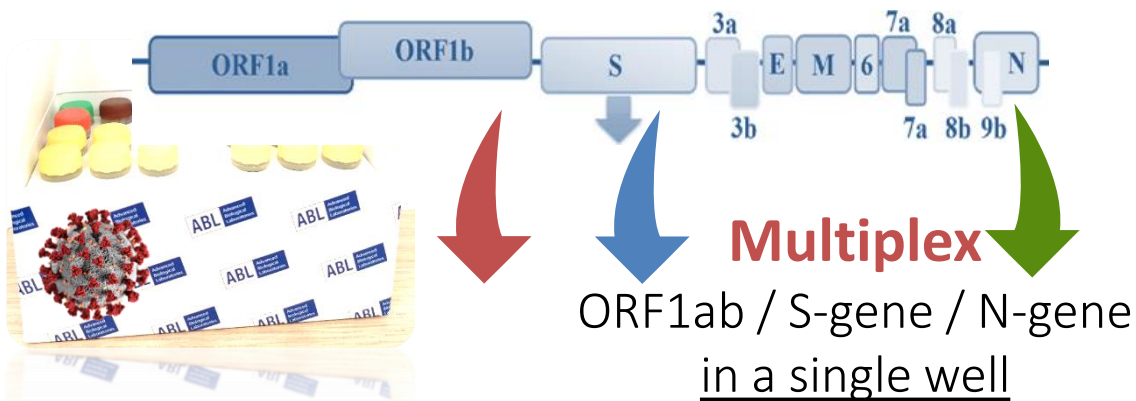


## UltraGene Assay SARS-CoV-2 Multi Variants Deletions V1

Direct qPCR Assay for SARS-CoV-2 Screening and  
“UK”, “South African” and “Brazilian” Variants Identification



**3** GENES  
**5** TARGETS  
**4** DELETIONS

SCREENING  
&  
IDENTIFICATION  
of **3** VARIANTS

- Reflex qPCR test to be used on all SARS-CoV-2 positive samples from your routine
- Specific amplification of N-gene + amino-acid deletions located on:
  - ORF1ab gene
  - S-gene
- SARS-CoV-2 lineage B.1.1.7 (i.e. **United Kingdom** VOC 202012/01, VOC 202102/02; “UK”)
- SARS-CoV-2 lineage B.1.351 (i.e. **South Africa** VOC 202012/02; “SA”)
- SARS-CoV-2 lineage P.1 (i.e. **Brazil** VOC 202101/02; “BR”)



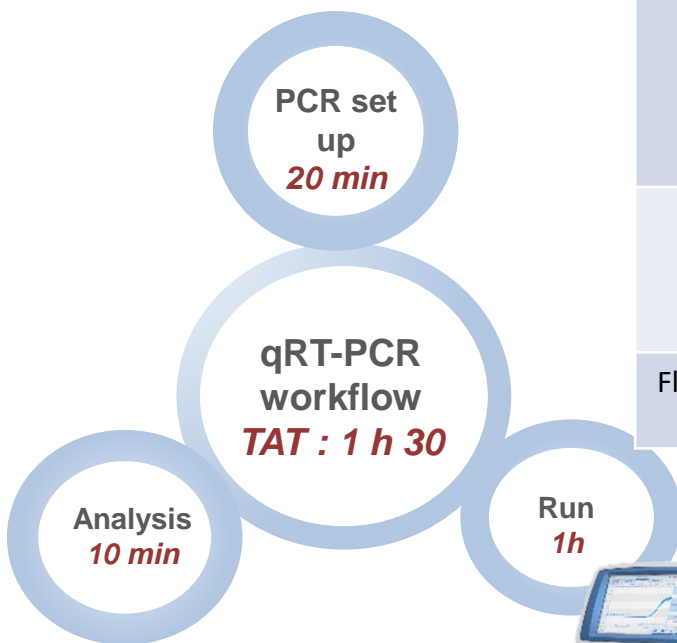
# SPECIFICATIONS & WORKFLOW

IVD Rx only



- Ultra-fast : full workflow **<1h30** from extracted RNA (up to 96 samples)
- N-gene to be used as an internal control in the same well
- For samples with qPCR positive result from an approved detection assay
- Positive & negative controls included
- Compatible with 4 fluorescence channels (FAM, ROX, HEX, Cy5) qPCR instruments
- Flexible format (50 tests per kit - ref.: 160A50 or 1000 tests per kit - ref.: 160A1000) to be used in runs from 12 to 384 samples
- Can be bundled with 4-channel qPCR instruments for 48 or 96 samples

| Features              | UltraGene Assay SARS-CoV-2 Multi Variants Deletions V1   |
|-----------------------|--|
| Specimen              | Upper respiratory specimens (nasal, mid-turbinate, nasopharyngeal, oropharyngeal swab specimens and nasopharyngeal wash/aspirate or nasal aspirate and bronchoalveolar lavage (BAL) fluid specimens) |
| Extraction            | Magnetic beads   |
| Fluorescence channels | FAM, ROX, HEX, Cy5   |





## COVID-19

### Variants screening through qPCR on positive samples

|  |          |
|--|----------|
| UltraGene Assay SARS-CoV-2 Multi Variants Deletions V1 (CE IVD - 50 tests)   | 160A50   |
| UltraGene Assay 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 |

### 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)                       | 116A+124A      |

### Detection (1<sup>st</sup> intention screening)

|  |          |
|--|----------|
| 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 |

### Viral quantification

|   |         |
|---|---------|
| UltraGene SARS-CoV-2 Quantitative Assay V1 (50 tests)   | Q2 2021 |
| UltraGene SARS-CoV-2 Quantitative Assay V1 (1000 tests) | Q2 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)<br>(ML)   | S-12-023 |

## **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 | 149A48 |
| Ultragene qPCR system - 96 samples format - 4 channels with Gradient | 149A96 |

## **Liquid handling robots**

|                    |           |
|--------------------|-----------|
| DeepChek Pipetting | I-18-PIP2 |
|--------------------|-----------|

## **RNA/DNA extraction**

|                   |         |
|-------------------|---------|
| CleanPrepX System | AS00001 |
|-------------------|---------|

## **Sample collection**

|   |          |
|---|----------|
| Clinical specimen nasopharyngeal collection kit (CE IVD Import)               | 135B_1   |
| Clinical specimen oropharyngeal collection kit (CE IVD Import)                | 135A_4   |
| Sterile saliva collection container for saliva specimens (CE-IVD)             | 144A250  |
| DNA/RNA stabilization solution for nucleic acids (CE IVD)                     | 148A50   |
| Saliva collection kit (funnel + tube with solution inactivation/preservation) |          |
| - 50 tests (CE IVD Import)  | 144C50   |
| - 1000 tests (CE IVD Import)  | 144C1000 |