

COVID-19: Testing strategy

25 March 2021

Introduction

Denmark and the rest of the world are still in the midst of a COVID-19 pandemic. In Denmark, the focus is on limiting the spread of infection, protecting vulnerable population groups, avoiding an overstretched healthcare system and maintaining the highest possible activity level in society. The essential tools for combating the spread of the pandemic remain the Danish Health Authority's general guidance on preventing infection, such as good hygiene and physical distancing, which can keep the epidemic in check in line with an ever-increasing proportion of Danes being vaccinated.

The continued epidemic in Denmark and the spread of various coronavirus variants underline the need to identify infected persons and break the chains of infection. Massive testing is one crucial element in this approach. Testing is the first measure that can help detect and reduce the spread of infection and is the starting point for initiating self-isolation and contact tracing.

Testing has been and remains a key element in the fight against COVID-19 in Denmark. Denmark is one of the countries in the world that tests the highest proportion of its population.

About the testing strategy

Denmark's testing strategy has been updated on an ongoing basis. This has been done based on experiences with testing during the epidemic so far, new knowledge about, for example, the infection-reducing effect of frequent testing and the emergence of new testing technologies, etc.

The testing strategy has been extended with antigen testing (quick tests), which, as a screening tool, can contribute to reducing the spread of infection in connection with the gradual reopening of activities in Danish society in Spring 2021. PCR testing remains the foundation of the Danish testing strategy, because this is the most virus sensitive and most reliable method. It also allows for sequencing of the samples to determine whether a specific coronavirus variant is involved.

The actions and initiatives described in the strategy have either been initiated by the authorities or will be launched in the coming period. The strategy will be developed

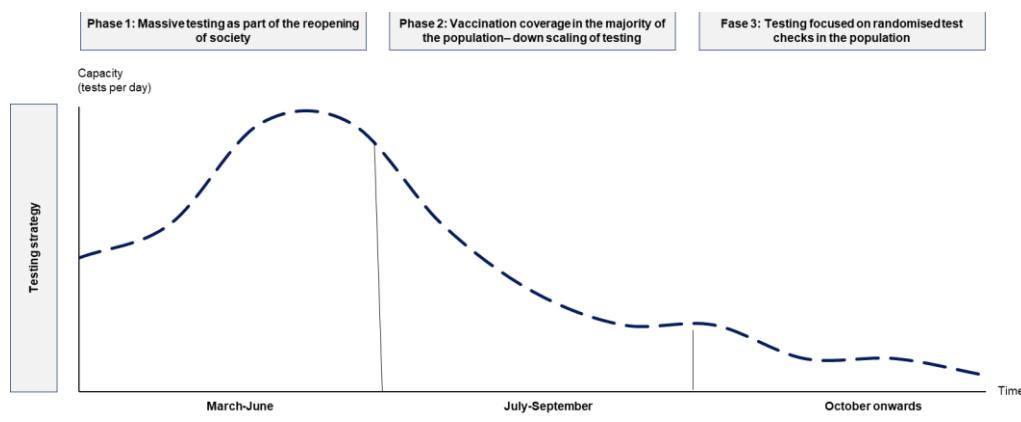
on an ongoing basis as we continue to learn more about the epidemic, and the vaccination campaign will also have an impact on the need for testing.

Most recently, the Danish Government and a wide majority in the Danish Parliament have adopted a framework agreement for the reopening of Denmark. Under this agreement, further work on a three-phased testing strategy approach will be done, with the current testing setup being continuously adjusted in line with the reopening of Danish society and with an increasingly larger proportion of the population being vaccinated:

- Phase 1: In the first phase, the gradual reopening of society is supported by massive testing using both PCR and antigen tests – as part of the rollout of the coronavirus passport. This first phase has thus already been commenced.
- Phase 2: In the second phase, when a larger proportion of the population has been vaccinated and the summer season is likely to reduce the infection rate, the testing programme is expected to be scaled down. In this phase, the testing will be targeted at the areas in which it is needed and against non-vaccinated groups.
- Phase 3: In the third phase, which will presumably commence around the autumn, testing is expected to be used primarily as part of the monitoring of the epidemic, including in relation to new mutations and the spread of infection. In this phase, the focus will be on randomised test checks in the population for monitoring purposes, supported by, for example, testing of wastewater and possibly other methods.

