

September 2023

Impact of the Omicron variant of SARS-CoV-2 on BTNX’s Rapid Response[®] COVID-19 Antigen Rapid Test Cassette – At Home (COV-19C25B) and Rapid Response[®] COVID-19 Antigen Rapid Test Device (COV-19C25 / COV-19C5)

The new variant of SARS-CoV-2, Omicron (B.1.1.529), was first reported to WHO on Nov. 24th, 2021, from South Africa, where infections have risen steeply. Since then, it has caused great concern globally. This new variant carries over 30 genetic changes due to mutations, primarily affecting the Spike (S) protein of SARS-CoV-2.

Omicron is made up of several sub-lineages. Of them, BA.1 BA.2, BA.4, BA.5 (and its subvariants BQ.1, BQ.1.1 and XBB) have spread rapidly and caused concern around the globe at various points in time.

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 and the Rapid Response[®] COVID-19 Antigen Rapid Test Device are designed to detect the SARS-CoV-2 viral **nucleocapsid protein**.

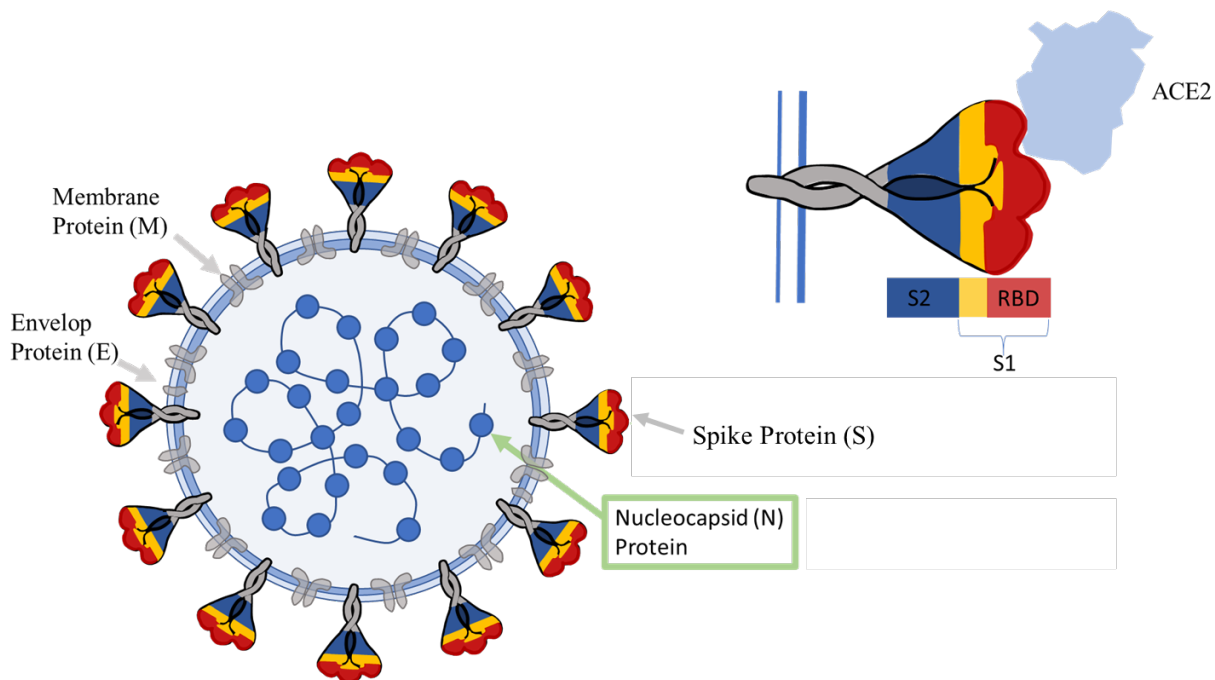


Figure A Structure of SARS-COV-2

**Illustrative purpose only*

Response[®] COVID-19 Antigen Test Cassette – At Home and the Rapid Response[®] COVID-19 Antigen Rapid Test Device were tested with Omicron variants BA.1, BA.2 BA.4 and BA.5 recombinant proteins and with positive samples, confirmed by sequencing. It was confirmed that both tests accurately detect these strains at or near the same limit of detection. BTNX continues to follow the latest findings on COVID-19 and remains committed to maintaining the highest level of excellency in our products.