

Xpert®  
Flu

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

## Xpert® Flu

Immediate Flu results you can trust.  
*Stop the spread.*

CE IVD In Vitro Diagnostic Medical Device

 **Cepheid®**  
A better way.

*“An easy-to-use, rapid PCR-based 2009 H1N1 test can assist clinicians in making real-time medical decisions that help hospitals significantly improve their patient management.”*



*Preveen Ramamoorthy, Ph.D.*  
*Director of Molecular Diagnostics*  
*National Jewish Health, Denver CO*

## The Need

The appearance and worldwide spread of 2009 H1N1 virus has 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 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) and Nasopharyngeal (NP) Swab to accommodate wide range of specimen types.

# Performance

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

		FDA Cleared Molecular Assay		
		+	-	TOTALS
Xpert Flu	+	125	0	125
	-	1	231	232
		126	231	357

**SENSITIVITY: 99.2%** (95% CI = 95.7–100%)  
**SPECIFICITY: 100%** (95% CI = 98.4–100%)  
**ACCURACY: 99.7%** (95% CI = 98.5–100%)  
**PPV: 100%** (95% CI = 97.1–100%)  
**NPV: 99.6%** (95% CI = 97.6–98.9%)

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

		FDA Cleared Molecular Assay		
		+	-	TOTALS
Xpert Flu	+	40	0	40
	-	0	317	317
		40	317	357

**SENSITIVITY: 100%** (95% CI = 91.2–100%)  
**SPECIFICITY: 100%** (95% CI = 98.8–100%)  
**ACCURACY: 100%** (95% CI = 99.0–100%)  
**PPV: 100%** (95% CI = 91.2–100%)  
**NPV: 100%** (95% CI = 98.8–100%)

## Xpert Flu Assay Performance vs. Reference Method with NP Swabs—2009 H1N1

		Viral Culture + DFA/Sequencing		
		+	-	TOTALS
Xpert Flu	+	85	0	85
	-	0	182	182
		85	182	267

**SENSITIVITY: 100%** (95% CI = 95.6–100%)  
**SPECIFICITY: 100%** (95% CI = 98.0–100%)  
**ACCURACY: 100%** (95% CI = 98.6–100%)  
**PPV: 100%** (95% CI = 95.6–100%)  
**NPV: 100%** (95% CI = 98.0–100%)

**WORKFLOW:**

# 3 Easy Steps

Total hands-on time: <2 Minutes

1

Transfer 300µl of prepared sample into the large hole



2

Dispense elution reagent into small hole



3

Insert Cartridge and start assay



**ORDERING INFORMATION**

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

Cepheid.



The molecular revolution is here.

**CORPORATE HEADQUARTERS**

904 Caribbean Drive  
Sunnyvale, CA 94089 USA

TOLL FREE +1.888.336.2743  
PHONE +1.408.541.4191  
FAX +1.408.541.4192

**EUROPEAN HEADQUARTERS**

Vira Soleih  
81470 Maurens-Scopont, France

PHONE +33.563.82.53.00  
FAX +33.563.82.53.01  
EMAIL cepheid@cepheideurope.fr

[www.Cepheidinternational.com](http://www.Cepheidinternational.com)



THE PURCHASE OF THIS PRODUCT ALLOWS THE PURCHASER TO USE IT FOR THE PERFORMANCE OF DIAGNOSTIC SERVICES FOR HUMAN IN VITRO DIAGNOSTICS. NO GENERAL PATENT OR OTHER LICENSE OF ANY KIND OTHER THAN THIS SPECIFIC RIGHT OF USE FROM PURCHASE IS GRANTED HEREBY. NO OTHER RIGHTS ARE CONVEYED EXPRESSLY, BY IMPLICATION OR ESTOPPEL TO ANY OTHER PATENTS. FURTHERMORE, NO RIGHTS FOR RESALE ARE CONFERRED WITH THE PURCHASE OF THIS PRODUCT.