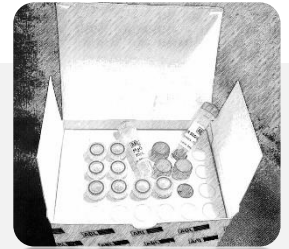


Improving Disease Management

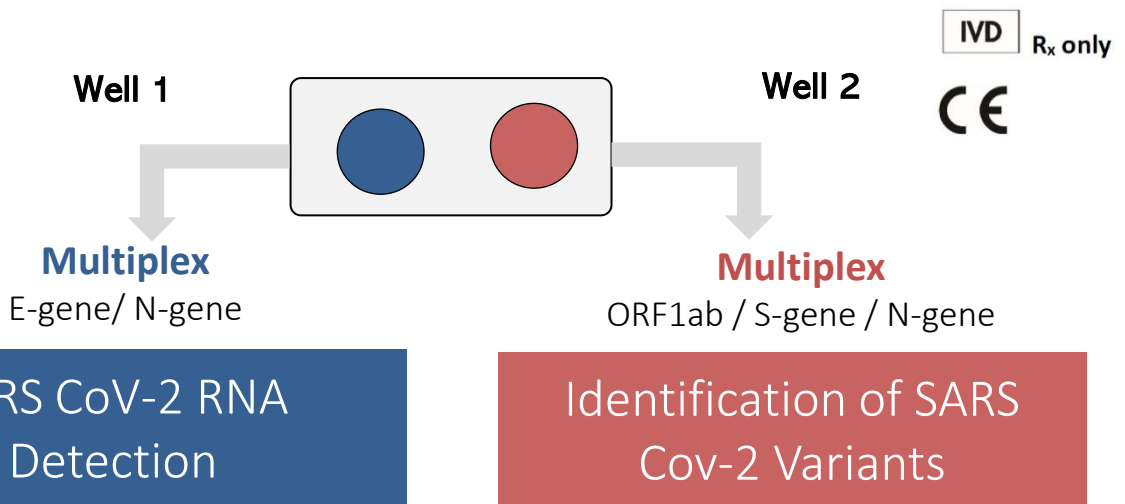
UltraGene[®] SARS-CoV-2 Triplex Assay

SARS-CoV-2 RNA Screening and Variants Determination in a Single qPCR Assay.



TRIPLEX ASSAY

- SARS-CoV-2 RNA detection
- Detection of a SARS-CoV-2 variant from a wild-type strain
- Distinction of main circulating SARS-CoV-2 variants (UK, BR and SA)



Detect RNA from the SARS-CoV-2 nucleocapsid (N) gene and envelope (E) gene in upper respiratory. It also includes an extraction, reverse transcription, and PCR amplification positive control

Detect RNA from the SARS-CoV-2 nucleocapsid (N), Spike (S) and ORF1ab allowing precise identification of lineages B.1.1.7, B.1.351 and P.1.

Proprietary, ABL S.A. - April 2021

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

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



FEATURES

Features

UltraGene® SARS-CoV-2 Triplex Assay

Formats	<ul style="list-style-type: none">▪ 1000 tests screening / 50 tests multi-variants (160A1000_50)▪ 1000 tests screening / 1000 tests multi-variants (160A1000_1000)
Content	<ul style="list-style-type: none">▪ RT-PCR Premix▪ Primer/Probe Mix▪ Internal control▪ Positive & negative controls
Specimen	<ul style="list-style-type: none">▪ Upper respiratory specimens (nasal, mid-turbinate, nasopharyngeal, oropharyngeal swab specimens and nasopharyngeal wash/aspirate or nasal aspirate and bronchoalveolar lavage (BAL) fluid specimens)
Extraction	<ul style="list-style-type: none">▪ Magnetic beads
Compatibility with qPCR platforms	<ul style="list-style-type: none">▪ Any qPCR instrument compatible with the FAM, HEX, ROX, Cy5 channels.▪ Validated for use with QuantStudio 5 Real-Time PCR Instrument & UltraGene qPCR 48
Hands-on-time	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ ~1h10
Analytical sensitivity (Limit of Detection (LoD))	<ul style="list-style-type: none">▪ 1150 TCID₅₀/mL for the QuantStudio 5 Real-Time PCR instrument▪ 115 TCID₅₀/mL for SARS-CoV-2 with the UltraGene qPCR 48 instrument
Clinical sensitivity	Performance against the expected results are: <ul style="list-style-type: none">▪ Positive Percent Agreement 30/30 = 100% (95% CI: 88.65%-100.00%)▪ Negative Percent Agreement 30/30 = 100% (95% CI: 88.65%-100.00%)
Clinical reproducibility	<ul style="list-style-type: none">▪ EQA Pilot Study: 100% clinical accuracy



