same as scenario 1</p>
<p>Scenario 6:</p> <p>Only positive self-test results are reported to public health authority.</p> <p>NO proxy self-test testing denominator.</p> <p>Individuals with positive self-tests NOT encouraged to retest using laboratory-based method.</p>		<p>Same as scenario 2</p>

<p>Scenario 7: NO self-test results are reported to public health authority.</p> <p>Have proxy self-test testing denominator (based on e.g. distribution data).</p> <p>Individuals with positive self-tests encouraged to retest using laboratory-based method.</p>	<p>Common surveillance impacts for scenario 7 and 8:</p> <ul style="list-style-type: none"> • Testing rates and test positivity rates would be calculated using laboratory-based results and incorporate the denominator of proxy self-testing data. • Reduced likelihood of double counting positives as laboratory-confirmed test is the only test result reported to public health. • Increased likelihood of underreporting of positive cases if self-test results are not sent to public health authorities and if there are barriers to confirmatory tests. • Public health authorities might see a decrease in laboratory-based testing (in preference for self-tests) if self-tests are easier for individuals and if there is no incentive to obtain a laboratory-based result (e.g. for a certificate). • Proxy self-test denominator data, alongside laboratory-based testing data, could be used to monitor testing use trends. <p>In addition, these scenarios would not allow public health authorities to undertake public health timely response activities (such as contact tracing) based on self-test results. The individual with the positive self-test result would be responsible for their own self-isolation and contact tracing (however public health authorities could provide clear instructions with self-test kits about what the recommendations are to assist with this).</p>	<p>Additional surveillance impacts specifically for scenario 7:</p> <ul style="list-style-type: none"> • Laboratory-based testing of confirmatory self-tests may be biased towards positive results (inflating the test positivity rate) if confirmatory tests are required. • If the individual incentive to retest is not high, there is likely to be under-representation for retesting which would negatively impact surveillance and limit the ability of PH authorities to understand the epidemiological situation. In this scenario, it may be beneficial for PH authorities to incentivise retesting (for example, by issuing certificates alongside the laboratory-based results) however the risk of doing this that the laboratories and PH authority may be overburdened when the incidence is high.
<p>Scenario 8:</p> <p>NO self-test results reported to public health authority.</p> <p>Have proxy testing denominator (based on e.g. distribution data).</p> <p>Individuals with positive self-tests NOT encouraged to retest using laboratory-based method.</p>		<p>Additional surveillance impacts specifically for scenario 8:</p> <ul style="list-style-type: none"> • In this scenario, the ability of public health authorities to understand the epidemiological situation will be very limited if self-test use is high and individuals have no recommendation to retest. • All indicators (notification rate, testing rate, and test positivity) would under-estimate the true epidemiological situation. • A widespread shift away from laboratory-based testing (and reporting) would impact the ability to monitor, or identify, variants of concern as there would be fewer samples available for sequencing.
<p>Scenario 9:</p> <p>NO self-test results reported to public health authority.</p> <p>NO proxy self-test testing denominator.</p> <p>Individuals with positive self-tests encouraged to retest using laboratory-based method.</p>	<p>Same surveillance impacts as scenario 7 and 8 with additional impacts:</p> <p>These are the potential scenarios if self-tests are used in the 'private market' without any involvement with or reporting to PH authorities.</p> <p>In these scenarios, it would not be possible to calculate the notification rate, testing rate, or test positivity rate based on self-testing data. These indicators would all be calculated using laboratory-based results.</p>	<p>Same as scenario 7</p>
<p>Scenario 10:</p> <p>NO self-test results reported to public health authority.</p> <p>NO proxy self-test testing denominator.</p> <p>Individuals with positive self-tests NOT encouraged to retest using laboratory-based method.</p>		<p>Same as scenario 8</p>