Figure 1 outlines the possible overall phases of the testing strategy with reopening of society and in line with a larger proportion of the population being vaccinated. It is based on a certain degree of uncertainty due to vaccine rollout, mutations etc.

Figure 1: Possible testing strategy phases (illustrative)



COVID-19 testing in the current phase (phase 1)

Purpose of testing in handling of COVID-19 epidemic

The overall objectives of the testing programme are:

- To identify people infected with COVID-19 by means of intensive and targeted testing to isolate and, if required, treat those infected.
- To identify and break chains of infection quickly by ensuring self-isolation of the infected person, tracing close contacts, preventing the spread of infection in situations in which it is not possible to follow the health authorities' recommendations for preventive measures, as well as to handle outbreaks.
- Protect vulnerable persons against infection.
- To screen in special sectors and more widely in society to support a more rapid reopening of society.
- To monitor continuously the infection rate in different parts of society, including antibodies and new coronavirus variants, to strengthen epidemic control and infection management.

Overall organisational principles for the Danish testing programme

To meet the objectives above, the testing programme follows the *overall principles* below:

- Test results must be available as soon as possible, so that contact tracing and self-isolation can be initiated. All citizens must have quick access to their own test results regardless of whether they have taken a PCR test or an antigen test.
- Tests must be easily available to all citizens in Denmark. There must consequently be a finely meshed network of testing stations ensuring wide geographical coverage throughout Denmark.
- Local testing capacity must be built up in relevant sectors.
- The testing programme must be sufficiently mobile and flexible, so that the testing can be proactive and targeted at precisely the areas where the largest infection reduction is achieved.
- The Danish testing capacity must be used to the greatest possible extent and may be adjusted upwards and downwards as needed.
- Testing must be included in the national monitoring of COVID-19.

Organisation of testing programme

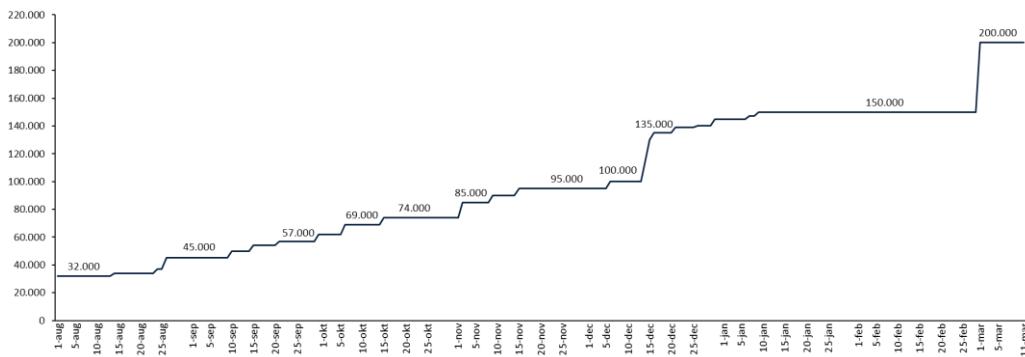
The testing programme is organised in two tracks: a health track and a societal track. The health track is conducted under the auspices of the regional health service. A

societal track, TestCenter Denmark, was created in April 2020 as an important testing capacity supplement. Testing in the health track takes place, for example in hospital departments and regional COVID-19 assessment clinics, while testing in the societal track is done in permanent testing stations, in flexible mobile units and other testing facilities. The societal track also uses antigen tests, which are performed by private suppliers. Antibody tests are also used in certain parts of the societal track.

The Regions are responsible for the healthcare management of the sampling for PCR tests in the health track and the societal track. The PCR test samples in the health track are generally analysed at the regional clinical microbiological departments, while the PCR test samples in the societal track are analysed at laboratory facilities under Statens Serum Institut. In both the health track and the societal track, the positive samples are screened for relevant coronavirus variants concurrently with virus in the positive samples being sequenced by WGS.

