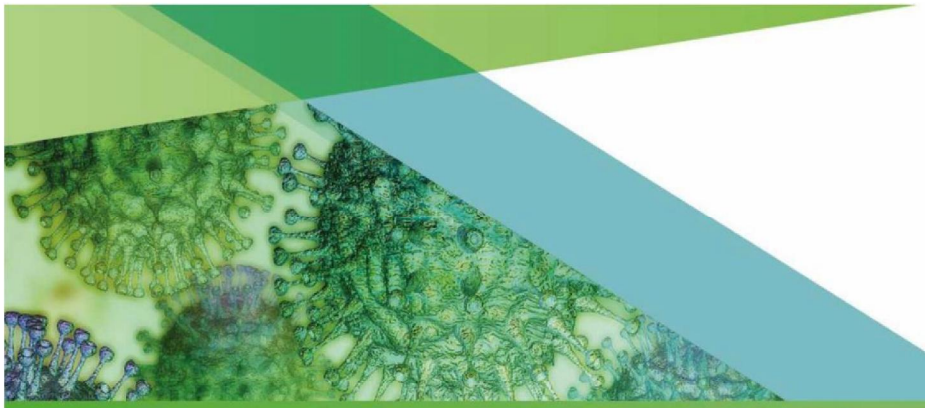

Response to the EC request 182 – *Not for publication*

ECDC response on the use of COVID-19 self-testing in the EU/EEA

8 March 2021

Key points

- Self-testing for SARS-CoV-2 involves collection of a specimen, conducting a rapid test and interpreting the test results by the individual.
- Two types of rapid tests are currently available for self-testing: the rapid antigen detection tests (RADTs) and the loop-mediated isothermal amplification (LAMP) tests.
- Self-tests offer advantages from a public health and disease control perspective compared to professionally administered RADTs or RT-PCR tests by making testing more accessible.
- Self-tests can be done at home and provide results quickly (within 30 minutes), which may improve timeliness of and adherence to self-isolation and other non-pharmaceutical interventions.
- Health authorities could incorporate the use of self-tests as a complement to the current testing
- There may be situations where self-tests are more useful, such as for screening asymptomatic or pre-symptomatic individuals prior to social interactions and in occupational settings (e.g. in schools and healthcare settings) where frequent testing is required.
- Self-tests should include clear instructions for performing the test, interpreting the result, reporting the result, as well as local recommendations for self-isolation and any further actions required.
- A clear process for individuals to report their results to public health authorities for surveillance, contact tracing & other public health response measures should be ensured. Existing mobile apps (or similar) may be of use for reporting of self-test results.
- Access to self-tests should be equitable, and clear communication about the benefits and intended use of these tests will be integral.

Introduction

SARS-CoV-2 diagnostic self-testing requires individuals to collect a specimen from their own nose/throat, conduct the test and interpret the results according to the instructions provided. These tests can be done at home, without the involvement of any health professionals or laboratory staff. Although self-tests require an individual to collect their own specimen, they should not be confused with self-swabbing where self-collected samples are then processed at a laboratory or other health-care setting by a trained person.

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* [1]. In order for the test result to be registered with the public health authorities (PHAs), the individual would need to actively report the result. Testing by self-swabbing and subsequent laboratory processing of the sample would normally lead to registration of the result by the PHAs.

A summary of the general characteristics of self-swabbing and self-testing are provided in Table 1.

