

Respiratory diagnostics

# A 4-in-1 viral testing solution

## Test for SARS-CoV-2, influenza A and B viruses, and RSV in one patient sample using one IVD kit

COVID-19, influenza, and respiratory syncytial virus (RSV) can have serious consequences for vulnerable populations, including the elderly and those with pre-existing medical conditions. Testing is critical for early detection and treatment, as well as for preventing the spread of these illnesses. In addition, accurate and timely diagnosis can help health care providers make informed decisions about patient care and resource allocation.

COVID-19, influenza, and RSV infections share several of the same symptoms, making it challenging to differentiate between them based on symptoms alone. Common symptoms include fever, cough, sore throat, fatigue, and body aches. Given the potential severity and contagiousness of these illnesses, accurate laboratory testing is essential to correctly diagnose and distinguish between them.

The Applied Biosystems™ TaqPath™ COVID-19, Flu A, Flu B, RSV Select Panel is a multiplex, real-time PCR *in vitro* diagnostic (IVD) test for detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A virus, influenza B virus, and RSV.



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### IVD

Clinically validated so you can be confident in your results



### Four-in-one

Detect and differentiate 4 respiratory viruses from 1 patient sample



### Under control

RNase P helps ensure sample integrity, quality, and extraction



### Built for Dx

Validated with instrumentation built for diagnosis

## Features and benefits of the TaqPath COVID-19, Flu A, Flu B, RSV Select Panel

### Targets included:

- 3 SARS-CoV-2 targets (*Orf1a*, *Orf1b*, and *N* genes)
- 2 influenza A virus targets (*PB1* and *M* genes)
- 2 influenza B virus targets (*M* and *NS* genes)
- 3 RSV targets (*NP*, *M*, and *L* protein genes)
- RNase P (human sample collection control)



### Fully validated IVD workflow from sample to automated results:



#### Receive samples

- Nasopharyngeal (NP) swabs
- Anterior nasal (AN) swabs

#### Prep samples (extraction)

- Thermo Scientific™ KingFisher™ Apex Dx Purification System
- Applied Biosystems™ MagMAX™ Dx Viral/ Pathogen NA Isolation Kit

#### Run PCR

- Applied Biosystems™ QuantStudio™ 5 Dx Real-Time PCR Instrument, 96-well, 0.2 mL block

#### Get results

- Applied Biosystems™ Diomni™ Enterprise Software V4.1

## Intended use

The TaqPath COVID-19, Flu A, Flu B, RSV Select Panel is a multiplex, real-time reverse transcription polymerase chain reaction (RT-PCR) *in vitro* diagnostic test for the qualitative detection and differentiation of SARS-CoV-2, influenza A virus, influenza B virus, and RSV. Nucleic acids are isolated and purified from nasopharyngeal (NP) swab and anterior nasal (AN) swab specimens obtained from individuals exhibiting symptoms of a respiratory tract infection. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza, and RSV can be similar. This test is intended to aid in the differential diagnosis of SARS-CoV-2, influenza A, influenza B, and RSV A/B (undifferentiated) infections in humans and is not intended to detect influenza C virus infections.

Nucleic acids from the viral organisms identified by this test are generally detectable in NP and AN swab specimens during the acute phase of infection. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and symptoms of respiratory tract infection are indicative of the presence of the identified virus and can aid in diagnosis if used in conjunction with other clinical and epidemiological information, including laboratory findings.

The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out coinfection with other organisms. The organism(s) detected by the TaqPath COVID-19, Flu A, Flu B, RSV Select Panel may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2, influenza A virus, influenza B virus, or RSV infections.

The TaqPath COVID-19, Flu A, Flu B, RSV Select Panel is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures.

## About Diomni software

### Streamlined efficiency from samples to insights

Diomni software connects an unlimited number of supported extraction and qPCR systems and streamlines the entire workflow from sample extraction through analysis, automatically delivering results directly to your LIS.



#### Receive test orders from LIS

Diomni software automatically receives samples with associated test orders for sample traceability



#### Integrate at extraction step

Diomni software connects to the KingFisher Apex Dx system



#### Start run

qPCR instrument performs the test based upon the assay design



#### QC check

Diomni software automatically performs QC check



#### Analyze results

Diomni software performs automatic interpretive analysis of data



#### Send to LIS

Diomni software automatically sends configurable results/reports to the LIS

## Ordering information

Product	Quantity	Volume	Cat. No.
<b>TaqPath COVID-19, Flu A, Flu B, RSV Select Panel, 200 reactions</b>			
TaqPath COVID 19, Flu A, Flu B, RSV Select Assay	2 tubes	150 µL	A56123
TaqPath COVID 19, Flu A, Flu B, RSV Select Positive Control	6 tubes	250 µL	
TaqPath COVID 19, Flu A, Flu B, RSV Select Negative Control	6 tubes	250 µL	
TaqPath 1-Step Select Master Mix (No ROX)	2 tubes	1 mL	
<b>TaqPath COVID-19, Flu A, Flu B, RSV Select Panel, 1,000 reactions</b>			
TaqPath COVID 19, Flu A, Flu B, RSV Select Assay	10 tubes	150 µL	A56124
TaqPath COVID 19, Flu A, Flu B, RSV Select Positive Control	12 tubes	250 µL	
TaqPath COVID 19, Flu A, Flu B, RSV Select Negative Control	12 tubes	250 µL	
TaqPath 1-Step Select Master Mix (No ROX)	10 tubes	1 mL	

## Other workflow components

Workflow step	Product	Cat. No.
<b>Sample extraction</b>	KingFisher Apex Dx Purification System with 96 Deep-Well Head	5400930
	MagMAX Dx Viral/Pathogen NA Isolation Kit	A52735, A52736
<b>Real-time PCR</b>	QuantStudio 5 Dx Real-Time PCR Instrument, 96-well, 0.2 mL block	A47326 (with laptop)
		A47327 (with desktop)
<b>Results</b>	Diomni Software, TaqPath, 1-year license	A40004207
	Diomni Software, TaqPath, 2-year license	A40004208
	Diomni Software, TaqPath, 3-year license	A40004206

Find out more at  
[thermofisher.com/taqpathcovid19fluinflubrsv](https://thermofisher.com/taqpathcovid19fluinflubrsv)

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