



**Xpert<sup>®</sup>**  
Flu

Immediate Flu results you can trust.



**Xpert<sup>®</sup> Flu**

Detection of Flu A and Flu B with  
2009 H1N1 Call Out

 **Cepheid<sup>®</sup>**  
A better way.

*Laboratory diagnosis of pandemic (H1N1) 2009 virus has important implications for case management, such as infection control procedures, consideration of antiviral treatment options and avoiding the inappropriate use of antibiotics. Reverse transcriptase polymerase chain reaction (RT-PCR) will provide the most timely and sensitive detection of the infection.*



*Clinical Management of Human Infection with Pandemic (H1N1) 2009: Revised Guidance - World Health Organization*

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## The Need

The appearance and worldwide spread of 2009 H1N1 virus highlighted the need for healthcare institutions to reassess their testing programs. Rapid determination of Flu A and Flu B infection and identification of 2009 H1N1 can assist hospitals in better managing patients presenting with Influenza Like Illness (ILI).

**A study published by the CDC in 2009 found that Current available rapid diagnostic tests exhibit limited sensitivity (10–70%) compared to RT-PCR for detection of 2009 H1N1, and are unable to discriminate influenza strain type.**

Source: MMWR Weekly August 7, 2009 / 58(30); 826–829

## The Solution

Rapid and accurate determination of Flu A and Flu B infection and identification of 2009 H1N1 strain type maximizes medical decision making – enabling testing to take place in *real time* during a patient presentation:

- Rapid identification of infection improves isolation and infection control measures and enhances patient flow and bed utilization.
- Accurate detection and differentiation of Flu A from Flu B infection and simultaneous identification of 2009 H1N1 flu strain reduces the need for additional or confirmatory testing.
- Less than two minutes hands-on time improves lab workflow efficiencies.
- Innovative single-use cartridge design enables on-demand STAT testing.
- Accepts Nasal Aspirate/Washes (NA/W) or Nasopharyngeal (NP) Swab to accommodate wide range of specimen types.

# Performance

## Xpert Flu Performance vs. Reference Method with Archived NA/W Specimen—Influenza A

		FDA Cleared Molecular Comparator		
		+	-	TOTALS
Xpert Flu	+	159	0	159
	-	1*	265	266
		160	265	425

POSITIVE AGREEMENT: **99.4%** (95% CI = 96.6–100%)  
 NEGATIVE AGREEMENT: **100%** (95% CI = 98.6–100%)

\*Testing by sequencing: no sequence match for Flu A, H1N1 or Flu B

## Xpert Flu Performance vs. Reference Method with Archived NA/W Specimen—Influenza B

		FDA Cleared Molecular Comparator		
		+	-	TOTALS
Xpert Flu	+	40	0	40
	-	0	385	385
		40	385	425

POSITIVE AGREEMENT: **100%** (95% CI = 91.2–100%)  
 NEGATIVE AGREEMENT: **100%** (95% CI = 99.0–100%)

## Xpert Flu Performance vs. Comparator Method with NP Swab Specimen—2009 H1N1

		FDA Cleared Molecular Comparator & Sequencing		
		+	-	TOTALS
Xpert Flu	+	29	1 <sup>a</sup>	30
	-	0	142	142
		29	143	172 <sup>b</sup>

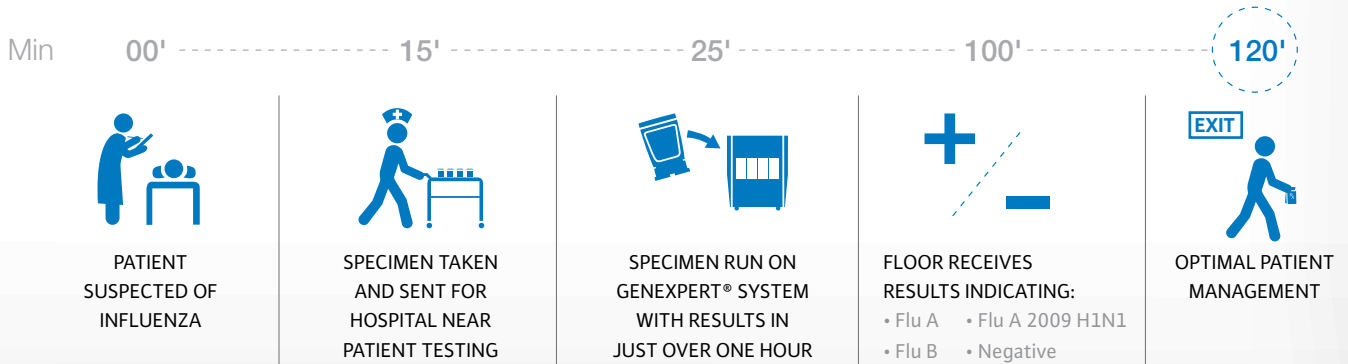
POSITIVE AGREEMENT: **100%** (95% CI = 88.1–100%)  
 NEGATIVE AGREEMENT: **99.3%** (95% CI = 96.2–100%)

<sup>a</sup> No sequencing results available.

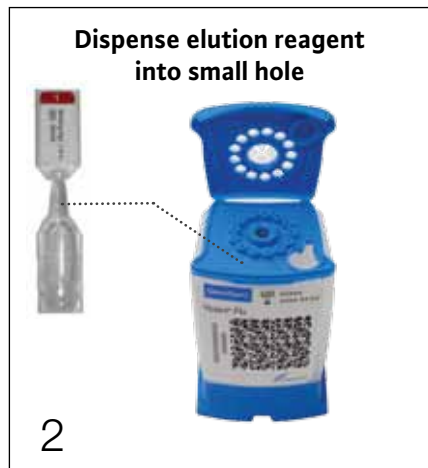
<sup>b</sup> Sequence confirmation not available for one sample.

# Answers your need in 2 hours or less

**Xpert Flu provides useful and timely information to clinicians for improved patient management.**



**WORKFLOW:**  
3 Easy Steps



**TOTAL HANDS-ON TIME <2 MINUTES  
RESULTS IN 75 MINUTES**

**ORDERING INFORMATION**

Xpert® Flu (10 Cartridges with reagents) ..... Catalog No. GXFLU-10



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