Table 1. Summary of self-swabbing and self-testing characteristics

	Self-swabbing	Self-testing
Description (general)	• Requires individual to perform the collection of the specimen by themselves and then send it to a laboratory where the test is performed. • Specimen collection can be supervised (e.g. by a HCW) or unsupervised (e.g. at home). • The results are reported back to the individual and to the relevant PHA according to the national legislation.	• Requires individual to collect the specimen by themselves, as well as to perform the test and interpret the test result according to instructions.
Test methods	• RT-PCR • RADT • RT-LAMP	• RADT • RT-LAMP
Specimen types	• Nasal swab • Throat swab • Saliva • Combination of above	• Nasal swab • Throat swab • Saliva • Combination of above
Advantages (general)	• Reduced risk of transmission to others associated with travelling to see a HCW or attend a testing clinic. • Convenience of collecting the sample at any time. • Reduced burden on HCW/testing clinic staff to collect specimens, and reduced occupational exposures to HCWs. • Specimen processing done by HCW/laboratory with robust quality assurance (QA) procedures in place. • Results routinely reported to PHA.	• Reduced risk of transmission associated with travelling to see a 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 (when factoring in HCW and/laboratory staff time, laboratory consumables, etc.). • Reduction of equipment and person/machine time needed and pressure on healthcare system.
Disadvantages (general)	• Might lead to sub-optimal sample quality affecting reliability of results. • Arrangements for collection/posting of sample by/to laboratory are needed. • Waiting time for results (up to 1-3 days).	• 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 PHA, which has implications for surveillance and public health response. • May require confirmatory testing (if positive result), which may cause increased burden on healthcare system. • False negative results might convey a 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).

Abbreviations used: RT-PCR – reverse transcription-polymerase chain reaction; RADT – rapid antigen detection test; RT-LAMP - reverse transcription loop-mediated isothermal amplification; HCW - health care worker; PHA - public health authority; QA – quality assurance.

This document is focusing on self-testing for direct detection of SARS-CoV-2 virus particles in order to identify infectious individuals and prevent further virus transmission.

What are self-tests and their availability

Self-testing is a process, where a person collects his or her own specimen (can be nose swab, throat swab, saliva or a combination of all), following detailed instructions that accompany the test kit or even an instructional video, if link is provided. The person then performs the test and interpret the result, according to the instructions provided, without any support of, or supervision by, a health care professional. The rapid antigen detection tests (RADTs) and the loop-mediated isothermal amplification (LAMP) tests are relatively simple methods that can be used by a lay person, therefore making these tests suitable for self-testing. It is very important that the manufacturer and/or the local health care authorities provide well-designed, easy to read, locally adapted and user friendly instructions for the sampling and test procedures (e.g. environmental conditions, incubation times, time between sampling and reading, correct interpretation of a positive and a negative results, etc.) in an illustrated way, so that they can be easily followed by a lay person. All the above can significantly reduce errors in performance of a rapid self-test, as described from existing experience of self-testing kits for other pathogens [2].

Currently, there are only a couple of tests on the market, intended for self-testing (or at home-testing). The first COVID-19 self-testing kit designed specifically for at home use, received emergency use authorization (EUA) in the U.S. by the Food and Drug Administration (FDA) on 17 November 2020 [3], for people >14 years of age. This is currently sold in the U.S. but requires a prescription.

According to a recent inventory performed by the European Commission (EC), as of 3rd February 2021, there are 41 RADTs with a 'CE' marking in use by at least one EU/EEA Member State, and 28 of these tests have completed validation in at least one EU/EEA Member State. A common list of COVID-19 rapid antigen tests, where results are mutually recognised by the EU/EEA Member States was published on 17th February 2021 [4,5]. These tests have a CE marking, meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity and have been validated by at least one Member State as being appropriate for a specific use in the context of COVID-19 detection. Currently, there are 16 RADTs on this list [4], however none of them are currently registered with intended use as a self-test.

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

A few studies have reported on the quality of specimens taken by lay persons versus trained health care professionals, as well as the overall performance of a self-test compared to the gold standard SARS-CoV-2 detection method, which is the RT-PCR.

