

## MANUFACTURER DECLARATION

December 10<sup>th</sup>, 2021

### 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) and B1.1.529 (Omicron variant). These practical tests evidenced, that the performance of the test is not affected by any of these mutations.

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