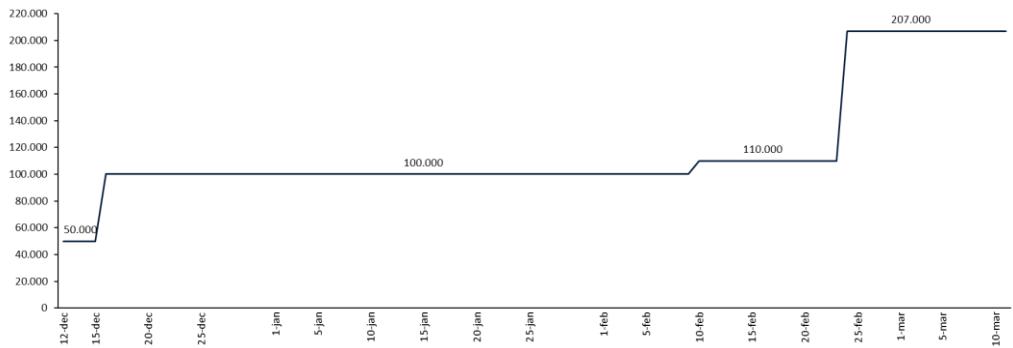
PCR testing capacity has been increased markedly in Denmark since Spring 2020. Overall, up to 200,000 people can currently be PCR tested daily.

Figure 2: PCR testing capacity



The societal track also includes an antigen testing track, where, by agreement with the Regions, private suppliers offer antigen testing with a current capacity of about 200,000 daily tests. In addition, local antigen testing capacity has been significantly increased in the municipalities and at various institutions.

Figure 3: Antigen testing capacity



In relation to antigen testing, it is planned that up to 500,000 daily antigen tests can be done during May 2021 if necessary. This is a marked increase in antigen testing capacity. This will allow the total testing capacity to reach 700,000 daily tests (PCR and antigen tests) during May.

The total testing capacity as at 1 March 2021 could accommodate more than 400,000 daily tests in Denmark in the societal track and the health track combined (PCR and antigen testing). This means that more than 48% of the population can be tested on a weekly basis – a percentage that puts Denmark among the world leaders in relation to our population size. Added to this is the local antigen testing capacity in the municipalities and at various institutions, where, for example, screening has been initiated in schools and educational establishments.

The ongoing management and coordination of the testing capacity in the societal track are anchored in the steering committee for TestCenter Denmark, in which all relevant players in the field participate. The steering committee has been set up to ensure coherence and interdisciplinary coordination of the overall testing programme.

Strategic use of COVID-19 testing

The ambition is that testing is to contribute to identifying infected persons, breaking chains of infection, protecting vulnerable groups at risk of a serious course of illness if infected with COVID-19 infection and monitoring the infection situation in society, including the occurrence of new coronavirus variants. Testing plays a crucial role in the reopening of society, and it is one of the prerequisites for our ability to reopen and keep the activity level in society as high as possible during the ongoing vaccination campaign.

The Danish testing programme consists of two test types, PCR tests and antigen tests, which can supplement each other and have different advantages and disadvantages. PCR testing is still the most reliable test type and makes it possible to identify special coronavirus variants. Antigen testing should therefore be seen as a supplement to PCR testing.

Use of PCR testing

The Danish testing strategy is based on the use of PCR testing, which is offered both in the healthcare system and in TestCenter Denmark – see the health authorities' guidance for handling COVID-19 in the healthcare system: <https://www.sst.dk/da/Udgivelser/2021/Retningslinjer-for-haandtering-af-COVID-19>. High-quality PCR analyses are used to obtain very accurate test results, while also allowing efficient and cost-effective analysis of large numbers of samples. The target groups for PCR tests are basically the following:

- Testing of symptomatic persons and close contacts of persons who have tested positive for COVID-19.
- Testing of patients with an expected need for hospitalisation for more than 24 hours as well as patients who are to undergo certain special procedures.
- Testing of asymptomatic patients/citizens and staff in the healthcare and elderly care sector, residential care centres, total institutions, etc. in connection with ascertained COVID-19 in the department/institution.
- Testing in connection with outbreaks.
- Routine testing of staff in the care and hospital sector.
- Testing in connection with interruption of self-isolation, including entry into Denmark.
- Follow-up testing of persons who have tested positive by antigen testing.

In addition, the PCR testing capacity is made available to all citizens.

It is a key priority to quickly test citizens who need to be tested, and that they also receive their test results quickly, so that necessary measures such as contact tracing and self-isolation can be taken quickly. The objective is that 80% of those who are to be tested will have access to be tested within 24 hours, and that 80% will receive their test results the day after the test was done. Test results are posted on a number of platforms, including sundhed.dk.

