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Impact of the Omicron variant of SARS-CoV-2 on BTNX's Rapid Response[®] COVID-19 Antigen Rapid Test Cassette – At Home (COV-19CSHC / COV-19C25B), Rapid Response[®] COVID-19 Antigen Rapid Test Device (COV-19C25) and Response[®] Influenza AB + COVID-19 Antigen – 3 in 1(COF-19CPC25)

The emerging Omicron sub-lineages, KP.3, KP.1.1, KP.1.1.1, KP.2, KP.2.3, JN.1.11, JN.1.16.1, JN.1.7, KR.1, KS.1, LB.1, JN.1, XDV.1, KW.1.1, JN.1.13.1, KQ.1, JN.1.18, JN.1.8.1 and JN.1.32, 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 Cassette – At Home, Rapid Response[®] COVID-19 Antigen Rapid Test Device, and the Rapid Response[®] Influenza AB + COVID-19 Antigen – 3 in 1 Test are designed to detect the SARS-CoV-2 **nucleocapsid** (N) protein.

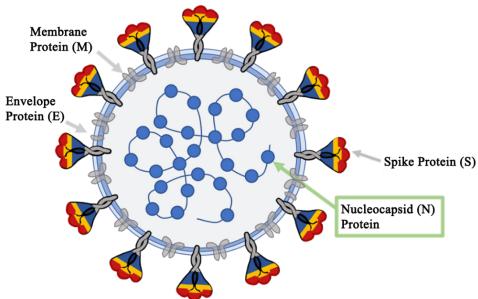


Figure A. Structure of SARS-CoV-2 **Illustrat*

*Illustrative purpose only

In silico studies showed that nucleocapsid mutations of KP.3, KP.1.1, KP.1.1.1, KP.2, KP.2.3, JN.1.11, JN.1.16.1, JN.1.7, KR.1, KS.1, LB.1, JN.1, XDV.1, KW.1.1, JN.1.13.1, KQ.1, JN.1.18, JN.1.8.1 and JN.1.32 are not located in the target epitopes of the Rapid Response® COVID-19 Antigen Test Cassette – At Home, the Rapid Response® COVID-19 Antigen Rapid Test Device, and the Response® Influenza AB + COVID-19 Antigen – 3 in 1; thus, all three tests can still detect these new variants.

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