

SIMPLEXA™ INFLUENZA A

(2009)

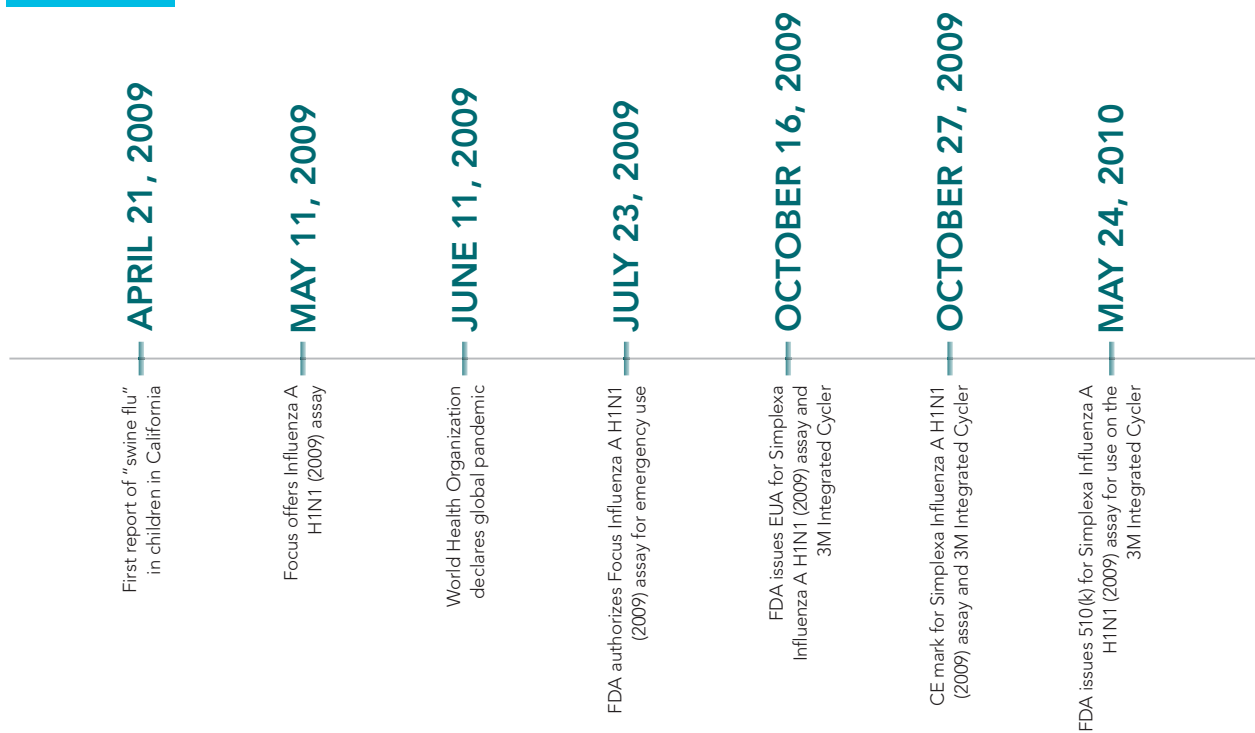
THE 2009 H1N1 SIMPLEXA ASSAY

Target, identify and differentiate H1N1 in your lab.

While the initial threat to world health has been alleviated, H1N1 is different from other flu A viruses and may challenge health care professionals and organizations for years to come. Which is why reliable detection by molecular testing continues to be extremely important—especially for higher-risk patient populations.

With the Simplexa Influenza A H1N1 (2009) assay and the 3M Integrated Cycler, you can use the same chemistry Quest Diagnostics utilizes in its own labs to detect and differentiate H1N1 in your lab, quickly and accurately.

