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It's official: our SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0 can detect Omicron

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On the 24th of November 2021 Omicron variant (B.1.1.529) was first reported to WHO from South Africa.[1] Few days later it was designated as a SARS-CoV-2 Variant of Concern (VOC). [2] The main concerns for this variant are its large number of mutations (at least 30 amino acid substitutions in the spike protein, which modulates infectivity and immune evasion), resistance to vaccines and high transmissibility.[3],[4],[5]

[1] Classification of Omicron (B.1.1.529): SARS-CoV-2 Variant of Concern, (2021). Retrieved 6 January 2022, from [https://www.who.int/news/item/26-11-2021-classification-of-omicron-\(b.1.1.529\)-sars-cov-2-variant-of-concern](https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern)

[2] Update on Omicron, (2021). Retrieved 6 January 2022, from <https://www.who.int/news/item/28-11-2021-update-on-omicron>

[3] Science Brief: Omicron (B.1.1.529) Variant, (2021). Retrieved 6 January 2022, from <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-omicron-variant.html>

We now have proof from our partner diagnostic laboratory that our new SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0 can detect Omicron (B.1.1.529) from real clinical samples all on its own with 100% detection rate. This product is supplied for Research Use Only and is supplied with primers, probes and positive control needed for SARS-CoV-2 detection.

[4] Brandal Lin T., MacDonald Emily, Veneti Lamprini, Ravlo Tine, Lange Heidi, Naseer Umaer, Feruglio Siri, Bragstad Karoline, Hungnes Olav, Ødeskaug Liz E., Hagen Frode, Hanch-Hansen Kristian E., Lind Andreas, Watle Sara Viksmoen, Taxt Arne M., Johansen Mia, Vold Line, Aavitsland Preben, Nygård Karin, Madslie Elisabeth H. Outbreak caused by the SARS-CoV-2 Omicron variant in Norway, November to December 2021. Euro Surveill. 2021;26(50):pii=2101147. <https://doi.org/10.2807/1560-7917.ES.2021.26.50.2101147>

[5] Understanding Omicron: Changes In The Spike Protein And Beyond And What They Portend, (2021). Retrieved 6 January 2022, from <https://www.forbes.com/sites/williamhaseltine/2021/12/08/omicron-the-sum-of-all-fears/?sh=58e370895b51>

SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0

Features

- **High specificity** – targets 3 highly conserved regions of SARS-CoV-2 genome. In silico no cross-reactivity for 42 pathogens with clinical symptoms similar to SARS-CoV-2.
- **Great analytical sensitivity** – the limit of detection (LoD) of 5-10 viral RNA copies per reaction.
- **Reliable performance** – tested and confirmed in clinical setting.
- **Suitable for screening** – pooling of up to 5 samples without loss in sensitivity.
- **Excellent for high throughput workflow** – reactions can be premixed up to 12h in advance and stored at +4°C or -20°C before adding the sample.
- **Fast time to results** – one-step RT-qPCR test results in one hour.

Kit components:

- 40x One-step SOLIScript® CoV Mix
- 5x One-step Probe CoV Mix
- 20x SARS-CoV-2 Primer/Probe Mix (N/E/RdRP)
- SARS-CoV-2 Positive Control (N/E/RdRP)
- Water, nuclease free

For Research Use Only

**Your fast track to an
IVD-certified kit!**

Experimental assessment of the sensitivity of SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0 in the detection of SARS-CoV-2 Omicron variant (B.1.1.529/BA.1) based on a synthetic viral control

Synthetic viral control from Twist Bioscience [(Control 48 (B.1.1.529/BA.1))] consists of six non-overlapping 5 kb fragments generated from Twist Gene Fragments then transcribed into ssRNA. Twist Bioscience synthetic viral controls provide coverage of greater than 99.9% of the bases of the SARSCoV-2 viral genome. The results indicate great sensitivity of the molecular assay with SARS-CoV-2 synthetic viral control for Omicron variant.