Use of antigen testing

The Danish testing strategy was supplemented with antigen testing in December 2020. Antigen testing is based on the detection of virus proteins (antigens) and is done by, for example, a nasal swab. A major advantage of antigen testing is that the test results are available within 15-30 minutes, so that chains of infection can be broken more quickly. The greatest disadvantage of the use of antigen testing is that the sensitivity and reliability of these tests are lower than in PCR testing. This means that some of the test results will be either false negatives or false positives.

Antigen testing is most effective if it is used widely in a population with a high infection rate and if persons are tested several times a week. Due to its lower sensitivity, this type of test should not be used for persons with COVID-19 symptoms

or for close contacts of persons infected with COVID-19, who should always take a PCR test.

Antigen testing is recommended for groups where it is meaningful to screen more systematically for the purpose of preventing outbreaks of infection and in connection with reopening of society. See the Danish Health Authority's recommendations for antigen testing and its use:

<https://www.sst.dk/da/Udgivelser/2021/Anbefalinger-for-brug-af-antigentest>.

In accordance with these recommendations, antigen testing is to be targeted at the following:

- In connection with receipt of a notification of close contact via the smitte|stop contact tracing app.
- Screening of 'other contacts', for example in workplaces in case of infection.
- Wide and frequent screening of the population from 12 years of age and upwards, with the focus being on groups affected by the reopening of society, for example in the education sector and cultural activities.
- Testing of all persons with physical workplace attendance and especially those who cannot avoid contact with a large number of persons.
- Screening of selected groups where prevalence is assumed to be particularly high, for example selected age groups or areas with a high infection rate.
- Frequent screening of persons who work in special occupations where physical attendance is necessary and where experience with epidemics shows that there are outbreaks, such as in slaughterhouses, at construction sites and among prison staff. The list of these occupations will be further qualified on an ongoing basis in collaboration with the Danish Patient Safety Agency and Statens Serum Institut.
- Testing on entry into Denmark.
- Screening of visitors and spectators et al. in connection with large-scale cultural and sports events.
- Specific situations in which a quick test result is important, for example for quick initiation of infection tracing. Here antigen testing with concurrent PCR testing can be used.

Testing strategy tracks

The Danish testing strategy is based on a model for rollout of a wide testing programme through three main channels:

- Establishment of a finely meshed network of stationary antigen testing facilities, which, together with the PCR testing facilities, ensures wide availability of tests for all Danes.

- Establishment of local antigen testing capacity in, for example, the educational sector to increase user-friendliness and ensure high compliance in schools and institutions.
- A smaller and targeted mobile testing capacity that can be used in places and situations in which there is a very special need for testing.

Finely meshed network of permanent testing sites

A finely meshed network of permanent testing sites has been established, which ensures wide availability for all Danes, so that all Danes generally do not have more than 20 km to the nearest testing site – and in many cases less. The wide geographical coverage is ensured via both permanent antigen testing sites and permanent PCR testing sites. It is essential for quick identification of chains of infection that testing can be done close to the citizens.

Local testing capacity

In addition to the finely meshed network of permanent testing sites, a local antigen testing capacity is continuously built up, as seen in, for example, the educational sector, to increase user friendliness, to ensure high compliance and thus create the best foundation for epidemic monitoring and reopening of society. In principle, it will be possible to roll out the model anywhere with a certain testing volume, for example large institutions (daycare facilities, nursing homes etc.). New testing methods are also being considered in this connection, including the possibility of self-testing.

Mobile testing capacity

In addition to the permanent testing stations, which constitute the nucleus of the reopening strategy, a minor part of both the PCR testing capacity and the antigen testing capacity is mobile. The mobile capacity will be targeted at places and situations in which there is a very special need or persons who do not go to a testing site themselves. The mobile testing capacity makes it possible to quickly relocate and upscale sampling capacity locally and temporarily in the event of infection outbreaks or places with high infection rates, where the demand for testing often increases markedly. This applies both within and across regions.

Effective use of testing capacity

Experience shows that even ample testing capacity can suddenly come under pressure. There may consequently be a need to adjust access to testing to ensure maximum infection reduction. Concurrently, testing recommendations may change continuously in line with further restrictions or reopening, the infection rate development and the rollout of vaccines.

