


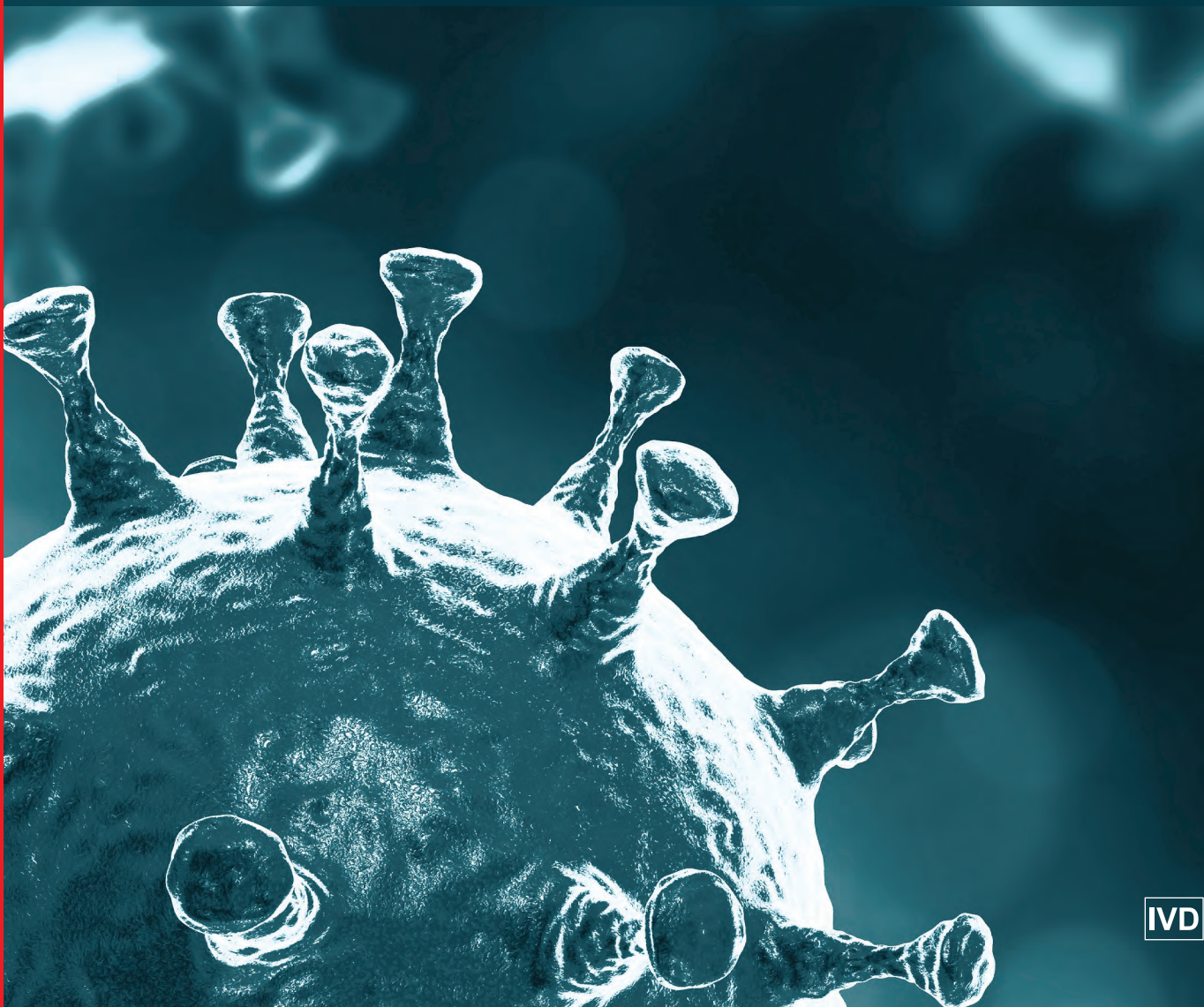
SARS-CoV-2

Real-time PCR kit for the qualitative detection of SARS-CoV-2 in clinical samples.

Vitassay qPCR SARS-CoV-2 allows the qualitative detection of 2019 Novel Coronavirus (SARS-CoV-2) by real-time RT-PCR in clinical samples. The product is intended for use in the diagnosis of SARS-CoV-2 infections alongside clinical data of the patient and other laboratory tests outcomes.

Vitassay qPCR SARS-CoV-2 is a ready-to used test which contains in each well all the necessary reagents for real-time PCR assay in a stabilized format. In addition, an internal control allows the detection of a possible reaction inhibition.

-  For the **Vitassay qPCR SARS-CoV-2**, the amplification of the target sequence **ORF1ab gene** is detected through the FAM channel, the amplification of the target sequence **N gene** is detected through the ROX channel whereas the internal control (IC) in HEX, VIC or JOE channel (depending on the equipment used).



Vitassay qPCR SARS-CoV-2 is based on the real-time amplification of specific conserved fragments of the ORF1ab and N genes encoded by the SARS-CoV-2.

The viral RNA extracted is transcribed into cDNA using a specific primer by reverse transcription step followed immediately in the same well by polymerase chain reaction. The presence of SARS-CoV-2 is detected by an increase in observed fluorescence during the reaction upon hydrolysis of the fluorescent probe.

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Quality Control

In order to confirm the appropriate performance of the molecular diagnostic technique, an Internal Control (IC) is included in each reaction. Besides, a positive and a negative control must be included in each assay to interpret the results correctly.

Analytical sensitivity

The analytical sensitivity was determined by analysis of 10-fold dilution series of SARS-CoV-2 template ranging from 10^7 to 10^1 copies/rxn.

Vitassay qPCR SARS-CoV-2) has a detection limit of ≥ 10 viral RNA copies per reaction.

