

January 18<sup>th</sup>, 2021

### Impact of New Variants of SARS-CoV-2 on Rapid Response™ COVID-19 Antigen Test

Two new SARS-CoV-2 variants, referred to as the B.1.1.7 and 501Y.V2, have caused great concern recently. The variants carrier several genetic changes due to mutations, primarily affecting the Spike (S) protein of SARS-CoV-2.<sup>1</sup>

BTNX’s Rapid Response™ COVID-19 Antigen Test Device is designed to detect the SARS-CoV-2 viral **nucleocapsid protein** . A UK government assessment has confirmed that SARS-CoV-2 rapid antigen tests designed with the same target successfully detected B.1.1.7.<sup>2</sup>

As of Jan.18<sup>th</sup>, 2021, no evaluation has been conducted to confirm that antigen test performance is not affected by 501Y.V2. However, as 501Y.V2 only carries one amino acid mutation on the nucleoprotein,<sup>3</sup> no major performance deficits are anticipated.

Scientists from Public Health England reported that viral load is significantly higher for patients infected with B.1.1.7. About 35% of patients infected with the new strain had very high levels of the virus in their samples, compared with 10% of patients with existing variants.<sup>4</sup> 501Y.V2 was also reported to be associated with higher viral loads compared with existing variants.<sup>5</sup> Based on this information, it is expected that our test could be more sensitive to the new variants, as illustrated in Figure A.

BTNX plan on carrying out additional in-vitro testing to confirm our test performance is not affected by the new variants. The results will be shared with public as soon as these investigations have completed. BTNX continues to follow the latest findings on COVID-19 and remains committed to maintaining the high level of excellency in our products.

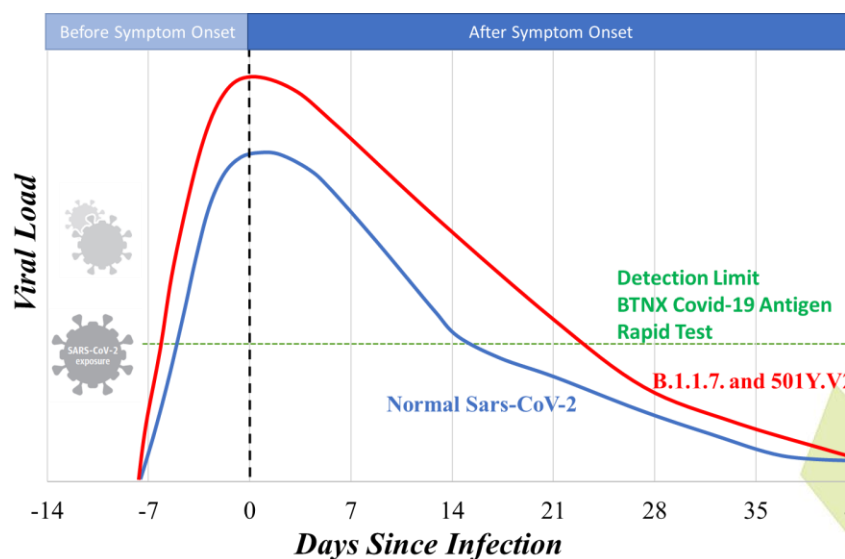


Figure A

*\* illustrative purposes only*

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