In the study done by Stohr et al. [6], a total of 3,215 participants received the self-testing kits BD Veritor System RADT or the Roche RADT, and used them on specimens from nasal swabs. Sensitivity after self-testing was compared to the gold standard method (RT-PCR) and 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 RDT. Both RADTs gave a very high specificity >99% (BD RADT: 99.7% (95%CI: 99.2-99.9); Roche RADT: 99.1% (95%CI: 98.5-99.5)). Samples with high concentration of virus RNA (low RT-PCR Ct values) gave higher sensitivity, without any difference in specificity. They also identified determinants independently associated with false-negative self-testing results, included higher age, low viral load and finding self-testing procedure difficult. The overall conclusion was that self-testing, using commercially available rapid antigen tests proved to be feasible and delivered reliable results. Of note, the sensitivity and specificity identified in the study did not meet the minimum performance requirements of ≥ 90% and ≥ 97% agreed as being appropriate for a specific use in the context of SARS-CoV-2 RADT performed in a laboratory.

In a study performed by Linder et al. [7], the agreement of results between a self-test and 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 comparable to those obtained by professionals.

The effect of the operator (person performing the test) on viral antigen sensitivity in RT-PCR-positive cases was investigated in a study by Peto et al. [8] 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 to a trained health care 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%).

The positive predictive value (PPV) of a test decreases with decreasing prevalence in the population where the test is being used. A test with a 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 suggesting that a only a minority of the 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 recommendable in such settings [9].

A recent modelling study by Larremore et al. [10] 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 in response to the pandemic. Bootsma et al. [11] had a similar finding from their modelling study, which indicated that a test with 80% sensitivity performed by at least 70% of the population once a week was estimated to 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.

In summary, the performance of the rapid tests when run as self-tests is slightly lower compared to when operated by professional staff. However, the performance should be put into the context of self-testing that can include factors which may balance the negative impact, for example repeated testing and accessibility of tests.

Current use and reporting practices

There is currently very limited information about the use of self-tests within the EU/EEA. Generally, self-tests can be incorporated into, or complement, the existing testing strategies of public health authorities or they can be used in the 'private market'. To date, self-tests 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.

In Austria, self-tests are being incorporated into the testing strategy of the Ministry of Health, although they were first available on the private market and could be purchased from pharmacies from January 2021 [12]. 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 [12-14]. The tests are accompanied by a leaflet that was prepared by the Austrian Ministry of Health with instructions on what to do if the test result is positive (including self-isolation and notification to the authorities) [13]. Although there is no formal surveillance associated with the results of these tests, under paragraph 3b of the Pandemic Act ('Epidemiegesetz 1950'), all positive results from self-administered tests must be reported to the official health hotline and have to be confirmed by authorities using a laboratory-based test (usually RT-PCR) [13]. In addition to this, it is anticipated that self-tests could be used in schools to test students. The tests will be self-collected twice (or possibly three times) per week under the supervision of teaching personnel or done at home by parents for younger children. All positive results will be reported to the school administration, parents (if done at school), and the public health authority. The same recommendation to confirm positive self-tests using a laboratory-based test (usually RT-PCR) [13] would apply.

The UK have 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 will be 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 [16]. These self-test kits will be distributed through schools for students and staff and made available at collection points or for home delivery for household contacts. Also across England, self-test kits are being distributed to residential aged care facilities for testing of staff and visitors [17], 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) [18]. Every result (positive or negative) can be reported through the NHS Track and Trace app, online, or by calling an information line ("119") [16]. 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 [3]. 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 [19]. Some self-test kits may be accompanied by mobile apps which can collect and report the results to the state health department [19].

In Germany, use of self-tests will initially be in the private market, however these tests could be incorporated into the national or state-level testing strategies. A number of self-tests were recently approved for sale in supermarkets, pharmacies, corner stores and on the internet, and more self-test kits are expected to be approved in the coming weeks [20]. The tests are estimated to be sold for less than €10, although the prices are yet to be announced and may become lower as more products become available on the market. 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 [21,22]. 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. Laboratory-based RADTs are currently used in schools (as well as in nursing homes and hospitals) to conduct regular tests on staff and students, however self-tests may replace some of the laboratory-based tests (details of this are not yet available). A pilot study conducted in Hesse, Germany, where teachers from primary and secondary schools across three school districts self-tested every 48 hours over a seven-week period [23]. This study demonstrated that self-tests were useful and accepted in occupational settings where testing had to be performed repeatedly, and that pre-symptomatic/mildly symptomatic cases could be detected using self-tests [23].

