

SARS-CoV-2 variants

Viruses constantly change through mutation, and new variants of a virus are expected to occur over time. Sometimes new variants emerge and disappear. Other times, new variants emerge and persist. Many variants of the virus that causes COVID-19 have been detected globally during this pandemic. Three variants of clinical concern have emerged over the recent months:

- UK Variant (B.1.1.7)
- South Africa Variant (B.1.351)
- Brazil variant (P.1)

The LumiraDx SARS-CoV-2 Ag Test uses antibodies (not nucleic acid based-primers like PCR) to capture SARS-CoV-2 nucleocapsid antigen (not the spike protein). Antibodies typically recognize 8-15 amino acid target sequences (equivalent to 24-45 nucleotide sequences). Thus, single nucleic acid point mutations are not likely to affect the performance of the LumiraDx SARS-CoV-2 Ag Test. Furthermore, mutations outside of the nucleocapsid viral coding region (ex Spike protein) would have no effect on the performance of the test.

The LumiraDx SARS-CoV-2 Ag Test detects the following variants, confirmed in lab and field testing:

- **UK Variant – B.1.1.7 (known in UK as 201/501Y.V1; VOC 202021/01)** – Tested by UK Department of Health and Social Care, COVID-19 Technologies Validation Group.¹

The South Africa Variant (B.1.351) and Brazil (P.1) are being tested now in lab and field.

We do not expect an issue based on current understanding of the genetic changes to the virus, but are continually testing the new variants of clinical concern as they arise to confirm.

More information about the variants is available:

www.cdc.gov

www.who.int

www.gov.uk

1. UK Department of Health and Social Care, COVID-19 Technologies Validation Group report on LumiraDx SARS-CoV-2 Antigen test Report (January 2021).