

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

For sensitive and reliable
detection of SARS-CoV-2
by one-step RT-qPCR

solisbiodyne.com



The SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0 is optimized for one-step RT-qPCR detection of SARS-CoV-2 viral RNA in RNA samples extracted from nasopharyngeal swabs, bronchoalveolar lavage, sputum, or any other respiratory sample. The kit is designed for multiplex detection of three distinct regions in the SARS-CoV-2 genome - the Nucleocapsid (N), Envelope (E) and RNA-dependent RNA polymerase (RdRP) genes; and the internal control - the human RNase P transcript (RPP30), all in a single reaction.

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

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.

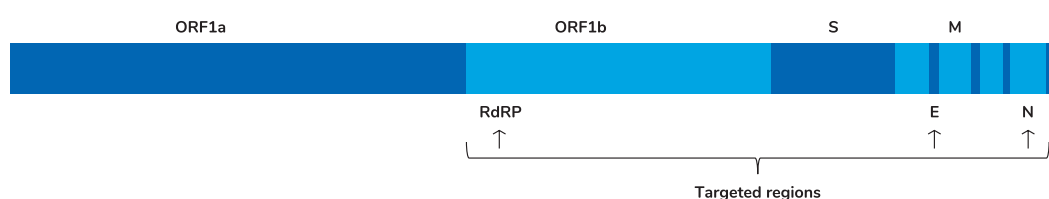


Figure 1. Structure of SARS-CoV-2 genome. SOLIScript® SARS-CoV-2 RTqPCR Multiplex Assay Kit 2.0 targets three conserved regions targets three conserved regions in the SARS-CoV-2 viral genome – RNA-dependent RNA polymerase (RdRP), Envelope (E), and Nucleocapsid (N).

Highly sensitive detection of three viral targets with LoD 5-10 copies/reaction

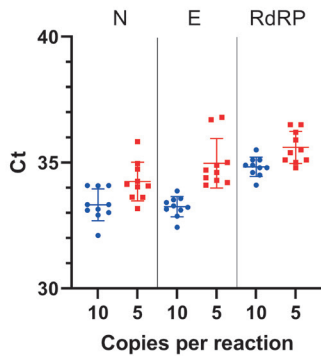


Figure 2. Assessment of SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0 limit of detection (LoD) using synthetic SARS-CoV-2 RNA. The number of synthetic viral RNA copies in 20 µl reaction mix is shown on the x-axis. Reactions were run on a Bio-Rad CFX96 qPCR cyclor with RT step at 50°C 10 min, followed by 95°C 10 min, and 45 cycles of 95°C 3 sec, 62°C 15 sec.

Performance validated using clinical samples

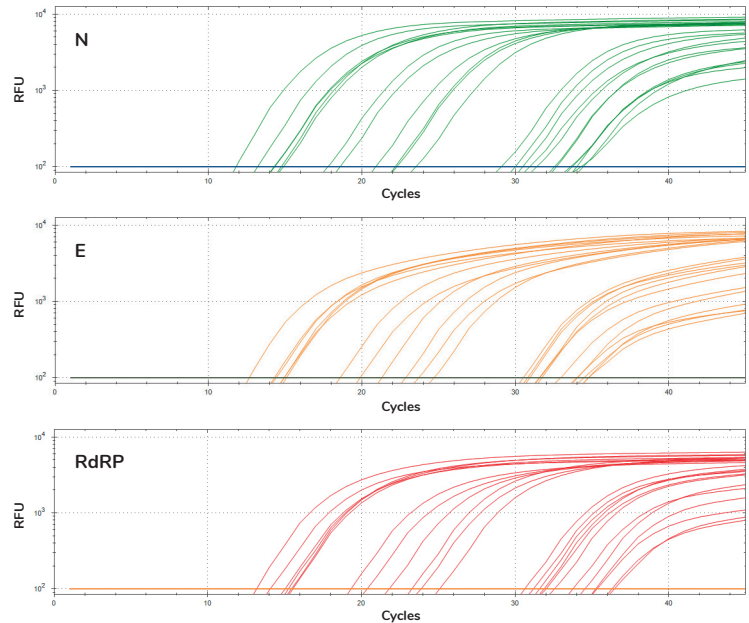


Figure 3. Validation of clinical performance of SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0. The kit was used to detect N (FAM), E (HEX), and RdRP (Texas Red) genes and the internal control RNase P (Cy5) (data not shown) using SARS-CoV-2 positive and negative clinical RNA samples. Individual samples are shown, with high to medium viral load detected at Ct <25 and low viral load detected at Ct >28. Reactions were run on Bio-Rad CFX96 qPCR cyclor 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.

		CE-IVD Certified Comparator		
		Positive	Negative	Total
SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0	Positive	52	0	52
	Negative	0	24	24
	Total	52	24	76

Positive Percent Agreement (95% CI) = 100% (93.15% - 100%)
 Negative Percent Agreement (95% CI) = 100% (85.75% - 100%)

Table 1. Clinical agreement study. The performance of SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit 2.0 with nasopharyngeal swab clinical samples was evaluated using 24 individual negative and 52 confirmed positive clinical samples. Clinical evaluation results show 100% PPA (Positive Percent Agreement) and 100% NPA (Negative Percent Agreement) with a 95% confidence interval.

Kit components:

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

For Research Use Only

We offer:

- Design and Manufacturing
- Reliable and long-term partnership
- All kit components from one supplier
- ISO 13485 certified Quality Management System
- Regular monitoring of emerging SARS-CoV-2 strains
- Custom formats (bulk and pre-aliquoted)
- Quick service and delivery
- White label product
- Technical support



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For further details and ordering please contact info@solisbiodyne.com or call +372 740 9960