

PlexPCR® Flu/RSV/SARS-CoV-2

REF 1703192

FOR PROFESSIONAL USE ONLY

1 Intended Use

The **PlexPCR**® Flu/RSV/SARS-CoV-2 kit is an in vitro diagnostic reverse transcriptase real-time PCR (RT-qPCR) test for the qualitative detection of Flu A, Flu B, RSV A, RSV B and SARS-CoV-2.

The **PlexPCR**® Flu/RSV/SARS-CoV-2 kit is intended to aid in the diagnosis of Flu A, Flu B, RSV A, RSV B and SARS-CoV-2 by a physician and should be used in conjunction with other clinical and laboratory information.

The **PlexPCR**® Flu/RSV/SARS-CoV-2 kit may be used with the following specimen type: nasopharyngeal swabs only.

The **PlexPCR**® Flu/RSV/SARS-CoV-2 kit is intended to be used in professional settings such as hospitals, reference, or state laboratories. It is not intended for self-testing, home use, near patient or point-of-care use.

The intended target population for the **PlexPCR**® Flu/RSV/SARS-CoV-2 kit are symptomatic patients suspected of having respiratory viral infection by their healthcare provider based on clinical presentation and/or history.

2 Kit contents

Number of tests: 192 reactions x 20 µL tests*

Cap colour	Contents	Quantity
Green	Plex Mastermix, 2x	2 x 1.2 mL
Yellow	Flu/RSV/SARS Mix, 20x	1 x 230 µL
Black	RNase Inhibitor, 50x	1 x 135 µL
Neutral	RTase, 100x	1 x 90 µL

*Additional volume supplied for compatibility with liquid handling instrumentation

3 Instructions

Please refer to the **PlexPCR**® Flu/RSV/SARS-CoV-2 Instructions for Use for the detailed protocol (Ref No IF-IV0026). This document can be obtained by contacting tech@speedx.com.au.

4 Shipping and storage

The components of the **PlexPCR**® Flu/RSV/SARS-CoV-2 kit are shipped on dry ice or ice gel packs. All components should be stored at -25°C to -15°C upon receipt. It is recommended that freeze/thaw cycles are limited to 10.

When stored under the recommended conditions and handled correctly, activity of the kits is retained until the expiry date stated on the label. Do not use past the expiry date.