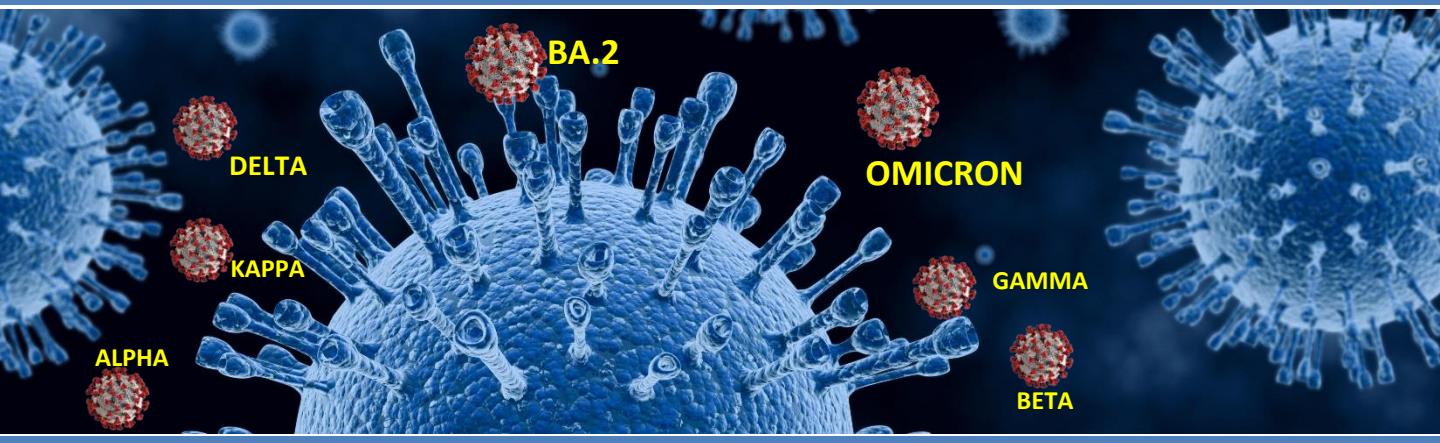
ABL Advanced Biological Laboratories

UltraGene Assay SARS-CoV-2 VOC Screening and Determination V1

CE IVD

SARS-CoV-2 qPCR Assay to detect all currently designated variants of concern (VOCs)

https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/



The **UltraGene Assay SARS-CoV-2 VOC Screening and Determination V1** (CE-IVD) is a rtRT-PCR Assay (nucleic acid technique (NAT)) intended for the qualitative detection of SARS-CoV-2 mutations L452R, K417N or K417T, E484A or E484K or E484Q, and the deletion 69-70 on the Spike (S) gene.

The test is targeting the S and N regions of SARS-CoV-2 patients' extracted RNA and already diagnosed PCR positive to SARS-CoV-2.

	69–70del	417N	417T	452R	484K	484A	484Q
Well	1	1	1	1	2	2	2
Alpha (UK)	☑						
Beta (SA)		☑			☑		
Gamma (BR)			☑				
Delta (IN)		(☑)		☑			
Omicron (BA.1)	☑	☑				☑	
BA.2		☑				☑	
Kappa				☑			☑

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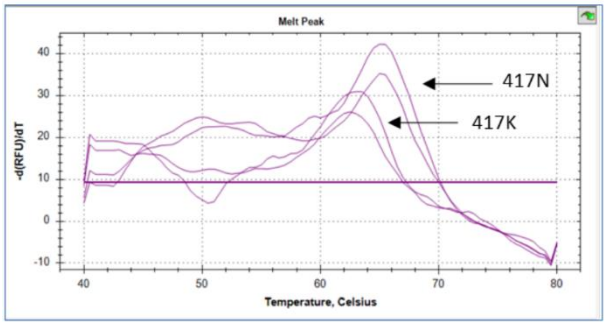
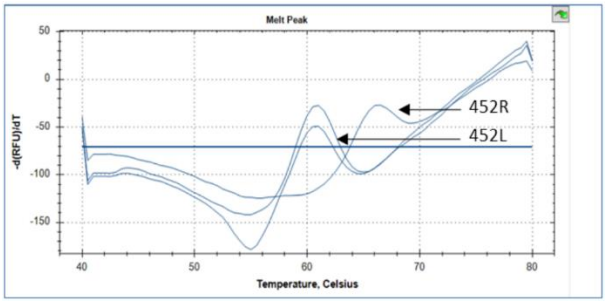
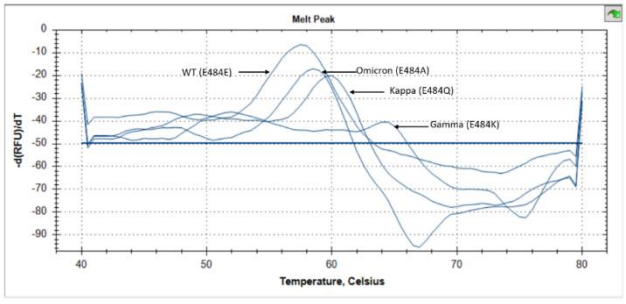
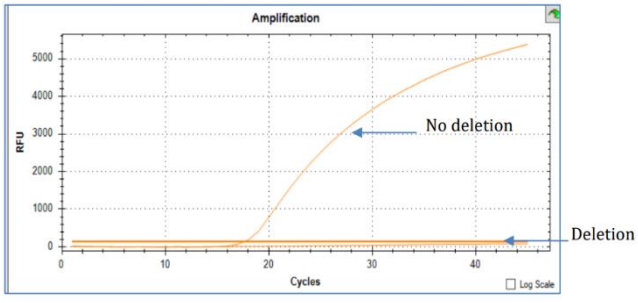
Performances

