gb SARS-CoV-2 Variant SA/BR, UK

NEW

Purpose of use

gb SARS-CoV-2 Variant SA/BR, UK is a CE certified in vitro diagnostic kit that enables multiplex detection of SARS-CoV-2 virus RNA (Wuhan coronavirus 2019) in RdRP gene and simultaneously the detection of mutations A570D a E484K in S gene. The A570D mutation occurs exclusively in lineage B.1.1.7 (a.k.a 20I/501Y.V1) referred to as the British variant. The E484K is an escape mutation that causes reduced binding of neutralizing antibodies and occurs in lineage B.1.351 (a.k.a 501Y.V2) referred to as the South African variant and lineage P.1 (a.k.a 501Y.V3) referred to as the Brazilian variant. The false negativity is checked by exogenous positive control with artificial sequence.

Principle of detection

The test is based on multiplex one-step RT-qPCR method. The analysis is performed using fluorescently labelled probes, which allow the detection of viral gene S (mutation E484K FAM channel, mutation A570D HEX channel), viral gene RdRP (ROX channel) and exogenous positive control (Cy5 channel) in one reaction. The kit contains all the necessary components to perform the test.

Available products

Cat. No.	Product	rxn
3239-100	gb SARS-CoV-2 Variant SA/BR, UK	100
3239-500	gb SARS-CoV-2 Variant SA/BR, UK	500

CE IVD one-step RT-qPCR kit contains reagents to provide 100/500 reactions (20 µl volume of each reaction).

CE IVD

Parameters of the diagnostic kit

- **CE IVD multiplex one-step RT-qPCR kit**
- **SARS-CoV-2 - detection of viral genes S and RdRP**
- **mutation E484K - South African variant B.1.351 (501Y.V2) and Brazilian variant P.1 (501Y.V3)**
- **mutation A570D - British variant B.1.1.7 (20I/501Y.V1)**
- **fluorescence channels FAM (E484K), HEX (A570D), ROX (RdRP), Cy5 (EPC)**
- **suitable for multi-channel PCR thermocyclers**
- **high sensitivity detection**
- **LOD is 3 copies of viral RNA per reaction (95% CI)**
- **positive and negative control for analysis validity confirmation**
- **exogenous control (EPC Template RNA) is an artificial RNA, which may be added either to the sample before the isolation or to the RT-qPCR reaction**
- **exogenous control serves for verification of extraction process and reveals possible inhibition of RT-qPCR**

Content of the diagnostic kit

*	Component [1]	Volume	Qty [2]	Conc.
🟢	Assay CoV-2 SA/BR, UK	0.5 ml[3]	1 | 5	4x
🔵	Master Mix OneStep Multi	1.0 ml[3]	1 | 5	2x
🔴	Positive Control CoV-2 SA	0.2 ml	1 | 1	4x
🟡	EPC Template RNA	1.0 ml	1 | 5	
⚪	Deionized Water	1.0 ml	1 | 1	

1) tube lid colour corresponds to reagent type
2) number for kit size of 100 / 500 reactions
3) volume equates to 100 PCR reactions of 20 µl volume

Validated for cyclers

- **CFX96/96Touch (Bio-Rad)**
- **QuantStudio 5 (Applied Biosystems)**
- **RG 3000 (Corbett Research)**