WORKFLOWS

Available in two models for two distinct workflows

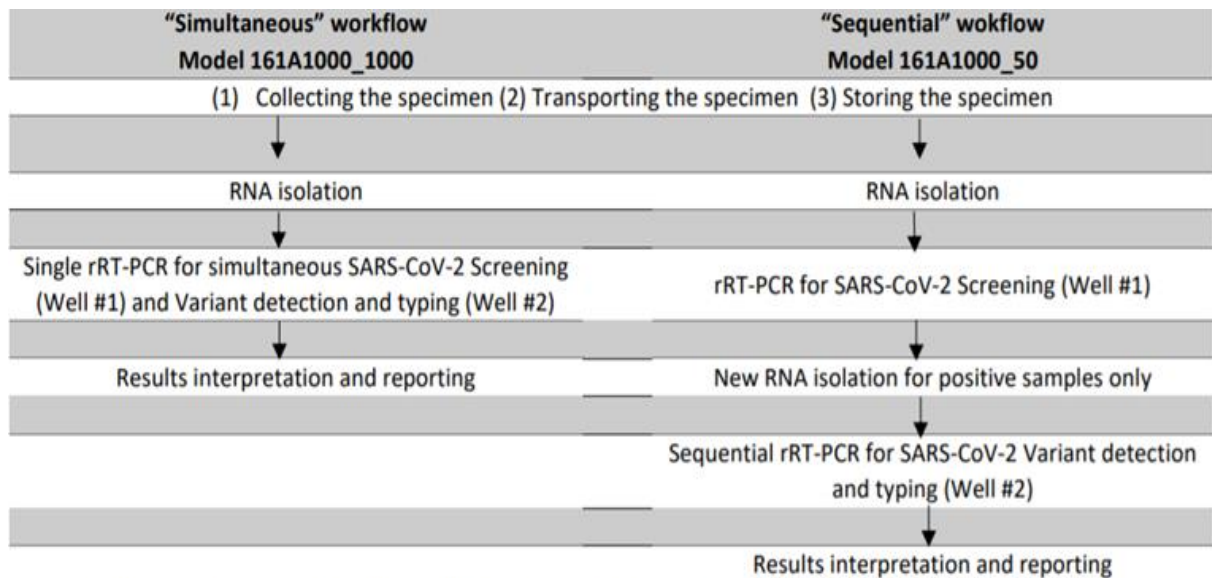
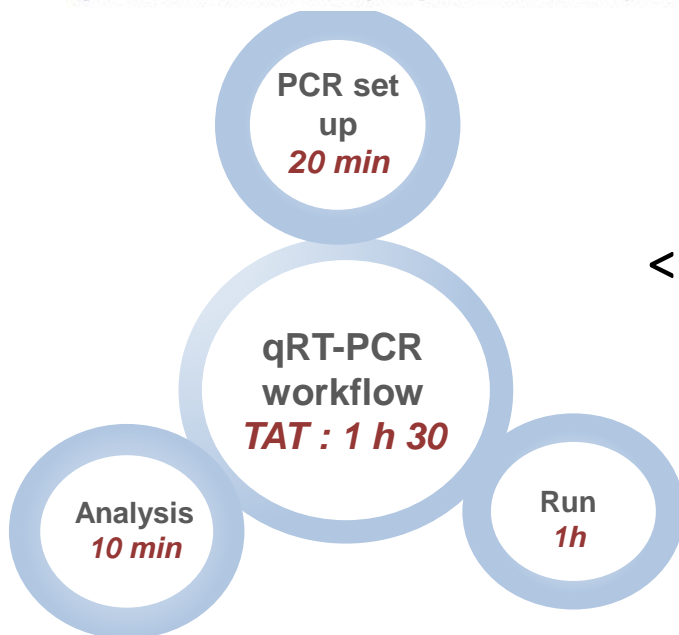


