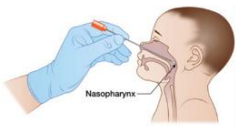
General

1. **The kit detects for Covid-19. How does it work?**
   The ProTect™ kit detects for the presence of the SARS-CoV-2 virus which causes Covid-19. It does that by detecting for the genetic material of the virus, which in this case is the ribonucleic acid (RNA). The kit targets multiple genes of the virus. Once it "finds" these genes, it makes many copies of that genes using a process known as polymerase chain reaction. As more copies of those genes are being made, it generates fluorescent signals that can be detected using a real-time PCR instrument. The PCR is a very accurate and sensitive test as it can detect for very low copies of the virus. Currently, the detection of the SARS-CoV-2 virus using PCR is the recommended method used by most countries for confirmation of Covid-19 infection in patients.

2. **What is the entire process for detecting for the virus?**
   First, a nasopharyngeal specimen is collected using a nasal swab. The swab is then immersed into a transport medium. Second, RNA extraction is carried out on the specimen. This process lyses the viral particles to release the RNA and then purifies it. This step must be carried out with an RNA extraction kit and a bench-top centrifuge. Third, the extracted RNA is put through the PCR process. If specimen contains the Sars-CoV-2 virus, the real-time PCR process will show a positive result, confirming the presence of the virus.



1. Specimen collection

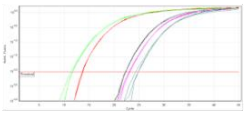
A nasopharyngeal specimen is collected from the patient using a nasal swab

2. RNA extraction

The specimen is then processed to extract out the RNA from the SARS-CoV-2 virus. This requires the use of a specialised RNA extraction kit and a centrifuge.

3. Polymerase chain reaction (PCR)

The extracted RNA is the put through a process called polymerase chain reaction. Here specific genetic signatures of the SARS-CoV-2 virus are being identified. If it is present, the process make many copies of the gene fragments. This process requires a specialised PCR kit and a real-time PCR instrument.



4. Results

If the virus is present, the real-time PCR instrument will detect fluorescent signals coming from the PCR reaction. This will confirm the presence of the virus.

3. **How long does it take?**
   The entire process from RNA extraction to PCR can be conducted in under 2 hours, with the PCR process requiring about 1h 15min.

4. **How is this different from the rapid test kits that can be performed in 15 minutes?**
   The rapid test kits that can generate results in 15 min detects for the antibodies present in an infected person. An infected person takes about a week to generate these antibodies in response to the viral infection. During this period, the rapid test may return a negative result due to the lack of antibodies even though the patient might be infected.

Technical

5. **What equipment do I need?**
   A real-time PCR instrument is needed. We recommend the following:

- ThermoFisher Scientific QuantStudio series (3, 5, 6 and 7) instruments and 7500 real-time system
- Bio-Rad CFX96 Touch™ Real-time PCR System
- Roche LightCycler® 96 and 480 Systems

6. **On which real-time PCR instrument has this been validated? Is it compatible with others?**
   The kit has been validated on ThermoFisher Scientific's Quantstudio 3 and Roche's LightCycler 480.

7. **How is this kit different from the Fortitude kit from A*Star?**
   Both the ProTect and A*Star's Fortitude use the PCR method to detect for the SARS-CoV-2 virus. The Fortitude detects for a single gene on the virus. The ProTect detects for multiple genes on the virus, in accordance to the US Communicable Disease Center (CDC) protocol. Detecting for multiple genes on the virus ensures that the kit can detect 100% of all the different strains of the virus. It also ensures that the kit can still detect the virus even if it mutates.

8. **Which targets on the SARS-CoV-2 virus does it detect?**
   It detects for the N gene of the SAR-CoV-2 virus, in accordance to US CDC recommended protocol.

9. **Each kit has how many tests?**
   Each kit has 100 tests.

Performance

10. **What is the sensitivity of the kit?**
    The kit can detect down to 10 viral RNA copies/reaction

11. **What is the specificity of the kit?**
    The kit has been tested to be specific to the SARS-CoV-2 virus based on *in silico* sequence validation.

12. **What is the efficiency of the assay?**
    The efficiency of the assay is more than 90%.

13. **What is the precision of the assay?**
    The assay has a precision of down to 2%

14. **What is the dynamic range of the assay?**
    The kit has a dynamic range of at least 6 logs.

Regulatory

15. **What regulatory approvals have been received for the kit?**
    The kit has received Singapore's Health Science Authority (HSA) provisional authorisation which means that it can now be used by the private and public hospitals and laboratories in Singapore to perform Covid-19 testing.

16. **Does the Singapore HSA approval mean that that the kits can be used outside of Singapore?**

It depends. The HSA authorisation allows the kit to be sold to public labs and hospitals in Singapore. In many other countries, the respective registration with the local regulatory body is still needed.

17. **Do the kits have CE Mark or US FDA approval?**
    No, they are presently not CE marked or US FDA approved.

Commercial

18. **What is the dimension and weight of each kit?**
    Each is contained in 2 small boxes. Each box is 73 x 49 x 54 (H) mm. Two boxes bundled together will be 73 x 98 x 54 (H) mm, weighing 100g

19. **What is the storage condition for the kits?**
    The kits are to be stored at -20 degC and repeated freeze thawing of the reagents are to be avoided.

20. **What is the shipping condition for the kits?**
    The kits are shipped in dry ice in a temperature controlled carton box. Each small carton measures 54 x 42 x 40 cm and weighs 25kg (including the dry ice) and can fit about 12 kits. For larger volume, we ship in specialised containers in a pallet.

21. **What is the minimum order quantity**
    The minimum quantity order is for 1,000 tests.

22. **How much is it to ship 1,000 tests?**
    The price varies depending on destination. Price can also fluctuate depending on availability of flights.

23. **What countries can we export to?**
    We currently can export to most places worldwide, subject to availability of freight.

24. **How many kits can fit into a pallet?**
    A single Euro pallet half-height with internal dimensions (1250 x 820 x 500mm) is estimated to be able to contain around 400-500 kits (or 40,000 to 50,000 tests).

25. **What should I do if I need a bulk order of a million test?**
    Due to the size of the order, please contact us to discuss the delivery schedule

26. **What is the expected lead time?**
    Lead-time is dependent on the quantity of orders.

[The End]