

## MANUFACTURER DECLARATION

February 15<sup>th</sup>, 2022

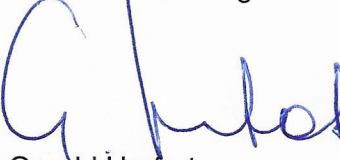
### TO WHOM IT MAY CONCERN

Various new SARS-CoV-2 mutations have been detected around the world this year. Recently the Omicron variant attracts a lot of attention. All the observed mutations primarily affect the spike protein (protein S) of the virus, which plays a key role in the process of receptor recognition and cell fusion. This explains why the virus became significantly more infectious from these mutations.

The AMP SARS-CoV-2 Ag Rapid Test detects the nucleocapsid protein (protein N) antigen, which is unaffected by recent mutations. Therefore, the new mutations, like many others that have occurred before already, have no impact on the performance of the test and the reliability of the test results.

This has also been verified by clinical evaluations of samples confirmed to contain the mutations B.1.1.7 (Alpha or UK variant), B.1.351 (Beta or South African variant), P.1 (Gamma or Brazilian variant), B.1.617.1 (Kappa variant), B.1.617.2 (Delta = Indian variant), B.1.617.3, C.37 (Lambda = Peruvian variant) or B1.1.529 (Omicron variant) – including sublines BA.1, BA.1.1 and BA.2. These practical tests evidenced, that the performance of the test is not affected by any of these mutations.

AMEDA Labordiagnostik GmbH



Gerald Herfort



AMEDA Labordiagnostik GmbH  
Krenngasse 12 - 8010 Graz - Austria  
Tel. +43 - 316 - 69 80 69. Fax ext. - 12

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**AMEDA Labordiagnostik GmbH**