



17 November 2020

## TestCenter Denmark - setup

### Background

As a consequence of the fast developing COVID-19 crisis in the spring of 2020, it was in April 2020 decided to establish TestCenter Denmark (TCDK) and within TCDK a high throughput laboratory with a capacity to analyze 20.000 PCR tests a day. The purpose of TCDK was and still is to support the ambition to provide free and easy access to testing for all persons in Denmark.

The test facilities of TCDK are located all over the country and offer tests to asymptomatic citizens and since October 2020 also citizens with mild symptoms. This setup is usually referred to as the “Community track”. Citizens with clear symptoms or in need of medical attention are tested within the health care system and the setup here is often referred to as the “Health track”.

In the beginning, the “Community track” offer was limited to certain population groups, but since late May, the offer was extended to include all adult Danish citizens and since then further expanded to also include foreigners living in Denmark and children from the age of 2. Foreigners not living in Denmark, but just visiting Denmark can also be tested free of charge in select test facilities. Furthermore, TCDK facilitates targeted efforts to specific population groups, for instance health care workers or staff working with the elderly or vulnerable groups in order to ensure an enhanced focus and fast response on possible cases in these employment groups. Targeted efforts also take place in the context of surveilling the epidemic and scientific projects related to combatting the epidemic.

The analytical facilities of TCDK are centralized while the actual sampling takes place in test stations located all over the country. A number of mobile test stations are also used to ensure coverage in places far from permanent test stations or if special conditions call for sending out mobile test stations. The sampling and the physical facilities for the test stations is a responsibility of the regions.

### Booking time for at test and sample results

Citizens can book time for a test in any test station in the country. The procedure is simple and fast. A citizen can also contact the region to book a time. Also, a number of “walk in” test stations are available. A good example is the test station in Copenhagen Airport or mobile test stations. Foreigners can be tested many places even without a Danish social security number – and for free. Citizens with symptoms must always contact their own general practitioner for a test in the health track.



Most sample results are available the following day after the sample has been taken. Citizens with a Danish national digital “Common Secure login” can see their sample results digitally on “sundhed.dk”. They can also call their own general practitioner. Both Danish citizens and foreigners will be contacted in case of a positive result. This is done by a newly established unit within the Danish Patient Safety Authority.

TCDK uses the existing national health care IT infrastructure to enable a highly automated process booking a test and retrieving relevant data at the sampling point to tracking the samples through analysis and further to the automated and digital delivery of sample results to the citizens and the general practitioners.

### **Criteria and facilities for analyzing the samples**

The analytic facility is established in temporary buildings in the State Serum Institute Campus in Copenhagen. The facility is using automated equipment (liquid handlers) already available at the campus as well as equipment ordered from different vendor/suppliers (Hamilton and Beckman Coulter). The analysis is built around flexible and automated equipment to ensure that capacity can be scaled up through automation and stable supply through flexibility. Another analytical facility is now being established in Aarhus to increase analytical capacity and ensure short waiting time for sample results.

PCR analyses used in TCDK must be reliable and meet clinical performance requirements regarding sensitivity and specificity. Reagents and materials used in the facility must not be in competition with similar reagents and materials used by the local regions for testing citizens with COVID-19 symptoms.

The ambition is that samples are received in the facility the same day the samples have been taken and that analysis is completed no later than the following day.

### **Analysis flow and equipment**

The analysis flow consists of three steps:



The samples are pharyngeal samples, taken with swabs placed in 1 ml matrix tubes each with a 2D bar code in the bottom. This way, samples can be received from testing stations in rack each fitting 96 tubes that fit the further process. In the sample preparation virus is released from the swabs by adding PBS and 200µL is transferred to a microtiterplate. This is handled by Hamilton Star liquid handlers.

RNA ekstraktion is done on Biomek i7 liquid handlers and consists of a bead-based kit from Beckman Coulter. Beckman Coulter has scaled up production to meet the need so far with respect to materials, reagents and consumables (including tips).

RT-qPCR analysis takes place on BioRad CFX96 real time PCR machines with Luna Mastermix and E gene primer/probes.



## Sensitivity and Specificity

The tests used by TCDK are so-called PCR tests. They are considered to be very accurate. Still, there are risks of errors, generally the following two:

- false-positive answers (Specificity)
- false-negative answers (Sensitivity)

False-positive answers (a person receives a positive test result, even though the test result is in fact negative) is a general phenomenon that applies to all COVID-19 PCR tests. It can never be ruled out that there are occasionally a few false-positives, but the State Serum Institute and TCDK do not have knowledge of specific false-positive answers. The design of the test (no theoretical genetic cross-reaction with other micro-organisms or human genome in databases), the validation (no cross-reaction with other micro-organisms or human genome in testing samples known to contain other viruses and human genetic material) and the execution ("cut off" for ct values of 38 (false positive is usually at ct values around 40)) of the diagnostic PCR tests, attributes a very high specificity (> 99.9%) which is generally confirmed when re-tested and/or gene sequenced.

In addition, there are false-negative answers (a person receives a negative test result, even though the test result is in fact positive). It is not possible to carry out major clinical studies of sensitivity as such, as there is no "fact list" that can be checked against. However, it can be stated that in the PCR tests used at SSI/TestCenter Denmark, the sensitivity is high, as the so-called analytical sensitivity in the tests is a few SARS-CoV-2 RNA copies.

## Capacity and Supply

Capacity has been incrementally expanded from 1.000 samples in March to 65.000 samples per 24 hours as of mid-November. Work to increase capacity continues and the aim is an analytical capacity of at least 95.000 tests a day by the end of the year. Optimization in both manual workflows and the automated workflows on robots has played a major role in increasing capacity in a situation, where supplies and equipment are scarce. The laboratory works in three shifts and has had to deal with the challenge of hiring and training sufficient staff for the very large sample flow.

Supply has faced – and still faces - challenges. Therefore, the laboratory has established a unit solely focusing on procurement and production of reagent and materials that cannot be sourced through the usual distributors. For some materials (e.g. plastic materials), it has been necessary to find vendors in Denmark or Europe capable of tailor made production, for instance 1mL matrix tubes.