

MiRXES

TO KNOW IS TO ACT



Fortitude SARS-CoV-2 & FluA/B Test

Syndromic
testing
solution

Fortitude SARS-CoV-2 & FluA/B Test



Multi-target detection

Detection of SARS-CoV-2, Influenza A and Influenza B in one reaction.



Fast results

1h 30min turnaround time after RNA extraction.



Reliable performance

High sensitivity and specificity. Zero cross-reactivity with 45 different respiratory tract-associated organisms.



Lab ready

Compatible with current industry-standard RT-PCR instrument & data analysis software without additional installations.



Quality assured

End-to-end process validated.

> 98.2% of aligned sequences homologous to either ORF or N sequence of the MiRXES Fortitude SARS-CoV-2 & FluA/B Test.
Expected to pick up all variants in current database including B.1.1.7 lineage British variant and B.1.351 lineage South African variant.

**Real-time Reverse
Transcription PCR in
vitro diagnostic kit.**

**Qualitative detection
of RNA specific to
SARS-CoV-2, Influenza
A, and Influenza B.**

**Specimens: nasopharyngeal/
oropharyngeal swabs,
nasopharyngeal wash/aspirate,
nasal wash/aspirate and anterior/
mid-turbinate nasal swabs.**

Product features

Fluorophore	Analyte	Limit of Detection
FAM	ORF1ab & N gene	0.25 GE/ μ L
HEX/VIC	Flu A	1 GE/ μ L
Texas Red	Flu B	8 GE/ μ L
Cy5	Human RNase P	-

Pack size

200 reactions per kit

High throughput

96-well plate format

Workflow recommendations

RNA Extraction

↳ QIAamp Viral RNA Mini Kit

Real-time PCR instrument

↳ Applied Biosystems™ 7500 Fast Real-Time PCR System

↳ Bio-Rad CFX96 Real-Time PCR System

Data analysis

↳ C_t / C_q cut-off

Human RNase P as whole

workflow control

↳ (swab to RT-qPCR)

MiRXES Fortitude SARS-CoV-2 & FluA/B Test Clinical Evaluation

Virus	No. of samples	Comparator				% Agreement (95% CI)	
		Concordant Positive (N)	Discordant Positive (N)	Concordant Negative (N)	Discordant Negative (N)	PPA	NPA
SARS-CoV-2	88	50	0	38	0	100% (91.1% - 100%)	100% (88.6% - 100%)
Flu A	115	60	0	55	0	100% (92.5% - 100%)	100% (91.9% - 100%)
Flu B	115	29	0	86	0	100% (85.4% - 100%)	100% (94.7% - 100%)

Evaluated using:

- 50 SARS-CoV-2 positive and 38 SARS-CoV-2 negative nasopharyngeal swabs samples.
- 60 Flu A and 29 Flu B positive, and 26 Flu A and Flu B negative nasopharyngeal and throat swabs samples.
- Compared with an EUA-approved SARS-CoV-2 PCR detection kit.

Regulatory approval

- ✓ CE-IVD Marked
- ✓ Health Sciences Authority (HSA) Provisional Authorization



Co-Developed with:



Experimental Drug Development Centre
Bioinformatics Institute
Diagnostics Development Hub



About MiRXES

Harnessing microRNA discoveries, solving real-world issues, eradicating diseases, and improving lives.

Spun off from Singapore's Agency for Science, Technology and Research (A*STAR) in 2014, MiRXES' microRNA technology platform is reaching across the world and various industries spanning the medical, pharmaceutical, agricultural and veterinary fields to enable the discovery of game-changing biotechnology applications that solve real-world issues and improve lives.

Talk to us

Interested in learning more about our products and services? Our specialists are here to take the time to talk to you. From basic questions to complex inquiries, we're here to help!

Contact

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