In addition, efficient use of testing capacity entails that the capacity is also utilised during periods in which the Danes themselves do not have a particularly high demand for testing. In such cases, the authorities will encourage the population or parts thereof to be tested so that the infection can be identified and chains of infection can be broken.

Behaviour and communication

In the final analysis, the success of the strategy will depend on the Danes being tested with the necessary frequency. In this connection, a number of communication activities have been planned at local and national levels, and oriented towards different population groups. The national communication activities include the preparation of a map of testing sites which can be accessed via coronasmitte.dk, and the preparation of a digital coronavirus passport, where Danes can easily and quickly access and document test results and COVID-19 vaccination.

Implications of vaccination campaign

Based on the existing knowledge, the Danish Health Authority will continuously assess whether there is scope for a gradual relaxation of infection prevention recommendations for persons who have been vaccinated, including testing recommendations.

Since 18 March 2021, the Danish Health Authority's recommendation has been that vaccinated staff in nursing homes, care homes, relief places and social institutions etc. may refrain from being tested regularly if the vaccination rate among residents is more than 80% and if they themselves have completed their vaccination (i.e. 14 days after the second vaccination, regardless of vaccine) and are asymptomatic. The current recommendation is that vaccinated persons who are defined as close contacts be tested, see the programme for close contacts. Reference is made to the Danish Health Authority's recommendations for vaccinated persons: <https://www.sst.dk/da/Udgivelser/2021/Anbefalinger-for-vaccinerede-personer>

Antibody testing

Antibody testing is used for test checks of the population for use in the ongoing monitoring of the epidemic. At the end of February 2021, Statens Serum Institut launched the fourth round of the National Prevalence Study, which helps the health authorities establish how widespread the COVID-19 virus has been in Denmark. Antibody testing is done by measuring antibodies in blood samples from randomly selected citizens to acquire knowledge of the percentage of the population who have already had the infection or are protected via antibodies developed after vaccination.

Antibody testing aimed at monitoring vaccination effectiveness (the Enforce project) is also essential, not least to show the duration of protective antibodies to clarify any need for revaccination. As vaccination is voluntary, antibody testing could

also be a method for non-vaccinated persons to demonstrate that they have antibodies after natural infection.

Whole-genome sequencing

Where possible, whole-genome sequencing is done for all PCR positive tests from both health and societal tracks. The purpose of whole-genome sequencing is to establish new coronavirus mutations and variants of particular interest, to be able to map outbreaks and chains of infection, to identify re-infections and vaccine failures etc.

Coming testing phases (phases 2 and 3)

In line with a larger proportion of the population being vaccinated and seasonal reduction in new infections, the testing programme will gradually transition to phase 2 (expected at the beginning of summer). From then, the testing programme will be scaled down quickly and be targeted at groups that have not been vaccinated, such as under 16-year-olds, migrant workers or non-vaccinated travellers entering Denmark. Testing can also be used to a greater extent as, for example, a condition for participation in special activities with many participants.

Phase 3 is expected to commence in the autumn when there is adequate vaccination coverage in the population. The infection rate is generally expected to be very low during this phase unless mutations occur which can significantly evade vaccine-induced immunity. If vaccine-induced herd immunity is maintained during this phase, there will be low spread of infection in society, and testing for COVID-19 will form part of the general diagnosis apparatus in the healthcare system, such as testing for other respiratory tract infections such as influenza, and the need for standing testing capacity is likely to be very limited. During this phase, the public offer of testing will be based on PCR testing if the testing is primarily to be used for disease identification. Especially phase 3 is characterised by great uncertainty and will depend on a number of factors, including vaccination rollout and epidemic development as well as new coronavirus mutations that may affect the vaccination campaign.

Future development in testing

There is an ongoing development in testing, and new testing methods are expected to be taken into use in the coming months, for example saliva testing, detection of COVID-19 virus through wastewater monitoring etc. The strategy will be revised in the light of this, so that the experiences gained with the current testing setup will be assessed as well as the need for testing once a large proportion of the population has been fully vaccinated. Also in connection with the reopening of the educational sector, experiences are gained with new testing systems, including supervised self-testing, which can form the basis for the further development of testing.

