

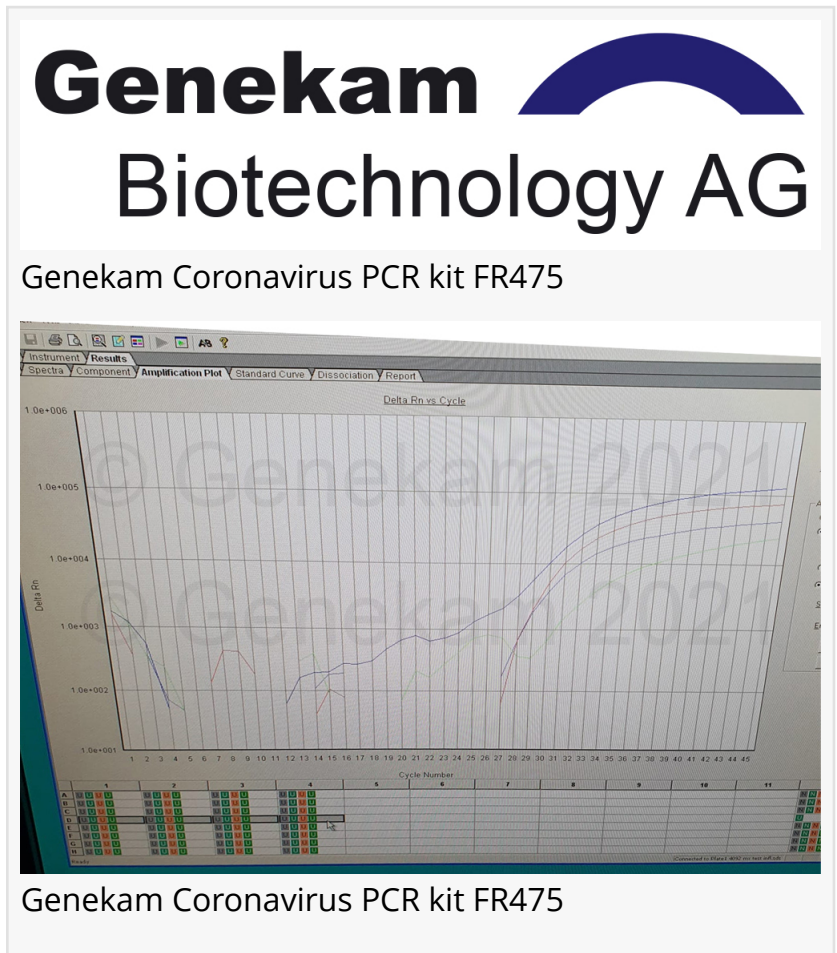
Genekam Coronavirus PCR kit detects samples with different mutations like Omicron and delta without loss of performance

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Coronaviruses are getting mutated, hence there are different mutations like B.1.1.529, B.1.1.671, B.1.17, P1 and B.1.135. These mutations are causing that many PCR tests do not give the correct results, hence it leads to false results. Therefore, many manufacturers around the world as well as FDA have given the warnings as approved kits do not give correct results. Even CDC tests have been removed from the FDA list of emergency approvals. Omicron variant has a lot of mutations in the genome of the virus; hence many kits may not be able to detect this.

