Datasheet

RT-PCR quantitative COVID-19 assay CE-IVD (48 reactions)

Product Name	RT-PCR quantitative COVID-19 assay CE-IVD (48 reactions)
Catalogue Number	CLO-RT-25
IVD or RUO	IVD
CE Marked	Yes
Size	48 reactions

Description:

This COVID-19 system is a quantitative test that allows the quantification, by means of Real Time PCR, of the N region (nucleocapsid phosphoprotein) of novel Coronavirus (COVID-19). The Procedure allows the detection of the RNA target by means a retro-amplification reaction in a microplate. The analysis of the results is made using a Real Time PCR analyser instrument (thermal cycler integrated with a system for fluorescence detection).

Product Features:

Intended Use: This product is a quantitative test that allows the quantification, by means of Real Time PCR, of the N region (nucleocapsid phosphoprotein) of novel Coronavirus (COVID-19).
3 Targets of the N* region
N*1: Real Time Detection and Quantification
N*2: Real Time Detection
N*3: Real Time Detection

Usage of samples: This product must be used with extracted RNA from biological samples: Nasopharyngeal/oropharyngeal swabs, sputum and serum.

Storage: Store the product at –20°C. An intact and well stored product has a stability of 12 months from the date of production. Do not use beyond the expiration date which appears on the package label. Repeated thawing and freezing of reagents (more than twice) should be avoided, as this might affect the performance of the assay. The reagents should be frozen in aliquots if they are to be used intermittently.

Shipping: The kit is shipped on dry ice. The kit components should be frozen. If one or more components are not frozen upon receipt or if the tubes have been compromised during transport, contact BioServUK for assistance.

Regulatory/ Restrictions: For in-vitro diagnostic use only. This product is for professional use only.

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Materials Supplied:

The kit contains enough reagents to perform 48 amplification tests.

1. 3 Positive controls for each region
2. 4 standards for the quantification
3. Mastermix for detection of N1 and N2
4. Mastermix for detection of N3 and IC
5. 48 test for the detection of N1 and N2
6. 48 test for the detection of N3 an IC

Content

	Quantity	Description
R1	3 x 180 µl	**Amplification mMix** dNTPs, Tris-HCl, KCl, $MgCl_2$, Taq Polymerase, *AmpErase* Uracil N-Glycosylase (*UNG*) Nuclease-free water, ROX (Pink Cap)
R2	3 x 280 µl	**N1-N2 probe Mix** Upstream primer, downstream primer, Target probe N1 (FAM), Target probe N2 (VIC), Nuclease-free water, (White Cap)
R3	3 x 280 µl	**N3-RP probe Mix** Upstream primer, downstream primer, Target probe N3 (VIC), Inhibition Control (RP) probe (CY5), Nuclease-free water (Yellow Cap)
R4	3 x 35 µl	**N1 Positive Control** synthetic RNA corresponding to N1 region at the concentration of 10^5 copies/µl (Blue Cap)
R5	3 x 35 µl	**N1 Positive Control** synthetic RNA corresponding to N1 region at the concentration of 10^4 copies/µl (Green Cap)
R6	3 x 35 µl	**N1 Positive Control** synthetic RNA corresponding to N1 region at the concentration of 10^3 copies/µl (Yellow Cap)
R7	3 x 35 µl	**N1 Positive Control** synthetic RNA corresponding to N1 region at the concentration of 10^2 copies/µl (White Cap)
R8	3 x 35 µl	**N2 Positive Control** synthetic RNA corresponding to N2 region (Red Cap)
R9	3 x 35 µl	**N3 Positive Control** synthetic RNA corresponding to N3 region (Pink Cap)
R10	1 x 50 µl	Negative Control

Figure 1: Describes the content of the materials supplied.

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Precautions

- This kit is for in vitro diagnostic (IVD), for professional use only and not for in vivo use.
- After reconstitution, the amplification master mix must be used in one time. Repeat thawing and freezing of reagents (more than twice) should be avoided, as this might affect the performance of the assay. The reagents should be frozen in aliquots, if they are to be used intermittently.
- At all times follow Good Laboratory Practice (GLP) guidelines.
- Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.
- Avoid any contact between hands and eyes or nose during specimen collection and testing.
- Handle and dispose all used materials into appropriate bio-hazard waste containers. It should be discarded according to local law.
- Keep separated the extraction and the reagents preparation.
- Never pipette solutions by mouth.
- Avoid the air bubbles during the master mix dispensing. Eliminate them before starting amplification.
- Wash hands carefully after handling samples and reagents.
- Do not mix reagents from different lots.
- It is not infectious and hazardous for the health (see Material Safety data Sheet – MSDS).
- Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
- Read carefully the instructions notice before using this test.
- Do not use beyond the expiration date which appears on the package label.
- Do not use a test from a damaged protective wrapper.

Limit of the method

The extreme sensitivity of gene amplification may cause false positives due to cross-contamination between samples and controls. Therefore, you should:

- Physically separate all the products and reagents used for amplification reactions from those used for other reactions, as well as from post-amplification products;
- Use tips with filters to prevent cross-contamination between samples;
- Use disposable gloves and change them frequently;
- Carefully open test tubes to prevent aerosol formation;
- Close every test tube before opening another one.

The proper functioning of the retro-amplification mix depends on the correct collection, correct transportation, correct storage and correct preparation of a biological sample.
As with any diagnostic device, the results obtained with this product must be interpreted taking in consideration all the clinical data and other laboratory tests done on the patient.
A negative result obtained with this product suggests that the RNA of COVID-19 was not detected in RNA extracted from the sample, but it may also contain COVID-19-RNA at a lower titre than the detection limit for the product (detection limit for the product, see paragraph on Performance Characteristics); in this case the result would be a false negative.
As with any diagnostic device, with this product there is a residual risk of obtaining invalid, false positives or false negatives results.