



MICROCHIP RT-PCR SYSTEM FOR RAPID COVID-19 DETECTION FROM SALIVA SAMPLES

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) also known as 2019 novel coronavirus (2019-nCoV). Since the World Health Organization (WHO) declared the coronavirus outbreak pandemic, there is a dire need of its detection accurately, rapidly, and cost effectively. The standard method of testing is real-time reverse transcription polymerase chain reaction (RT-PCR) performed on respiratory samples such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate.

To achieve rapidity, cost-effectiveness, minimization of reagent consumption, decrease of human errors, Lumex Instruments Canada has developed a **Microchip RT-PCR COVID-19 detection system for saliva samples** that use a pre-loaded microchip kit with the US CDC recommended primers & probes lyophilized in the microchip for testing of the SARS-CoV-2, as research use only (RUO) application. The N1 primer-probes target region within the SARS-CoV-2 nucleocapsid gene (N), and HsRPP30 targets RNase P gene present in the human genome.

FEATURES and BENEFITS:

- Current real-time PCR assays and PCR instruments consume large volume of reagents (20 µl reaction) and require extraction of RNA from respiratory samples (swabs, sputum, etc). The test can be costly, takes long time, requires laboratory infrastructure and suffer from potential bottleneck of reagents and consumables supply in the event of disease outbreaks.
- Main advantages of the Microchip RT-PCR COVID-19 detection system for **saliva** samples are low reagent consumption (1.2 µl reaction), fast analysis (10 min sample prep + 30 min PCR time), shipment under ambient conditions and simplified processes of sample prep and PCR analysis. Sample throughput is 324 samples per 8-hour work shift.
- The Microchip RT-PCR COVID-19 detection system would provide sensitive, specific, and fast detection of SARS-CoV-2 viral RNA using less reagents and consumables.
- Ease of use with lyophilized PCR reagents in the microchips will significantly improve reliability of analysis in fast-responder settings by reducing operator-associated errors.
- The Microchip RT-PCR COVID-19 detection system – compact and low-energy requiring – is ready to be deployed as point-of-analysis network.



USER-FRIENDLY SOFTWARE

Designed to acquire real-time PCR data and allows simplified operation steps. It offers auto-interpretation of results, allows manual analysis of data, and prints report in compliance with 21 CFR part 11 requirements.

FLUORESCENCE DETECTION

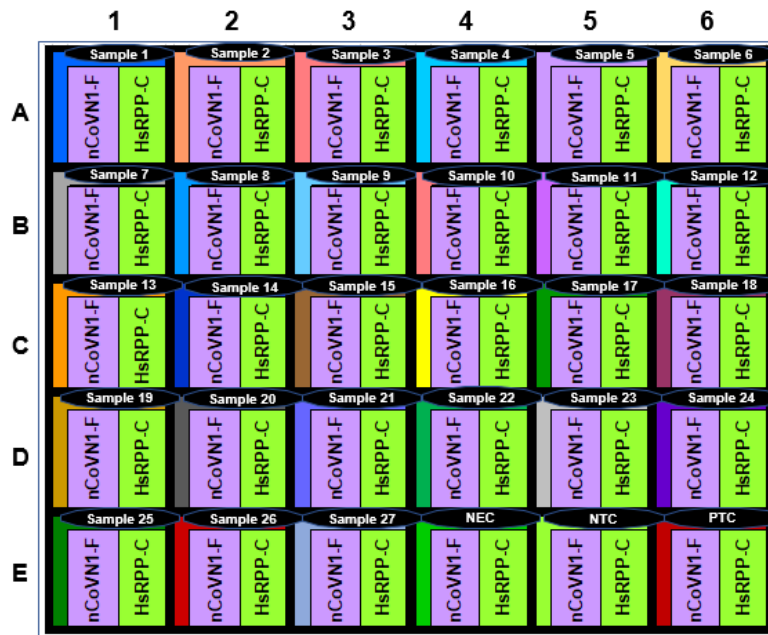
Two detection channels of AriaDNA analyzer report the following panels of targets:

Channel 1 (FAM)	SARS-CoV-2 N-gene: N1
Channel 2 (Cy5)	Human RNase P gene HsRPP30 (Internal Control)





LAYOUT OF MICROCHIP



Target panel:

- nCoV1 (SARS-CoV-2 N1)
- HsRPP30 (Internal Control)

Controls:

- NEC (Negative extraction control)
 - Run with NEC sample
- PTC (Positive template control)
 - Run with SARS-CoV-2 RNA
- NTC (No template control)
 - Run with nuclease free water

Number of samples per chip:

- 27 patient samples

ANALYSIS FLOW CHART

- 1. Pre-loaded microchips:** Require a separate purchase of the following kits to run the test:
 - a. Sample prep reagents:** To process saliva samples, use simplified RNA clean-up procedure by following instruction manual supplied with the microchips.
 - b. Master Mix solution:** The master mixes Quantabio qScript™ XLT One-Step RT-qPCR ToughMix or Promega GoTaq Probe 1-Step RT-qPCR System are recommended. Consumption of the Master Mix per sample will be reduced 10 times compared with the recommended volumes for conventional PCR.
- 2. Test procedure:** Mix the cleaned-up saliva sample with Master Mix reagents and then dispense this mixture into microchip by following instruction manual supplied with the microchips. Then insert the microchip into AriaDNA analyzer and run the analysis with a pre-set protocol on a computer.
- 3. Estimated sample throughput:** 12 microchips per day per instrument (8h work shift), i.e. 324 samples per work shift. A reasonable amount to order per 1 instrument per 1 month is 250 microchips (10 boxes). Larger quantities of microchips can be blanket ordered.

RESULTS

- Obtain real-time RT-PCR results and print report in 30 minutes.
- Detection limit equals 1×10^3 copies in 1 mL of the sample.

For research use only (RUO). Positive results should not be used as the sole basis for treatment or other patient management decisions. Positive results are indicative of active infection with 2019-nCoV provided other clinical observations, patient history and epidemiological information are in line with the results. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The information and specifications in this publication are subject to change without notice. To get more specific information, please contact Lumex Instruments representative: sales@lumexinstruments.com