September 2023

Impact of the EG.5 and BA.2.86 variants of SARS-CoV-2 on BTNX's Rapid Response® COVID-19 Antigen Rapid Test Device (COV-19C25)

The emerging variants of SARS-CoV-2, EG.5 and BA.2.86, have caused great concern recently. These new variants carry over 40 genetic changes due to mutations, primarily affecting the Spike (S) protein of SARS-CoV-2.

As illustrated in Figure A, SARS-CoV-2 has several structural proteins including Spike (S), Envelope (E), Membrane (M) and Nucleocapsid (N) proteins. BTNX's Rapid Response® COVID-19 Antigen Rapid Test Device is designed to detect the SARS-CoV-2 viral **nucleocapsid protein**.

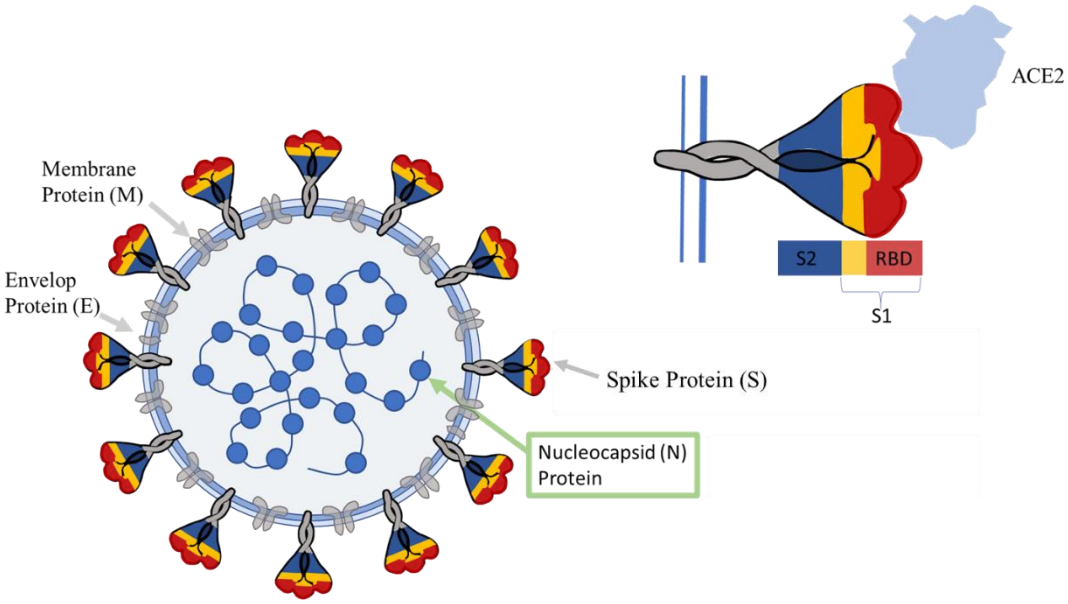

Figure A Structure of SARS-COV-2 **Illustrative purposes only*

Mutations of the nucleocapsid protein of the EG.5 variant include P13L, Δ31-33, R203K, G204R and S413R. Mutations of the nucleocapsid protein of the BA.2.86 variant include P13L, Δ31-33, R203K, G204R, Q229K, G243S, E378Q and S413R. These mutations are not located in the target epitopes of the Rapid Response® COVID-19 Antigen Test Device, so no effect on the performance is to be expected.

Additional analytical studies of EG.5 and BA.2.86 are in progress. The results will be made available as soon as the investigations have concluded.

BTNX continues to follow the latest findings on COVID-19 and remains committed to maintaining the highest level of excellency in our products

722 Rosebank Rd, Pickering, Ontario, L1W 4B2 | Tel: (905) 944-9565 | Toll Free: 1-888-339-9964 | Fax: (905) 944-0406