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RealStar® and AltoStar® SARS-CoV-2 RT-PCR kits detect E gene and S gene variants of SARS-CoV-2 sequences

The RealStar® SARS-CoV-2 RT-PCR Kit 1.0 (Cat. #821015/Cat. #821019) and the AltoStar® SARS-CoV-2 RT-PCR Kit 1.5 (Cat. # AS0821513/Cat. # AS0821517) are in vitro diagnostic tests, based on real-time PCR technology, for the qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA.

We are aware of the SARS-CoV-2 variant known as Omicron (B.1.1.529) which recently was first detected in South Africa and is defined by more than 30 variant spike protein mutations:

| • A67V | • ins214EPE | • E484A | • P681H |
|-----------------------------|-------------|---------------------------|---------|
| • H69del | • G339D | • Q493R | • N764K |
| V70del | • S371L | • G496S | • D796Y |
| • T95I | • S373P | • Q498R | • N856K |
| • G142D | • S375F | • N501Y | • Q954H |
| V143del | • K417N | • Y505H | • N969K |
| • Y144del | • N440K | • T547K | • L981F |
| Y145del | • G446S | • D614G | |
| N211del | • S477N | • H655Y | |
| • L212I | • T478K | N679K | |

These mutations do not impact the ability of the RealStar® SARS-CoV-2 RT-PCR Kit 1.0 and the AltoStar® SARS-CoV-2 RT-PCR Kit 1.5 to detect SARS-CoV-2 specific RNA.

Germany