Consideration on self-test use and possible impact from a public health perspective

Use of self-tests has been established for screening for other communicable diseases, such as HIV [2]. Offering self-testing for COVID-19 may increase the testing rate.

Introduction of self-tests into routine use for detection of infectious people needs to be well-planned and carefully implemented. In addition to the considerations in this document, the introduction of self-tests should follow the relevant recommendations and considerations described elsewhere, which are also applicable for rapid diagnostic tests intended for laboratory use [9,24].

Impact of the use of rapid self-testing on the implementation of prevention and control measures

There are few studies of 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" [25]. Mina et al. [26], also refers to a strategy for containment with a frequent use of cheap, simple, rapid tests 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.

Public health authorities should take the following into account when considering implementation of self-testing:

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 results to the local authority. Modification of mobile apps, such as those already in use for contact tracing, to also report self-test results may facilitate both simple reporting as well as contact tracing.

Contact tracing may be hampered if individuals do not report a positive test result to their public health authority. Where individuals do not report, it will not be possible to follow up their contacts.

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-isolation

One of the drivers of the pandemic is a 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 to being tested at a testing facility (especially if this requires an appointment). In a study from the US, use of tests with rapid turn-around and performed at home were preferred over tests with longer turn-around time performed at a healthcare provider's office [27].

At an individual level, earlier detection of infection allows more timely self-isolation 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.

The likelihood of a false negative is low given the high specificity of the existing tests. False positive results could occur, making an individual self-isolate when they do not need to, however if individuals with positive self-test results are retested using laboratory-based methods then the likelihood of unnecessary self-isolation is reduced.

Social measures

There is a paucity of studies which evaluate self-testing as a tool to complement physical distancing measures. 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 [23]. 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, where a PCR had detected a SARS-CoV-2 infection in four cases, but the antigen tests were negative.

Self-tests can 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, and for those requiring frequent testing such as in workplaces with high risk of occupational exposure (such as in healthcare), 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 a social event, school or workplace, it may be possible to relax physical distancing measures while still controlling transmission.

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 potential. 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.

Certificates and travel restrictions

It is not recommended that self-testing results be used as evidence of a SARS-CoV-2 positive test for the purposes of obtaining COVID-19 testing and/or recovery certificates. Equally, negative self-test results should not be used for official purposes (such as proof prior to travel). There is a risk that results (either positive or negative) could be reported for an individual who was not tested in order to get a certificate or to avoid travel measures such as quarantine. Self-swabbing and self-testing both introduce the risk that the individual who reports the result is not the same as the individual whose specimen was collected, unless the collection of the specimen is performed in front of the person authorising the result. Additionally, the results from self-tests do not provide the same level of confirmation as laboratory-based RT-PCR and RADT.

Impact of self-tests on surveillance

When widely deployed and used, self-tests have the potential to significantly affect the available data on number of tests performed and number of cases reported, unless registration of number of tests performed and number of cases with positive self-tests is ensured. If no confirmatory RT-PCR-testing is required, the PHAs would not capture the cases diagnosed with self-tests. If confirmatory RT-PCR is required, self-tests could increase the number of cases (and proportion of positive tests) compared with what was reported during previous time-periods. In addition, even if data on the number of self-tests and positive self-tests are captured, a drastic change in the overall number of tests performed will affect positivity rates and to a lesser extent case notification rates, making interpretation of trends for these indicators more challenging.

The current EU case definition for coronavirus disease 2019 (COVID-19) can 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". Currently, RADT results for tests performed outside of laboratories (but by trained health care personnel) are considered confirmed cases.

