AriaDNA

Real-time microchip PCR analyzer

MICROCHIP RT-PCR INFLUENZA AND COVID-19 DETECTION SYSTEM-007QU75

COVID-19 caused by the SARS-COV-2 virus, and influenza by influenza viruses are respiratory tract infections that display overlapping symptoms. Moreover, novel strains of influenza A and B viruses are unpredictable and may cause pandemics like 1918, 1957, 1968, 1977, 2009 by an H1N1, H2N2, H3N2, H1N1, and H1N1/09 subtypes, respectively. In the event of coinfections of these viruses, especially during the current COVID-19 pandemic, it is imperative to differentiate and identify the exact causative virus for appropriate therapeutic intervention.
Although current molecular-based tests offer an accurate and reliable solution to distinguish between influenza and SARS-CoV-2 virus from the same sample, a rapid, cost-effective, and less resource-demanding method is still needed to maximize clinical and societal benefits during pandemic bottlenecks.

Lumex Instruments Canada has developed a rapid, accurate, cost-effective, and less resource-demanding Microchip RT-PCR Influenza and COVID-19 detection system from upper respiratory tract samples (swabs).
The test kit employs a pre-loaded microchip kit with the primers & probes lyophilized in the microchip for testing of the Influenza A, B, and SARS-CoV-2, as research use only (RUO) application.

The Inf-A primers-probe target matrix (M1) gene of Influenza A virus, Inf-B primers-probe target nonstructural 2 (NS2) gene of Influenza B virus, while N1 primers-probe target nucleocapsid gene (N) gene of SARS-CoV-2 virus. The HsRPP30 primers-probe are used as an internal control targeting RNase P gene that presents in the human genome. The US Center for Disease Control and Prevention (CDC) has designed RT-PCR assays and published protocols for detection of these viruses.

FEATURES and BENEFITS:

- Current real-time PCR assays and PCR instruments consume large volume of reagents (20 µl reaction). The test can be costly and suffer from potential bottleneck of PCR reagent supply in the event of disease outbreaks.
- Main advantages of the Microchip RT-PCR Influenza and COVID-19 detection system are low reagent consumption (1.2 µl reaction), fast analysis, shipment under ambient conditions, and convenient process of PCR analysis.
- Ease of use with lyophilized PCR reagents in the microchips will significantly improve reliability of analysis in laboratory and fast-responder settings by reducing operator-associated errors.
- The Microchip RT-PCR Influenza and COVID-19 detection system – compact and low-energy requiring – is ready to be deployed as point-of-analysis network.
- Early detection of pathogens will minimize economic loss due to outbreaks. This technology would help maintain public health and improve effectiveness of quarantine measures. Microchip kits can be designed for specific pathogen applications in future outbreaks.

USER-FRIENDLY SOFTWARE

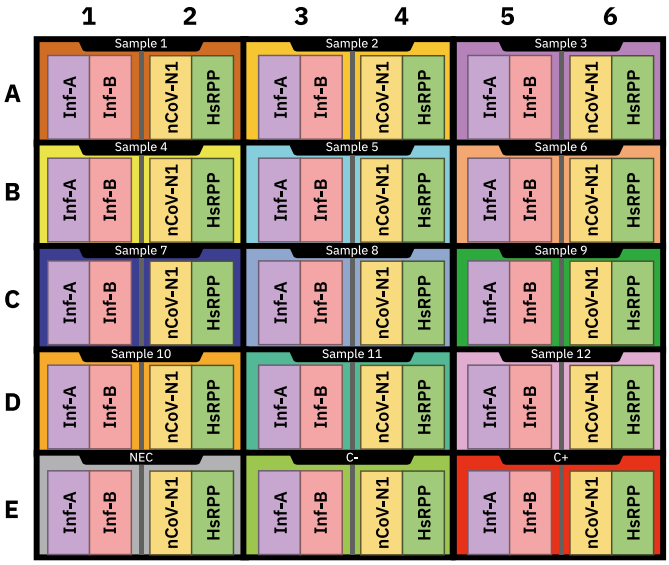
Designed to acquire real-time PCR data and allows simplified operation steps. It offers auto-interpretation of results, allows manual analysis of data, and prints a report in compliance with 21 CFR part 11 requirements.

FLUORESCENCE DETECTION

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

Channel 1 (FAM)	1. Influenza A, and 2. SARS-CoV-2 N-gene N1
Channel 2 (Cy5)	1. Influenza B, and 2. Human RNase P gene HsRPP30 (Internal Control)

LAYOUT OF MICROCHIP



Test panel:
- Inf-A (Influenza A)
- Inf-B (Influenza B)
- nCoVN1 (SARS-CoV-2 N1)
- HsRPP30 (Internal Control)

Controls:
- NEC (Negative extraction control)
- Run with NEC sample
- PTC (Positive template control)
- Run with Influenza A & B RNAs, and SARS-CoV-2 RNA
- NTC (No template control)
- Run with nuclease free water

Number of samples per chip:
- 12 patient samples

ANALYSIS FLOW CHART

1. Pre-loaded microchips: Require a separate purchase of the following kits to run the test:
a. RNA extraction kit: To extract viral RNA from upper respiratory tract samples (swabs), use Norgen Biotek Total RNA Purification Kit, https://norgenbiotek.com/product/total-rna-purification-kit
b. Master Mix solution: The mastermix Quantabio UltraPlex 1-Step ToughMix is recommended. Consumption of the mastermix per sample is reduced 3.3 times compared with the recommended volumes for conventional multiplex PCR.

2. Test procedure: Mix the RNA extracted from the sample with required 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: 7 microchips per day per instrument (8h work shift), i.e. 84 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 a report in 52 minutes. Detection limit equals 1.5×103 copies for Influenza A, 1.5×103 copies for Influenza B, and 1.5×103 copies for SARS-COV-2 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 Influenza A, Influenza B, or 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.