

November 30th 2021

STATEMENT

Products: BIOSYNEX COVID-19 Ag BSS, ref: SW40006, SW40006_BSX
BIOSYNEX COVID-19 Ag+ BSS, ref: SW40010
BIOSYNEX AUTOTEST ANTIGENIQUE COVID-19 Ag, ref: 859256/57/58, 859261/62/63
BIOSYNEX COMBO COVID-FLU BSS, ref: SW40008
BIOSYNEX COMBO COVID-FLU-RSV BSS, ref : SW40011

Object: Mutations of the new SARS-CoV-2 variants: B.1.1.7 (Alpha variant); B.1.351 (Beta variant); P.1 (Gamma variant), CAL.20C (Epsilon variant), B.1.617 (Delta variant) and B.1.1.529 (Omikron variant)

We, **BIOSYNEX SWISS S.A.**, Rue de Romont 29-31, 1700 Fribourg - SWITZERLAND, legal manufacturer of the above mentioned products hereby declare that:

- The main mutations of SARS-CoV-2 strains B.1.1.7, B.1.351, P.1., CAL.20C, B.1.617 and B.1.1.529 affects the Spike protein of the SARS-CoV-2 virus on its surface.
- By comparison of N-protein, there is no variation in the overlap of epitope(s) location(s) of anti-SARS-CoV-2 antibody used for the coating on the membrane and conjugation.
- Based on the available scientific data, our review of the literature and given that the above assays are qualitative rapid tests using monoclonal antibodies to the SARS-CoV-2 nucleocapsid protein from a nasopharyngeal (NP) or nasal (NS) sample, we can state these tests are not affected by the mutations mentioned in the subject.

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