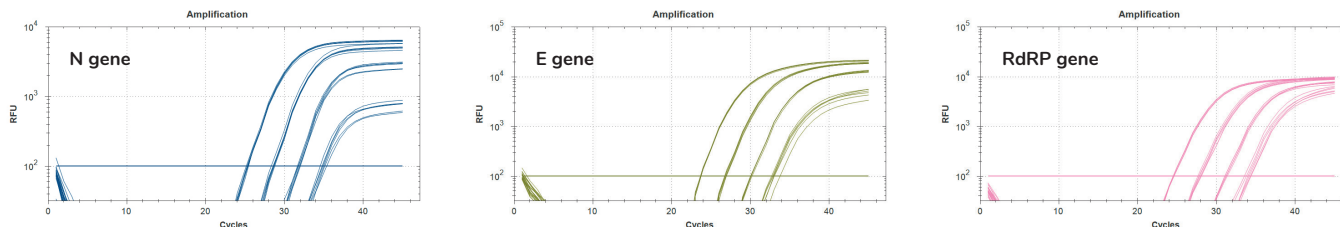


Figure 1. The molecular assay sensitivity test of SOLIScript® SARS-CoV-2 RTqPCR Multiplex Assay Kit 2.0 was performed with four 10-fold serial dilutions (10 000, 1 000, 100, 10 cp/reaction) of the Twist Bioscience Control 48 (B.1.1.529/BA.1). Reactions were run on Bio-Rad CFX96 qPCR cyler with RT step at 50°C 10 min, followed by 95°C 10 min, and 45 cycles of 95°C 3 sec, 62°C 15 sec.

External validation of the performance of SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0 using six different clinical RNA samples containing SARS-CoV-2 Omicron (B.1.1.529) genomic RNA

The results demonstrate that SOLIScript® SARSCoV-2 RT-qPCR Multiplex Assay Kit 2.0 shows 100% detection rate of all three SARS-CoV-2 targets: Nucleocapsid gene (N, detected in FAM channel), Envelope gene (E, VIC/HEX/JOE channel) and RNA-dependent RNA polymerase gene (RdRP, Cal Red 610/ROX/Texas Red channel).

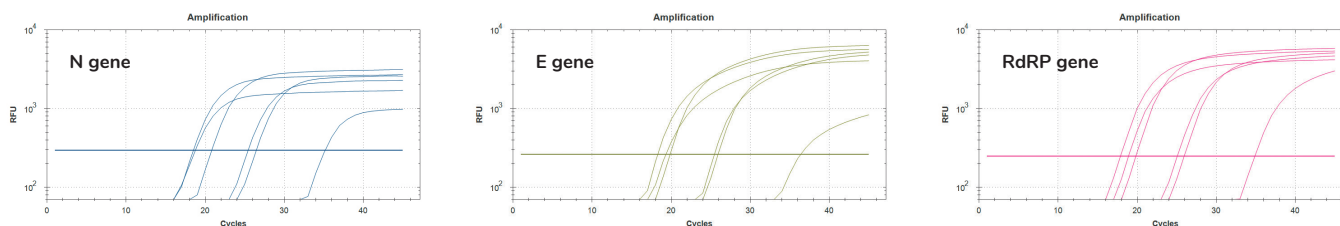


Figure 2. Validation of clinical performance and detection capacity of SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0 with six clinical RNA samples containing SARS-CoV-2 Omicron variant (B.1.1.529). Clinical RNA samples were extracted from nasopharyngeal swab specimens using automated RNA extraction with Thermo Scientific™ KingFisher™ Flex Purification System. Initial SARS-CoV-2 RNA detection and preliminary genotyping of SARS-CoV-2 variant was performed with the reference RT-qPCR method used in the diagnostic unit. Omicron SARS-CoV-2 variants were confirmed with NGS (Next Generation Sequencing). Reactions were run on Bio-Rad CFX96 qPCR cyler with RT step at 50°C 10 min, followed by 95°C 10 min, and 45 cycles of 95°C 3 sec, 62°C 15 sec.

Table 3. Cq (quantification cycle) values of SARS-CoV-2 gene targets across six tested clinical RNA samples containing SARS-CoV-2 Omicron variant (B.1.1.529). Results are shown for Solis BioDyne SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0, Laboratory Developed Test (LDT) of an independent diagnostic lab, as well as Seegene Allplex™ SARS-CoV-2 Assay (CE-IVD).

Sample	SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0, Cq			LDT test, Cq		Seegene Allplex™ SARS-CoV-2 Assay, Cq		
	N gene	E gene	RdRP gene	N gene	S gene	E gene	S/RdRP	N gene
Omicron_1	26.4	25.9	25.9	28.2	26.6	24.2	26.7	25.6
Omicron_2	35.2	36.4	34.9	42.0	34.9	36.7	38.7	39.7
Omicron_3	25.4	25.4	25.1	23.3	22.5	26.8	28.0	29.3
Omicron_4	18.7	19.3	18.9	17.4	19.4	17.7	18.8	18.3
Omicron_5	20.8	19.8	19.8	18.7	18.1	17.7	18.5	18.9
Omicron_6	18.5	18.2	17.8	17.3	16.7	16.6	17.8	18.3



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