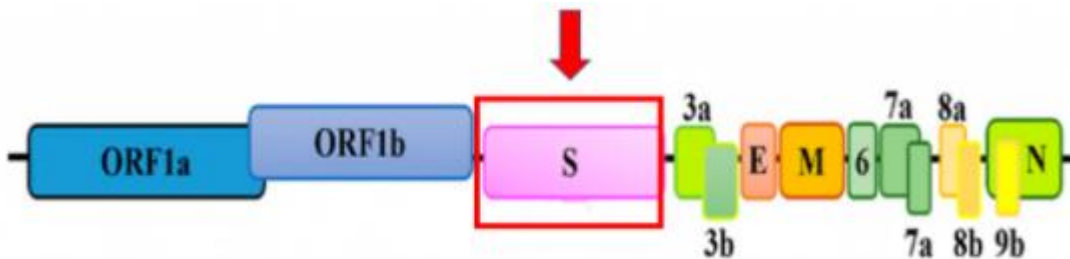


## Ultra Gene Assay SARS-CoV-2 452R & 484K & 484Q Mutations V1 **CE IVD**

The **Ultra Gene Assay SARS-CoV-2 452R & 484K & 484Q Mutations V1 (RUO)** is a RT-PCR Assay (nucleic acid technique (NAT)) intended to screen the emergence of SARS-CoV-2 genomic variations on the Spike (S) gene.



### Application (RUO)

***For Research Use Only (RUO). Not for use in diagnostic procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of disease.***

The Ultra Gene Assay SARS-CoV-2 452R & 484K & 484Q Mutations V1 is intended to screen the emergence of SARS-CoV-2 genome harboring the mutations L452R, E484K and E484Q on the Spike (S) gene.

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.

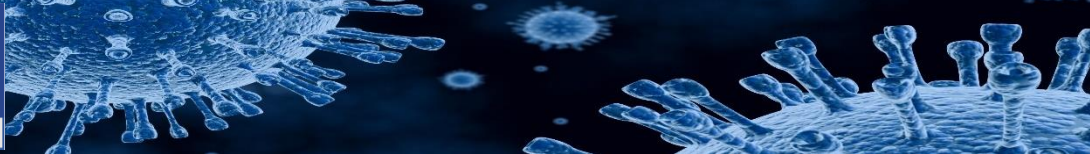


## CHARACTERISTICS AND PERFORMANCES

Features	
RNA extraction and purification of clinical specimen	<p>MagNa Pure 24 instrument (Roche; Catalog #07290519001B) with the MagNA Pure 24 Total NA Isolation Kit (Roche, Catalog #07658036001)</p> <p><i>Note: Any laboratory validated instrument for RNA extraction and purification using magnetic-bead technology shall work with the test (i.e. bioMérieux EMAG®, Perkin Elmer Chemagic™ 360, ThermoFisher Scientific MagMAX Viral/Pathogen Nucleic Acid Isolation Kit, Qiagen QIAamp Viral RNA Mini Kit, Biopur® Mini Spin Plus Kit and Magtivio MagSi-NA Pathogens)</i></p>
PCR	<p>ThermoFisher Scientific ProFlex™ PCR System (model 3 x 32-well (Catalog #4484073) or 96-well (Catalog #4484075) and associated specific material.</p> <p><i>Note: Any laboratory validated thermal cycler with enough ramp rate of <math>\geq 1^\circ\text{C/s}</math> shall be sufficient.</i></p>
Format / Models	- 50 tests/kit (165A50)
Content	<ul style="list-style-type: none"> <li>- Master Mix 2X, RT Mix, Enzyme Mix and Magnesium Sulfate</li> <li>- Specific Primers &amp; Probes for each mutation (L452R, E484K and E484Q) from S gene</li> <li>- Positive Control</li> <li>- Negative Control</li> <li>- PCR grade nuclease-free Water</li> </ul>
Hands-on-Time	0h15
Estimated Turnaround Time	~1h45

### Methodology

The Assay is a multiplex test targeting the S region of SARS-CoV-2 patients' extracted RNA in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, and oropharyngeal swab specimens, and nasopharyngeal wash/aspirate or nasal aspirate specimens) from individuals already tested positive to SARS-CoV-2.



## Intended user

The UltraGene SARS-CoV-2 SARS-CoV-2 452R & 484K & 484Q Mutations V1 (RUO) is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR. The current laboratory biosafety guidance for the 2019 novel coronavirus (SARS-CoV-2) shall be followed.



## Product References





### COVID-19

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

UltraGene Combo2Screen SARS-CoV-2 Assay (50/1000 tests)	139B50 / 139B1000
UltraGene Combo2Screen SARS-CoV-2 Assay ( + saliva) (50 tests/1000 tests)	139C50 / 139C1000

#### Variants screening through qPCR on positive samples

UltraGene SARS-CoV-2 Multi Variants Deletions V1 (50 tests/1000 tests) 	160A50 / 160A1000
UltraGene Assay SARS-CoV-2 N / Spike Δ 69-70 V1 (50 tests/1000 tests)	158A50 / 158A1000
UltraGene Assay SARS-CoV-2 E484K & N501Y mutations V1 (50 tests/1000 tests)	164A50 / 164A1000
<b>UltraGene Assay SARS-CoV-2 452R &amp; 484K &amp; 484Q Mutations V1 (50 tests) </b>	<b>165A50</b>
UltraGene Assay SARS-CoV-2 Triplex, Screening, Multi-Variants and Typing V1 (CE IVD) (1000 tests screening / 50 tests multi-variants)	161A1000_50
UltraGene Assay SARS-CoV-2 Triplex, Screening, Multi-Variants and Typing V1 (CE IVD) (1000 tests screening / 1000 tests multi-variants)	161A1000_1000

#### Variants screening through sequencing

DeepChek Assay Whole Genome SARS-CoV-2 Genotyping V1 (48 tests)	159A48
DeepChek® CoV-2 Software	S-12-023 (CVL)
DeepChek® NGS LIB PREP (24/48/96/384 indexes)	116A24/48/96/384 +124A24/48/96/384