	Details
Limit of detection	69–70del: 12.5 - 20.0 copies/µl 417N: 12.5 - 20.0 copies/µl 417T: 5.01* 10^1 $TCID_{50}$/mL 452R: 1.23 * 10^3 $TCID_{50}$/mL 484K: 3.16 * 10^3 $TCID_{50}$/mL 484A: 12.5 - 20.0 copies/µl 484Q: 1.23 * 10^3 $TCID_{50}$/mL
Inclusivity	The UltraGene Assay SARS-CoV-2 VOC Screening & Determination V1.X is expected to amplify and detect the targets in all current variants of the virus including alpha, eta and omicron, the ones harboring the deletion 69-70 on the S gene.
Cross-reactivity	For cross-reactivity wet testing, the UltraGene Assay SARS-CoV-2 VOC Screening & Determination V1.X did not react when tested with the microorganisms that are commonly found in upper respiratory specimens and tested at the indicated concentration : no Ct nor melting temperature were displayed for any contrived sample.
Clinical sensitivity	The positive (PPA) and negative (NPA) percent agreements between the UltraGene Assay SARS-CoV-2 VOC Screening & Determination V1.X and the CE-IVD assay are for the C1000 Dx Thermal Cycler: • PPA = 30/30 = 100% (95% C.I. = 88.65% - 100%) • NPA = 30/30 = 100% (95% C.I. = 88.65% - 100%)
Clinical evaluation	The UltraGene Assay SARS-CoV-2 VOC Screening & Determination V1.X detected any genomic variations of the samples: 100% clinical accuracy was obtained for the identification of the two variants of the study (Omicron and BA.2) compared with the SARS-CoV-2 whole-genome sequencing results.









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Overview

Features	UltraGene Assay SARS-CoV-2 VOC Screening and Determination V1
Models	▪ 50 or 1000 tests per kit ▪ Multiplex format in 2 wells per sample
Content	▪ Master Mix 2X, RT Mix, Enzyme Mix and Magnesium Sulfate ▪ S Specific Primers & Probes for each mutation (del 69-70, K417N/T, L452R, E484A/K/Q) from S gene ▪ Positive control ▪ Negative control ▪ Internal control (N-gene); N specific primer and probe ▪ PCR grade nuclease-free water
Specimen	▪ Upper respiratory specimens (nasal, mid-turbinate, nasopharyngeal, oropharyngeal swab specimens and nasopharyngeal wash/aspirate or nasal aspirate and bronchoalveolar lavage (BAL) fluid specimens) (already tested SARS-CoV-2 positive)
Extraction	▪ Magnetic beads
Compatibility with qPCR platforms	▪ Any qPCR instrument compatible with the FAM, HEX, ROX and Cy5 channels. ▪ Validated for use with C1000 Dx Thermal Cycler (Bio-Rad, Catalog # 1841000-IVD with CFX96-Dx ORM software version 3.1) (C1000 CFX96).
Hands-on-time	▪ Less than 20 minutes for up to 48 samples ▪ Less than 40 minutes for up to 96 samples ▪ Automation capacity (liquid handling robots available upon request)
Estimated turnaround time	▪ <2h

This nucleic amplification test is indicated for use on previously diagnosed COVID-19 patients ONLY. This test is NOT intended to be used as a screening or confirmation test for the detection, confirmation or quantification in upper respiratory specimens of SARS-CoV-2.

References & contact

- UltraGene Assay SARS-CoV-2 VOC Screening and Determination V1.x (CE IVD – 50 tests) REF 176A50
- UltraGene Assay SARS-CoV-2 VOC Screening and Determination V1.x (CE IVD – 1000 tests) REF 176A1000

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