TIMELINE:



Now FDA Cleared: the Simplexa Influenza A H1N1 (2009) assay on the 3M™ Integrated Cyclor.*

1. A real-time RT-PCR assay
2. Targets a region of the hemagglutinin gene of the 2009 H1N1 Influenza virus
3. Differentiates from the presence of other human influenza A viruses
4. Identifies patients infected with the 2009 H1N1 with consideration of symptoms, medical background and other factors

Clinical Agreement of Simplexa Influenza A H1N1 (2009) assay for 2009 H1N1 and Influenza A

	AGREEMENT WITH COMPOSITE REFERENCE METHOD ¹	SWABS ²	ASPIRATES ²
2009 H1N1 CLINICAL AGREEMENT	PERCENT POSITIVE AGREEMENT	100%	100%
	PERCENT NEGATIVE AGREEMENT	95.5%	92.5%
INFLUENZA A CLINICAL AGREEMENT	PERCENT POSITIVE AGREEMENT	100%	100%
	PERCENT NEGATIVE AGREEMENT	92.5%	96.1%

¹ Specimens were determined to be positive for 2009 H1N1 influenza by a composite reference method for the Flu A target including the Luminex xTAG RVP Flu A target, a validated PCR assay using primer and probe sequences published by the CDC and a well characterized PCR followed by sequencing.

² Prospectively collected samples. 299 prospectively collected nasal/nasopharyngeal swabs and 112 nasopharyngeal aspirates were analyzed.



The innovative technology of the 3M Integrated Cyclor frees your lab to run real-time PCR testing

- Fast ramp rates – amplification completed in under an hour
- Small footprint of less than one square foot
- Studio software is both intuitive and easy-to-use
- Single-click access to commonly used features
- Seamless integration into your lab system

*FDA has only cleared the product under 510(k) of the Act. This does not imply that FDA has officially approved the product under 515 of the Act, nor is FDA endorsing the product.

Free your lab with the Simplexa Influenza A H1N1 (2009) assay and the 3M™ Integrated Cyclers.

The Focus Diagnostics Simplexa Influenza A H1N1 (2009) assay is intended for use on the 3M Integrated Cycler for the in vitro qualitative detection and differentiation of influenza A and 2009 H1N1 influenza viral RNA in nasopharyngeal swabs (NPS), nasal swabs (NS), and nasopharyngeal aspirates (NPA) from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors.



SIMPLEXA INFLUENZA A H1N1 (2009)

CATALOG NUMBER	DESCRIPTION	REACTIONS PER KIT
MOL2500	Simplexa Influenza A H1N1 (2009)	100
KIT COMPONENTS	VIALS PER KIT	REACTIONS PER VIAL
Primer Mix (PM)	2	50
RNA Master Mix (RMM)	2	50
RT Mix (RT)	1	100
Armored RNA Internal Control (AR IC)	2	50
No Template Control (NTC)	2	8
H1N1 Positive Control (PC)	2	8

3M INTEGRATED CYCLER

CATALOG NUMBER	DESCRIPTION	QUANTITY
MOL1001	3M Integrated Cycler, 110V, laptop computer, accessories box and optional printer	1 each
MOL1011	3M Integrated Cycler, 220V, laptop computer, accessories box and optional printer	1 each
MOL1400	Universal Disc 96-well	100/case
MOL1401	Universal Disc 96-well	25/box
MOL1500	Universal Disc Sealers	250/box



Focus Diagnostics Cypress, California USA PH +1.714.220.1900 FX +1.714.220.1820

CE mark

www.focusdx.com • www.simplexadx.com • www.integratedcyclers.com

A collaboration of Focus Diagnostics, Inc. and 3M. Simplexa and the associated logo are trademarks of Focus Diagnostics. Focus Diagnostics and the associated logo are registered trademarks of Focus Diagnostics. 3M is a registered trademark of 3M Company. © 2010 Focus Diagnostics, Inc. DXBH11010

1. The purchase of this product grants the purchaser rights under certain Roche patents to use it solely for providing human in vitro diagnostic services. No general patent or other license of any kind other than this specific right of use from purchase is granted hereby. 2. The use of Scorpions® probes for human in vitro diagnostic purposes is covered by a license to Focus Diagnostics, Inc. from DxS, Ltd. 3. CAL Fluor™ and Quasar dyes are trademarks of Biosearch Technologies, Inc. (BTI). CAL Fluor and Quasar dye technology is licensed pursuant to an agreement with BTI, and these products are sold exclusively for clinical, diagnostic, or research and development purposes.