Technical Brief – April 9, 2021
SARS-CoV-2 variant detection by
Abbott Alinity m SARS-CoV-2 Assay (EUA) and RealTi*m*e SARS-CoV-2 Assay (EUA)

New SARS-CoV-2 variants have been identified, Abbott is continuously monitoring the global situation on SARS-CoV-2 through its Global Surveillance and Viral Discovery programs.

Abbott's SARS-CoV-2 assays target unique regions of the RdRp and N genes of the SARS-CoV-2 genome. Bioinformatics analysis confirmed that the target regions used in the Abbott Alinity m SARS-CoV-2 and RealTi*m*e SARS-CoV-2 assays would not be impacted by the following new variant strains.

Variant[1,2,7]	Mutations[2-7]
UK variant is VUI 202012/01	N, Spike protein and ORF regions
South Africa SARS-CoV-2 lineage (501Y.V2)	N, E, Spike protein and ORF regions
Brazil variant P.1, a sub-lineage of the B.1.1.28 strain	N, Spike protein and ORF regions
French variant, HMN.19B variant or Breton variant	N, Spike protein and ORF regions

If you have any questions on the above, please reach out to Technical Support at (800) 553-7042 or customerservice@abbottmolecular.com

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[1] https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html

[2] https://www.medrxiv.org/content/10.1101/2020.12.21.20248640v1.full.pdf

[3] https://www.gisaid.org/references/gisaid-in-the-news/uk-reports-new-variant-termed-vui-20201201/

[4] https://virological.org/t/preliminary-genomic-characterisation-of-an-emergent-sars-cov-2-lineage-in-the-uk-defined-by-a-novel-set-of-spike-mutations/563

[5] Abbott data on file

[6] https://virological.org/t/genomic-characterisation-of-an-emergent-sars-cov-2-lineage-in-manaus-preliminary-findings/586

[7]Early Release - Novel SARS-CoV-2 Variant Derived from Clade 19B, France - Volume 27, Number 5—May 2021 - Emerging Infectious Diseases journal - CDC

Emergency Use Authorization (EUA) Conditions

- Alinity m SARS-CoV-2 assay and RealTime SARS-CoV-2 assay have not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- The products have been authorized by FDA under an EUA for use by laboratories certified under CLIA, to perform moderate or high complexity tests;
- The products have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The emergency use of the products are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.