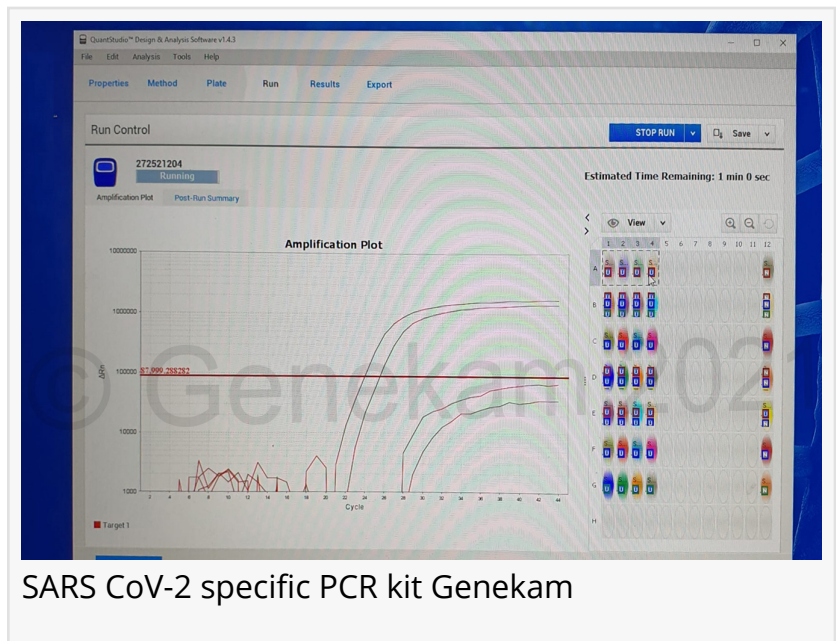
In Germany, there is very hot discussion going about the quality of rapid tests to detect these mutations today and it is being found that antigen tests have very low quality leading to many wrong results. This may indicate why we have so high incidences of infections around the world?

Genekam developed one of the first PCR for detection kit FR475 for SARS CoV-2 in Jan, 2020. This kit FR475 detects the samples with different mutations like Omicron, delta, Alfa etc perfectly, therefore these mutations have no impact on the results conducted with Genekam kit. This kit has been used last year in many countries as the countries using Genekam kit have last year very low incidents of coronaviruses, but with the time, WHO/CDC/FDA/CE approved kits came on the market, after that the incidents have increased so strongly that many countries lost their grip on the spreading of this virus.



These mutations are increasing with time; therefore all kits being used in coronaviral pandemic outbreak must give an assurance that approved kits or methods from CDC and WHO detects coronaviruses (SARS Co-V, Wuhan strain) properly and mutations does not have any impact on their performance.

Recent research work from Genekam is showing that some primers and probes for NP gene may like to give false wrong results as these in house kits are recommended from the world leading organization like WHO. It shows that one must have very good knowledge to develop a good assay for coronaviruses and laboratories must conduct their own quality control. Many laboratories are using such primers and probes; hence these laboratories must be screened for accuracy of their results.



Genekam FR475 kit is not the only one, which is giving excellent results. In 2016, Genekam created double check for Zika viruses as there are many strains, which are not being detected through normal commercial kits of many manufacturers. In 2017, Genekam kit for Influenza virus H5N1 outperformed the other kits in UEA as it detects samples from Africa, which were infected with H5N1 against the other commercial kits, which were fail to detect such infected samples.

The tests were conducted in a laboratory in Abu Dhabi. These examples show as this is very important to have a deep knowledge of virology to develop an excellent kit. Many of companies developing kits for pandemic viruses do not have any deep knowledge of virology, but they get approval from FDA, WHO and EU, hence it is time to compare the performance of different kits available on the market, so that poor quality kits (many of them are coming from big biotech companies) are removed from the market, but authorities are not interested to do this, hence this must be discussed in the press. Genekam is requesting such action for last 6 years. European countries have taken no action till today against such kits for coronaviruses as they are part of diagnostics. European community must access these kits for their ability to detect the Omicron, delta and other mutations.

Major mutations N501Y, E484K, N417N/T along many dozens of other common and rare mutations are matter of concern as N501Y occurs in receptor binding domain leading to increase in rate of binding between the receptors ACE2 and virus. It means rate of transmission will increase strongly. As these are mutations in spike and nucleoprotein regions, hence the immunity can decrease and recovered persons can reinfect, such mutations may lead to have

negative effect on vaccination as well as therapies available now. Therefore, it is important that laboratories use PCR kits, which detect samples with mutations too to provide good results. It is possible with Genekam FR475.

Genekam Biotechnology AG is a German company focusing on pandemic viruses for last 16 years as it has large number of tests for different pandemic outbreak causing viruses like Influenza, Zika, Ebola, dengue, coronaviruses and Rift valley virus. It is working on developing the therapeutic antibodies and small molecules to cure these viruses one day. It develops and manufactures its products in Germany.

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