

Now in Focus: All you need to make your lab even better.

Find out how we can help streamline your lab's workflow and improve patient management.

Call 1-562-240-6500 today or visit www.focusdx.com for more information.

Focus Diagnostics
Cypress, California USA
PH +1.562.240.6500
FX +1.562.240.6510



www.focusdx.com

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FDA recommends that influenza assays be periodically evaluated for their performance in light of ongoing antigenic drift that is characteristic of influenza viruses.²

The Focus Diagnostics Simplexa™ Flu A/B & RSV Direct assay is intended for use on the Integrated Cycler instrument for the *in vitro* qualitative detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) RNA in nasopharyngeal swabs from human patients with signs and symptoms of respiratory tract infection in conjunction with clinical and epidemiological risk factors. This test is intended for use as an aid in the differential diagnosis of influenza A, influenza B, and RSV viral infections in humans and is not intended to detect influenza C.

REFERENCES: 1. MOL2650, Simplexa Flu A/B & RSV Direct Kit, Package Insert Rev. F. 2. Guidance for Industry and FDA Staff – Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses. July 15, 2011. <http://www.fda.gov/RegulatoryInformation/Guidances/ucm079171.htm>.

Simplexa™ Flu A/B & RSV Direct Assay

YOUR FLU AND RSV TESTING NEEDS, COVERED.

Direct detection and differentiation of influenza A, influenza B, and RSV.



The Simplexa™ Flu A/B & RSV Direct Assay



Breadth, speed, simplicity, and flexibility. It's all in Focus.

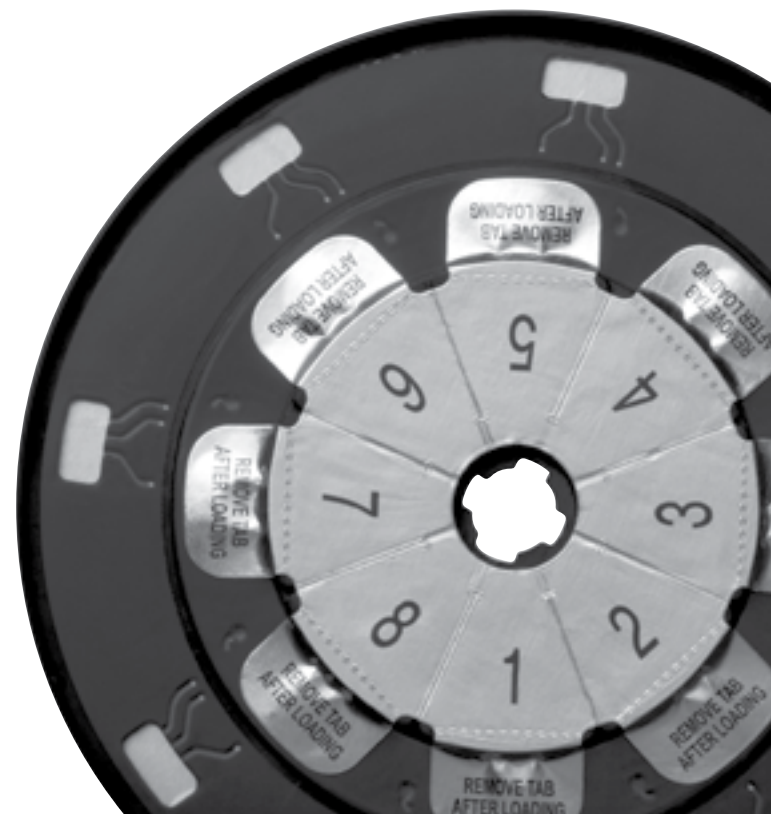
A comprehensive flu and RSV assay, with the speed, flexibility, and simple operation you need to optimize your lab's workflow. FocusDx has your lab covered with the Simplexa Flu A/B & RSV Direct assay.

A wider range of flu and RSV strains.

Our assay now detects and differentiates a total of 92 influenza A, influenza B, and RSV strains. And those include the 4 strains recommended by the World Health Organization for the 2015–16 Northern Hemisphere vaccine:

- A/Switzerland/9715293/2013 (H3N2)-like virus
- A/California/7/2009 (H1N1)-like virus
- B/Phuket/3073/2013-like virus
- B/Brisbane/60/2008-like virus

Included in the 92 strains are 20 avian influenza A and two swine influenza virus strains, which have the potential to cross over into human populations. No other cleared assay is close (that we know of).



Need a fast turnaround? You need our Integrated Cycler.

Our flu and RSV real-time RT-PCR assay is designed to run on our Integrated Cycler, a fast, compact instrument that easily integrates into your lab's operations. It also offers:

- A high sensitivity compared with culture and point-of-care influenza tests.¹
- Easy-to-interpret results in about an hour.
- No separate sample extraction steps necessary—no costly extraction instrumentation required.
- Convenience of running multiple samples at a time.
- All-in-one reaction mix packaged in single-use vials.

Our Integrated Cycler also gives you access to the expanding menu of straightforward, highly performing assays offered by Focus Diagnostics.

Easy steps for a simplified workflow.

With the simple workflow of Simplexa Direct Chemistry, more healthcare facilities are able to perform molecular diagnostics.* Results can be obtained in about an hour by following these intuitive steps:

- Scan the barcodes on the assay definition, the Simplexa Reaction Mix vial, the Direct Amplification Disc, and the patient sample vial.
- Lift the foil from a well on the disc. Pipette the reaction mix into the well marked "R."
- Pipette the unprocessed patient sample into the well marked "SAMPLE." Re-seal the well with foil and tear off the perforated edge
- Place the disc on the platen, close the lid, click "Save," then click "Run."

*This product achieved moderate complexity status for use in CLIA moderate and high complexity healthcare facilities.

