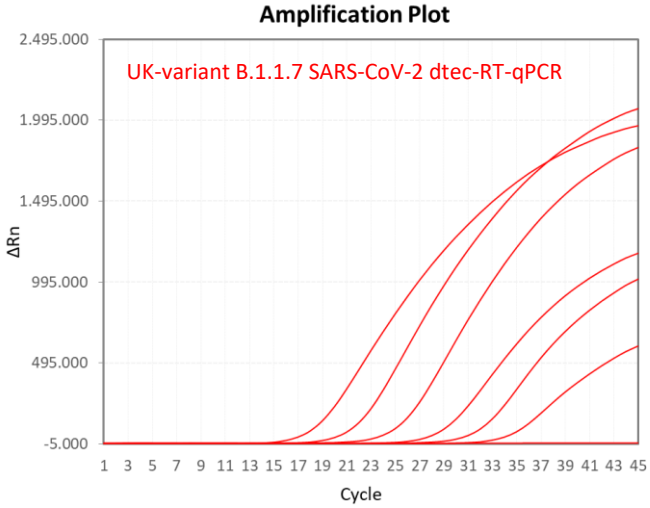
ANALYSIS REPORT

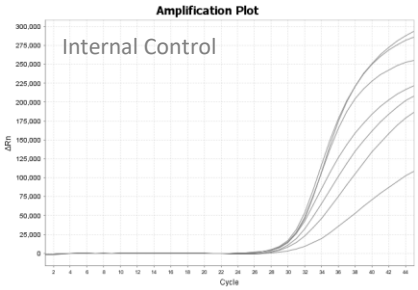
Results of the assay

The aim of the experiments performed was to validate the kit *UK-variant B.1.1.7 SARS-CoV-2 dtec-RT-qPCR* for detection of the SARS-CoV-2 lineage variant B.1.1.7, identified as VUI-202012/01 (Variant Under Investigation) and VOC-202012/01 (Variant of Concern).

Validation of the qPCR with the Standard Template (RED CAP)

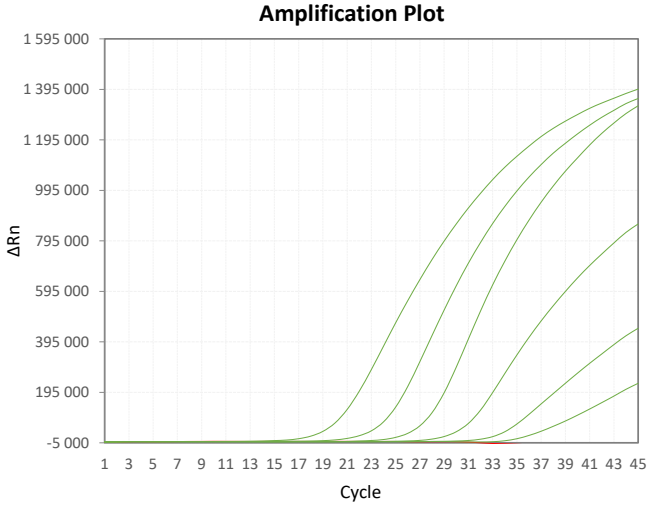
A serial decimal dilution of the *Standard Template* (RED CAP) was prepared from 10^6 to 10 copies as indicated in the product handbook. Both, the primer/probe (TUBE AMBER) with Internal Control and the *LyoMix RT-qPCR* (BLUE CAP), were validated in a QuantStudio 3 (ABI) Real-Time PCR device. Amplification results are show in the graph below for all the dilutions tested. An efficiency of 93.9 % was obtained with an R^2 of 0.999.





Verification with the synthetic RNA genome of England/MILK9E05B3/2020

A similar validation experiment is performed using a serial decimal dilution of a synthetic genome RNA of the lineage B.1.1.7 belonging to SARS-CoV-2. The results, showed the amplification of the RNA template with an efficiency of 89.8 % and R^2 of 0.998.