Figure 1: Details about the 2 workflows for the UltraGene Assay SARS-CoV-2 Triplex, Screening, Multi-Variants and Typing V1



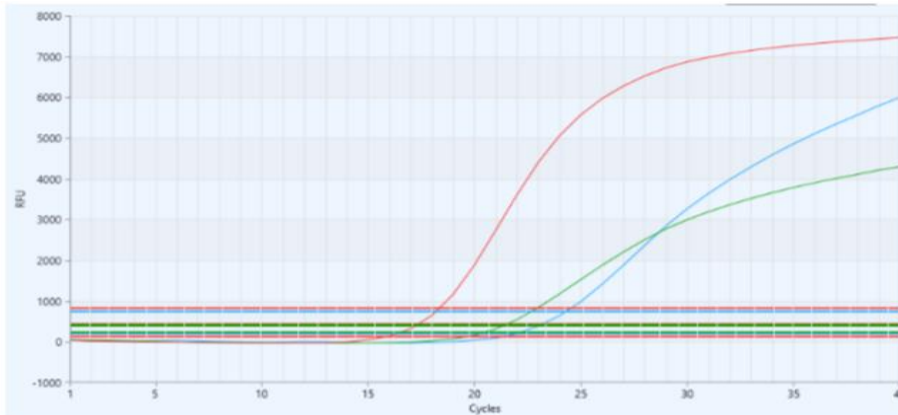
Ultra-fast : full workflow
<1h30 from extracted RNA
(up to 96 samples)





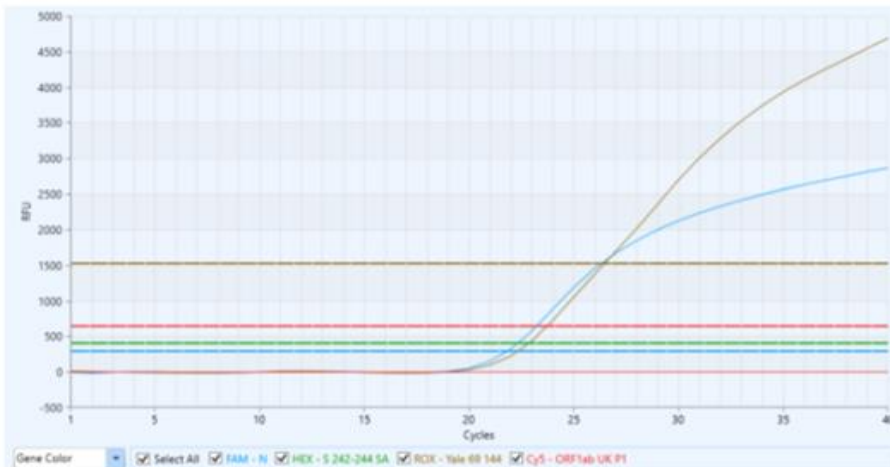
EXAMPLES OF RESULTS

SARS-CoV-2 Positive clinical specimen with Well 1

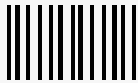


Exponential traces for all UltraGene Assay SARS-CoV-2 Triplex, Screening, Multi-Variants and Typing V1 targets in Well #1 which indicate a SARS-CoV-2 strain with no targeted deletions and positive N target.

