

MOLgen SARS-CoV-2 kit by Adaltis, addressed to OMICRON (B.1.1.529) new variant:

MOLgen SARS-CoV-2 Real Time RT-PCR Kit is used for the qualitative detection of Novel Coronavirus (SARS-CoV-2), by Reverse Transcription (RT) and Real Time Polymerase Chain Reaction (PCR) from RNA extracted from human respiratory specimens such as nasopharyngeal swabs, oropharyngeal swabs, salivary specimens and bronchoalveolar lavage fluid (BALF).

MOLgen kits are available in two formats: 3 genes or 4 genes kits.

For the 4 genes kit the primer and probe set is designed to detect SARS-CoV-2 identifying 4 targets: 3 specific for SARS-CoV-2 (N gene, S Gene, E gene) and 1 common for sabercoviridae (RdRp gene). The 3 genes kits containing only the N, E and RdRp and was proven as specific and sensitive, Favaro et al. Scientific Reports, 2021, 11, 18995.

The detection of amplified virus RNA fragment is performed in fluorimeter channel FAM (RdRp gene), ROX/Texas Red (E gene), Cy5.5/Alexa Fluor (S gene) and CY5 (N gene). The use of human beta actina as Internal Control (IC) on HEX channel ensure the monitoring correct amplification and cellularity of the samples.

The results of PCR analysis are taken into account in complex diagnostics of disease. The kit is validated for use with various RT-PCR machines: AMPLilab (Adaltis) and CFX96 (Bio-Rad). The kits were proven valid asgians SARS-CoV-2 and it variation alpha, betta, gamma and delta.

As Omicron emerged as the new variant of concern (VOC) (Nature Nov 2021, <https://www.nature.com/articles/d41586-021-03552-w?s=08>), (WHO nov26 2021, [https://www.who.int/news/item/26-11-2021-classification-of-omicron-\(b.1.1.529\)-sars-cov-2-variant-of-concern](https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern)) we have studied its sequence compare to our primer sequence in our kits. Based on the currently known variation as published in <https://www.gisaid.org/>; <https://nextstrain.org/>; <https://cov-lineages.org/>.

The new variant is highly mutated in the spike and RBD region. However, our MOLgen 4 genes kit is in such position where the S primers and probes chosen by Adaltis expert is evading the changes in the new variant. Hence this kit is still valid for OMICRON also in the S genes, which was under severe variation. The 3 gene kits, lacking S gene in also not affected by Omicron mutation, and it is still valid.

In conclusion, these mutations have no impact on the effectiveness or safety of the MOLgen assays.

MOLgen SARS-CoV-2 kit by Adaltis, addressed to OMICRON (B.1.1.529) new variant:

Sincerely,
Adaltis Srl.