Certificate of Analysis

SmartChip® Real-Time RT-PCR SARS-CoV-2 Reagents

Catalog No.	Amount	Lot Number
640256	1 Kit	2110107

Description

This assay is for Research Use Only. Not for use in diagnostic procedures.

The SmartChip Real-Time RT-PCR SARS-CoV-2 Assay is a real-time PCR assay intended for the qualitative detection of RNA from the SARS-CoV-2 virus in nasopharyngeal swabs.

The SmartChip Real-Time RT-PCR SARS-CoV-2 Reagents accommodate one chip run on the SmartChip Real-Time PCR System (Cat. No. 640022) with 378 samples and 6 controls (negative control in triplicate, positive control in duplicate, and an extraction control) in four hours of total processing time.

Package Contents

Box 1:

- 922 µl SmartChip Probe qPCR Master Mix
- 58 µl SMARTScribe™ Reverse Transcriptase
- 1 ml Negative Control
- 20 µl Positive Control RNA Mix
- 1 ml EASY Dilution (for Real Time PCR)

Box 2:

- 2 each 384-Well Source Plate
- 2 each 384-Well Source Plate Seal
- 1 each SmartChip MyDesign Chip, 250nl
- 2 each Blotting Paper
- 1 each Intermediate Film
- 1 each Cycler Sealing and Pressure Film

Storage Conditions

- Box 1: Store at –80°C.
- Box 2: Store at room temperature.

Expiration Date

- Specified on product label.

Shipping Conditions

- Box 1: Dry ice
- Box 2: Room temperature

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(012022)

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Product Documents

Documents for our products are available for download at **takarabio.com/manuals**
The following documents apply to this product:

- SmartChip Real-Time RT-PCR SARS-CoV-2 Assay User Manual

Quality Control Data

The kit components have been functionally tested by dispensing positive and negative control materials into the 384-Well Source Plate using the MultiSample NanoDispenser (MSND), followed by dispensing assays (primer/probe mixes) combined with RT-qPCR amplification reagents; the chip was sealed with the Cycler Sealing and Pressure film, and then subject to thermocycling and detection on the SmartChip Real-Time PCR System. No amplification (Ct <33.5) should be observed in the N1, N2, and RP wells containing the Negative Control (provided in the kit). In the wells containing the Positive Control RNA Mix, amplification should be observed in at least 4/5 replicate wells for each of the N1 and N2 assays, and amplification observed in both replicate wells (2/2) for the RP assay.

Expected performance of controls included in the 2019-nCoV diagnostic panel:

Control Type	External Control Name	Used to Monitor	2019 nCoV_N1	2019 nCoV_N2	RP	Expected Ct Values	Number of replicate wells
Positive	nCoVPC	Substantial reagent failure including primer and probe integrity	+	+	+	<33.5 Ct	>=4/5 for N1 and N2 assays; 2/2 for RP assay
Negative	NTC	Reagent and/or environmental contamination	–	–	–	None detected below 33.5	0/5 for N1 and N2, 0/2 for RP

It is certified that this product meets the above specifications, as reviewed and approved by the Quality Department.

Notice to Purchaser

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CATALOG NO.

640256

NOTICE TO PURCHASER:

Our products are to be used for **Research Use Only**. They may not be used for any other purpose, including, but not limited to, use in humans, therapeutic or diagnostic use, or commercial use of any kind. Our products may not be transferred to third parties, resold, modified for resale, or used to manufacture commercial products or to provide a service to third parties without our prior written approval.

Your use of this product is also subject to compliance with the licensing requirements, listed below if applicable, and described on the product´s web page at http://www.takarabio.com. It is your responsibility to review, understand and adhere to any restrictions imposed by these statements.

TRADEMARKS:

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