SARS-CoV-2 “SA” variant in Well 2



Exponential traces for two UltraGene Assay SARS-CoV-2 Triplex, Screening, Multi-Variants and Typing V1 targets in Well #2 which indicate a SARS-CoV-2 South Africa variant strain : deletion Δ 3675 (absence of signal for Cy5 channel), deletions Δ 242 (absence of signal for HEX channel) and positive N target



COVID-19

Detection & Variants screening through qPCR

UltraGene Assay SARS-CoV-2 Triplex, Screening, Multi-Variants and Typing

- 1000 tests screening / 50 tests multi-variants (CE IVD)	161A1000_50
- 1000 tests screening / 1000 tests multi-variants (CE IVD)	161A1000_1000
UltraGene SARS-CoV-2 Multi Variants Deletions V1 (CE IVD) (50 tests)	160A50
UltraGene SARS-CoV-2 Multi Variants Deletions V1 (CE IVD) (1000 tests)	160A1000
UltraGene Assay SARS-CoV-2 N / Spike Δ 69-70 V1 (50 tests)	158A50
UltraGene Assay SARS-CoV-2 N / Spike Δ 69-70 V1 (1000 tests)	158A1000
UltraGene Combo2Screen SARS-CoV-2 Assay (CE IVD) (50 tests)	139B50
UltraGene Combo2Screen SARS-CoV-2 Assay (CE IVD) (1000 tests)	139B1000
UltraGene Combo2Screen SARS-CoV-2 Assay (CE IVD + saliva) (50 tests)	139C50
UltraGene Combo2Screen SARS-CoV-2 Assay (CE IVD + saliva) (1000 tests)	139C1000

Variants screening through sequencing

DeepChek 8-plex CoV-2 Genotyping Assay (50 tests)	142A50
DeepChek Assay Whole Genome SARS-CoV-2 Genotyping V1 (48 tests)	159A48
DeepChek® - CoV2 Software	S-12-023 (CVL)
DeepChek® NGS LIB PREP (24/48/96 indexes)	116A24/48/96 +124A24/48/96

Viral quantification

UltraGene SARS-CoV-2 Quantitative Assay V1 (50 tests)	Q1 2021
UltraGene SARS-CoV-2 Quantitative Assay V1 (1000 tests)	Q1 2021

GENOTYPING THROUGH SEQUENCING

HIV

DeepChek® Assay PR/RT Genotyping and Drug Resistance (CE IVD)	121A24
DeepChek® Assay INTEGRASE Genotyping and Drug Resistance (CE IVD)	122A24
DeepChek® - HIV Software (CE-IVD)	S-12-023 (HL)
ViroScore® -HIV Software (CE IVD)	S-09-014

HCV

DeepChek® Assay NS5B / 5'UTR Genotyping	110B24
DeepChek® Assay CORE Genotyping	109A24
DeepChek® Assay NS5A Genotyping and Drug Resistance	105A24
DeepChek® Assay NS3 Genotyping and Drug Resistance	108A24
DeepChek® Assay NS5B Genotyping and Drug Resistance	107D24
DeepChek® - HCV Software (CE-IVD)	S-12-023 (CL)

HBV

DeepChek® Assay RT Genotyping and Drug Resistance 113A24
DeepChek® - HBV Software (CE-IVD) S-12-023 (BL)

CMV

DeepChek® Assay UL54 / UL97 Drug Resistance 117A24
DeepChek® - CMV Software (CE-IVD) S-12-023 (ML)

HSV

DeepChek® Assay TK / POL Drug Resistance 119A24
DeepChek® - HSV Software (CE-IVD) S-12-023 (SL)

16sRNA

DeepChek® Assay 16S rRNA BACTERIAL IDENTIFICATION 131A24

Tuberculosis

DeepChek® Assay 13-Plex KB DRUG SUSCEPTIBILITY TESTING 128A24
BacterioChek® - TB Software (CE-IVD) S-12-023 (TL)

SAMPLES COLLECTION & INSTRUMENTS

qPCR instruments

Ultragene qPCR system - 48 samples format - 4 channels with Gradient I-19-UG48E
Ultragene qPCR system - 96 samples format - 4 channels with Gradient I-19-UG96R

Liquid handling robots

DeepChek Pipetting I-18-PIP2

RNA/DNA extraction

CleanPrepX System AS00001

Sample collection

Clinical specimen nasopharyngeal collection kit (CE IVD Import) DW-80005-1B
Clinical specimen oropharyngeal collection kit (CE IVD Import) DW-80005-1A
Sterile saliva collection container for saliva specimens (CE-IVD) 144A250
DNA/RNA stabilization solution for nucleic acids (CE IVD) 148A50



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Proprietary, ABL S.A. - April 2021

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