ABL Advanced Biological Laboratories Diagnostics

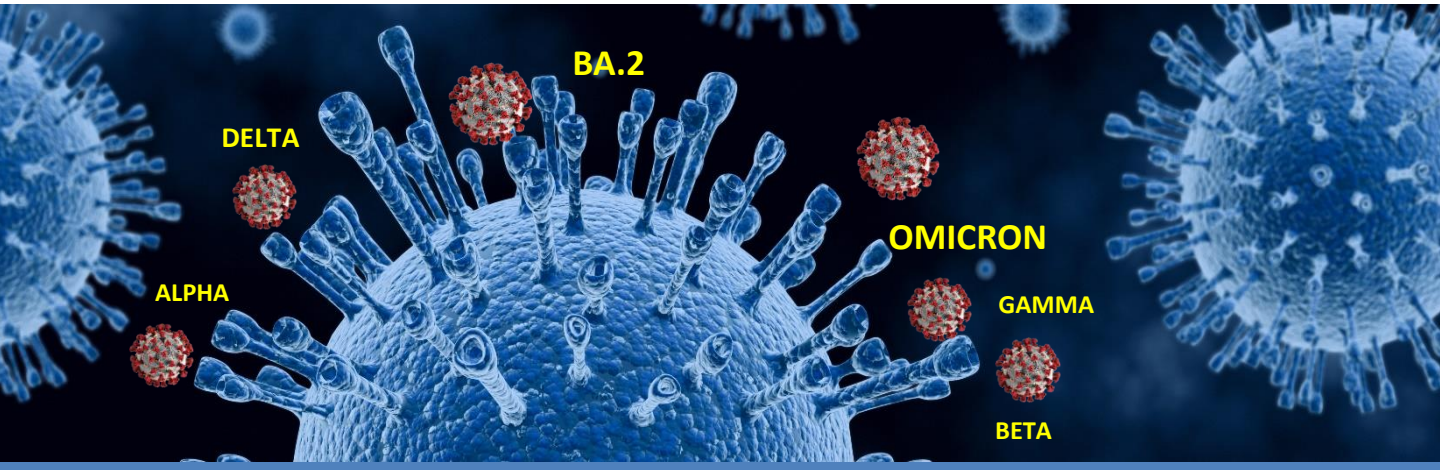
UltraGene Assay SARS-CoV-2 Universalis

(V2.X)

CE IVD

REF 169B

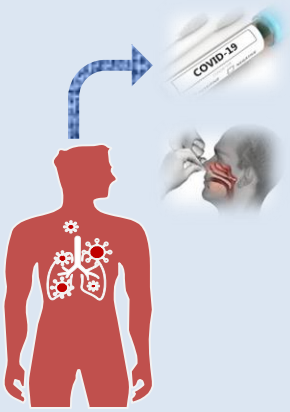
qPCR Assay to detect specifically the SARS-CoV-2 RNA including current circulating lineages without drop-out or lack of sensitivity



The UltraGene Assay SARS-CoV-2 Universalis (V2.X) is a real-time RT-PCR test intended for the qualitative detection of RNA from the SARS-CoV-2 in upper respiratory specimens from individuals suspected of COVID-19 by their healthcare provider

Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.

Workflow



Sample Collection

Manual | Automated

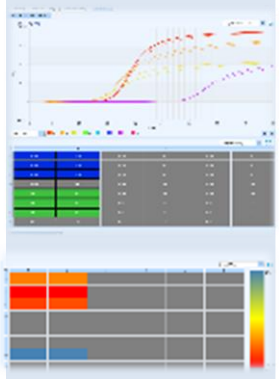
~25min ~30min

Extraction

~20min ~1h10

PCR Set Up | Run

rt-qPCR



Data Analysis

Please contact the ABL support team to request more information & registration status of the above mentioned products for your respective territories.

contact@ablsa.com
http://www.ablsa.com

Overview

Features	UltraGene Assay SARS-CoV-2 Universalis V2.X
Formats	▪ 50 or 1000 tests per kit ▪ Multiplex format in 1 well per sample
Content	▪ Master Mix 2X, RT Mix, Enzyme Mix and Magnesium Sulfate ▪ Specific Primers & Probes for each targeted gene: N, ORF1ab (RdRp) ▪ Positive control ▪ Negative control ▪ Internal control ▪ 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) from individuals suspected of COVID-19 by their healthcare provider
Extraction	▪ Magnetic beads ▪ Validated for use with: ✓ Seegene STARlet instrument (Cat. #67930-03) with Hamilton Run Control software (version 4.5.0.7977) ✓ Seegene STARMag 96 X 4 Universal Cartridge Kit (Cat. #744300.4.UC384) ✓ Any laboratory validated instrument for RNA extraction and purification using magnetic-bead technology shall work
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), ✓ QuantStudio 5 Real-Time PCR Instrument (96-Well 0.1mL Block) (Applied Biosystems, Catalog #A28133, Design & Analysis Software 1.5.2 / Firmware Version 1.4.0)
Hands-on-time	▪ Less than 20 minutes for up to 48 samples ▪ Less than 40 minutes for up to 96 samples
Limit of detection (LOD)	▪ 1.15 TCID50/mL for SARS-CoV-2 with the C1000 CFX96 Dx Thermal Cycler and the QuantStudio 5 Real-Time PCR Instruments.
Clinical performance evaluation	▪ The positive (PPA) and negative (NPA) percent agreements between the UltraGene Assay SARS-CoV-2 ▪ Universalis V2.X and CE-IVD EUA test are for the C1000 CFX96: ▪ • PPA = 28/28 = 100% (95% C.I. = 84.98% - 100%) ▪ • NPA = 30/30 = 100% (95% C.I. = 85.86% - 100%)
Clinical Accuracy	▪ 96%

UltraGene Assay SARS-CoV-2 Universalis (V1.x) (50 tests)	**169B50**
UltraGene Assay SARS-CoV-2 Universalis (V1.x) (1000 tests)	**169B1000**

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