An important challenge associated with interpreting surveillance results for self-tests is the possible lack of information regarding the number of tests performed (denominator information). Where the self-test kits are ordered from the local health authorities (such as in the UK), the number of tests requested could be tracked to give an estimate of tests conducted and testing rates. Additionally, where the positive self-test results are reportable to the local health authorities (such as in Austria, the UK and the US), cases can be recorded in the surveillance system, provided with advice, contact tracing can be initiated, and retesting using laboratory-based methods can be arranged (if necessary). Ideally, individuals should also be encouraged to report negative and unclear/invalid results to obtain an estimates of testing positivity. Integration with existing technology to report results, for example using mobile apps (as is done in the UK), would allow PHAs to collect results with minimal administrative burden.

Where self-tests are purchased privately (for example from a pharmacy) or conducted in a public setting (for example at a movie theatre or supermarket to gain entry), there is a risk that positive results will not be reported. In this scenario, and if no subsequent laboratory-based testing is done, the positive cases will not be counted in the surveillance system and public health authorities will not be able to provide advice to the individuals or initiate contact tracing. If self-tests are widely used in an area/region, without adequate reporting of results, the notification rate for that area/region would be under-estimated. This could have implications for local public health response measures. 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*. Testing rates and test positivity rates would be affected by the self-test reporting strategy within countries (all results versus only positive results versus no results) and whether individuals with positive self-tests need to undertake confirmatory laboratory-based testing (which would bias laboratory-based testing toward positive results and increase the test positivity rates). The change in testing rates and test positivity rates may make the current thresholds irrelevant or more difficult to apply, especially if there are different approaches across EU/EEA Member States to how the self-tests are used and what data are collected.

Not reporting positive self-test results would also impact the ability of local public health authorities to monitor activity, commence contact tracing, and provide advice. If self-testing is used in private settings, local PHAs should establish procedures to allow individuals to easily report their results to their primary health care provider and/or the local public health authority. Additionally, PHAs should work with the providers of these self-tests (i.e. where they are sold or used) to ascertain the number of tests conducted in order to estimate the test positivity.

Another surveillance consideration is the monitoring and detection of variants of concern (VOCs). An important drawback of rapid antigen tests is that the specimens cannot be further characterised, or sequenced. This is also true for self-tests, especially because the specimens are not shipped to a laboratory for testing. 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 [28], 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 bias) in the subset of individuals who are tested using laboratory-based RT-PCR methods compared with those who self-test.

Conclusions

Self-tests could offer many advantages from a public health (disease control) 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.

The value of the RADTs used for self-testing depends on the test characteristics (sensitivity and specificity). The specificity of currently available tests is very high. The lower sensitivity of available tests compared with RT-PCR reflects the high-sensitivity of RT-PCR in detecting SARS-CoV-2, including non-viable virus particles, and the ability of the subject to follow instructions.

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

If self-testing is made available, provisions should be in place for individuals to report their results to the local public health authority. This will ensure authorities can incorporate positive cases into the surveillance system, provide advice for isolation and other preventive measures, and commence contact tracing. Local PHAs may need to be additionally resourced to manage the potential increased workload due to the increased number of cases being detected.

The examples from Austria, the UK, Germany and the US give guidance about how self-testing could be an integrated component of the local public health authority's testing strategy. For integration with surveillance and public health response, self-testing should ideally include the following components:

- Self-test kits 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-test kits 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 isolation guidelines, informing contacts, seeking laboratory-based confirmation of the test, etc.);

  - how to report the results (ideally positive and negative); and
  - who to contact to seek professional advice/support.
- Public health authorities should have a system in place to collect the reported results (mobile app, cloud platform, dedicated hotline, or via HCWs etc.);
- 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 in order to monitor distribution, usage and performance of these tests.

Contributing ECDC experts (in alphabetical order)

[redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted].

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