GeneFinder™ COVID-19 Plus
Real*Amp* Kit *CE-IVD*

Frequently Asked Questions (FAQ)

Osang Healthcare Co., Ltd / ES Lee / Mar 28,2020

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1. **Target Genes : RdRp, N, E à Osang Healthcare(here after OHC) kit can detect all specific genes for SARS COV-2(COVID19).**
   - In the early days of COVID19, it was suggested detecting only RdRp and E gene, but according to recent papers and guides, it is suggested to detect all RdRp, N, E gene.

2. **120 minutes detection for COIVD-19 à 96 tests(including controls) within 2 hours.**
   - Most Real-Time PCRs require 90 to 120 minutes. In the case of RocheCobas6800, it is said to process 384 samples in an hour, but it takes about 3.5 hours to run 96 plates. The advantage of Roche is All-in-One, but the equipment is very large and if an error occurs in the during the process, detection of all loaded samples are stopped. Mass testing has its advantages, but may not be suitable for emergency use.

3. **Reverse Transcription reaction and Real-Time Polymerase Chain Reaction à RT real time PCR is a reliable method to detect RNA virus**.
   - It is common to test RNA viruses after transforming them into double-stranded through reverse transcription.

4. **Easy-to-use(One-Tube) and interpretation à Convenient to users(technician), others have to use 2 tubes.**
   - We can test three genes and ICs in one tube. On the other hand, Kogen kit uses 2 Tubes separately, but when using upper and lower respiratory tract samples in one patient, we only use 2 Tubes, but Kogen kits need to use 4 Tubes. As the number of tests increases, more inconvenient for quick testing.

5. **Reliable result à OHC did evaluate the kit by real specimen through IRB.**
   - Most companies claims that they finished the clinical evaluations. However, positive samples are often used with spikes. On the other hand, we have proven the results with 60 sputum real RNA positive samples extracted from real sputum and swab for the clinical evaluation.

6. **Internal/Positive/Negative Control à Quality control is very important to verify the process and result**.
   - The biggest issue in molecular diagnosis is contamination of the samples at the each stage of RNA extraction, amplification, and detection. Because of this, Quality Control in molecular diagnosis, using internal control such as positive and negative control reagents are the key to verify the each process. In the case of Roche, internal control reagents are packaged individually, but OHC's internal control reagents are all packed in one kit for better usability.

7. **Real-time RT PCR Rapid Assay test for COVID-19 – – it's a gene-based test so much more accurate than Rapid tests (Antigen & Antibody)**

- Rapid tests(Antibody/Antigen) are mentioned a lot nowadays due to its quick testing time and convenient test method.
- In the case of an antigen test using a swab, sensitivity is greatly reduced depending on the state of the sample. In addition, COVID19 is a risk of infection when handling specimens, which can burden the examiner.
- IgM is an antibody that can determine whether or not an infection is present, but since the virus is infected, the antibody does not appear immediately, but the antibody appears after a period of incubation called window period. Not suitable for diagnosis.
- IgG is a history-based test, and is a maintenance or sustained antibody test, so it does not fit the current situation.

8. **Quicker/easier to use (just swab nose or sputum)**

9. **Benchtop instrument - so no need to go to large, central labs and instead perform locally 96 tests in around 2 hours (including results)**

    - Our kits are compatible with Thermo Fisher ABI- 7500/7500 Fast and BioRad's CFX-96. These equipment are compact benchtop devices that can be easily used by small labs and small and medium hospitals.
    - It is the most common real time PCR instrument.

10. **EUA approval from FDA to sell to hospitals/clinics directly**

11. **CE certified already and sold hundreds of thousands to emergency government agencies in Europe, Asia, etc.**

12. **Easy 4 vial & 1 tube process – simple and error free (important in emergency and pop-up testing situations) – others use 6 and are much more complicated**
    - Applicable to description #4

13. **Open platform – can work on Thermo Fisher and Bio-Rad Analyzers and soon to be cleared for use on the Roche and Abbot platforms.**

    - Molecular Diagnostic reagents / equipment are largely divided into Open and Closed platforms.
    - Open platform literally does not specify the equipment and can be applied to equipment that has the Real Time PCR principle applied (although it must be validated).
    - Closed platform, like Roche, must use a dedicated Roche reagent, and in this case, a dedicated consumable such as a pipette tip must be used. In the case of dedicated consumables, the customer is not aware of it, but the actual cost is often very expensive. Therefore, in the case of a closed system, the total inspection cost including reagents and consumables can increase the total cost to detect the virus

14. **High volume capacity – Able to fulfil orders of 5 million or more in just 10-15 days; minimum order quantity is 100,000 tests**

15. **All manufacturing, storage, packaging and transportation processes are ISO & Korea GMP certified.**

16. **As a genetic test, has benefit of being able to detect ‘asymptomatic Covid-19 patients(early stage of virus infection’ -i..e show no symptoms but spread the virus**
    - Applicable to description #7