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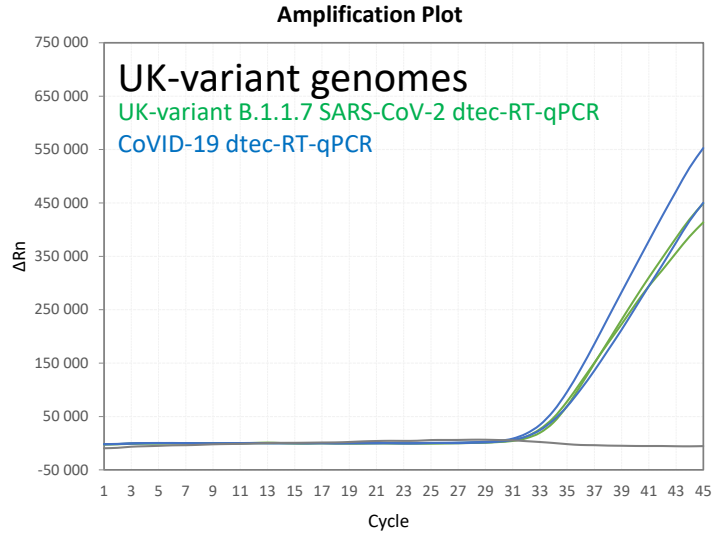
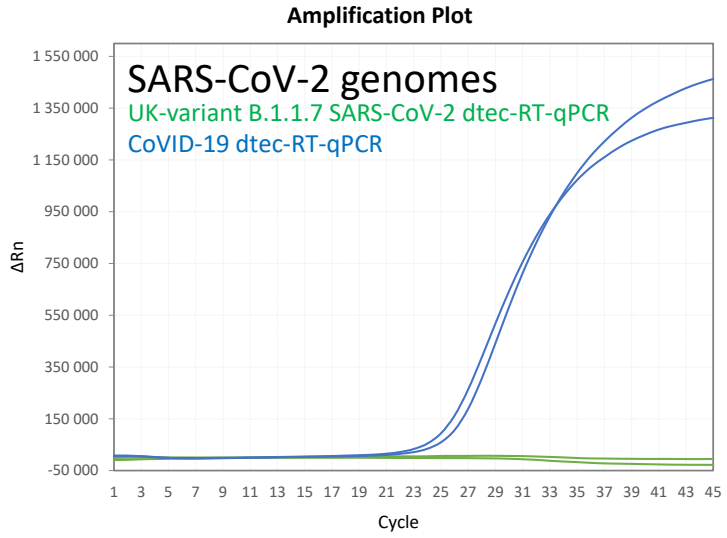
Specificity of the assay with synthetic RNA genomes

The specificity of the design was evaluated by using 500 copies of two synthetic RNA genomes of the SARS-CoV-2 lineage B.1.1.7 (England/205041766/2020 and England/MILK9E05B3/2020) to check INCLUSIVITY; and $5*10^4$ copies of two synthetic RNA genomes of SARS-CoV-2 (Wuhan-Hu-1 and Australia/VIC01/2020) to check EXCLUSIVITY. Additionally, samples were tested with the *CoVID-19 dtec-RT-qPCR* kit to confirm the presence of SARS-CoV-2 sequences.

The results with samples England/205041766/2020 and England/MILK9E05B3/2020 from the B.1.1.7 lineage showed positive amplification for CoVID-19 kit and for the UK-variant kit. Both kits yielded similar Cts for 500 copies of the UK-variant genomes.

As expected, with samples Wuhan-Hu-1 and Australia/VIC01/2020 amplification was positive for CoVID-19 kit and negative with the UK-variant kit (including $5*10^4$ copies). These results demonstrate that the UK-variant kit can amplify sequences belonging to the lineage B.1.1.7 but no other lineages of the SARS-CoV-2.





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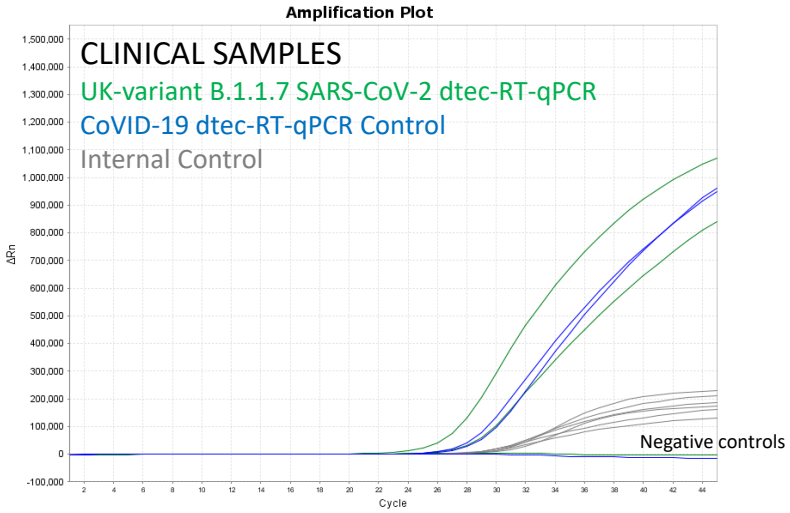
Validation with clinical samples

An additional assay was performed with the clinical samples 457638 (1) and 457638 (2) identified as B.1.1.7 lineage by sequencing their genomes. After RNA extraction, samples were analysed with the UK-variant and the CoVID-19 kits. The assay includes an exogenous Internal Control to check possible PCR inhibitors on the reaction.

Both samples showed positive amplification for both kits, confirming the capacity of the *UK-variant B.1.1.7 SARS-CoV-2 dtec-RT-qPCR* kit to detect the B.1.1.7 lineage in clinical samples and the diagnostic capacity of the *CoVID-19 dtec-RT-qPCR kit*.



Conclusions

All the assays performed suggest that the *UK-variant B.1.1.7 SARS-CoV-2 dtec-RT-qPCR* kit has a robust efficiency with both DNA and RNA templates and can detect and differentiate specifically the B.1.1.7 lineage of the SARS-CoV-2 (also known as VOC-202012/01). The *CoVID-19 dtec-RT-qPCR* kit positively detects the B.1.1.7 lineage samples of SARS-CoV-2.

Elche, 26th January 2021

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