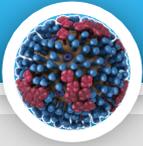


*Introducing:*  
**Xpert<sup>®</sup> Xpress Flu/RSV**



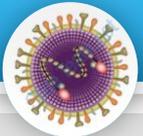
In Vitro Diagnostic Medical Device

# Clinical Background: Flu and RSV



## Influenza (Flu)<sup>1</sup>

- Primarily airborne transmission (i.e., coughing or sneezing)
- Symptoms include fever, chills, headache, muscle aches, malaise, cough, and sinus congestion



## RSV<sup>2</sup>

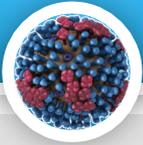
- Common cause of respiratory illnesses for babies
- RSV is very infectious and can live for hours on countertops and toys
- Emerging data on importance in adults
- Can manifest as pneumonia or bronchiolitis



1. <http://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm>

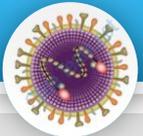
2. <http://www.aboutkidshealth.ca/En/HealthAZ/ConditionsandDiseases/InfectiousDiseases/Pages/Respiratory-Syncytial-Virus-RSV.aspx>

# Incidence and Prevalence of Flu and RSV in EU



## Flu

- 4 to 50 M symptomatic cases each year<sup>1</sup>
- ~ 39 K people die from flu complications each year<sup>2</sup>



## RSV

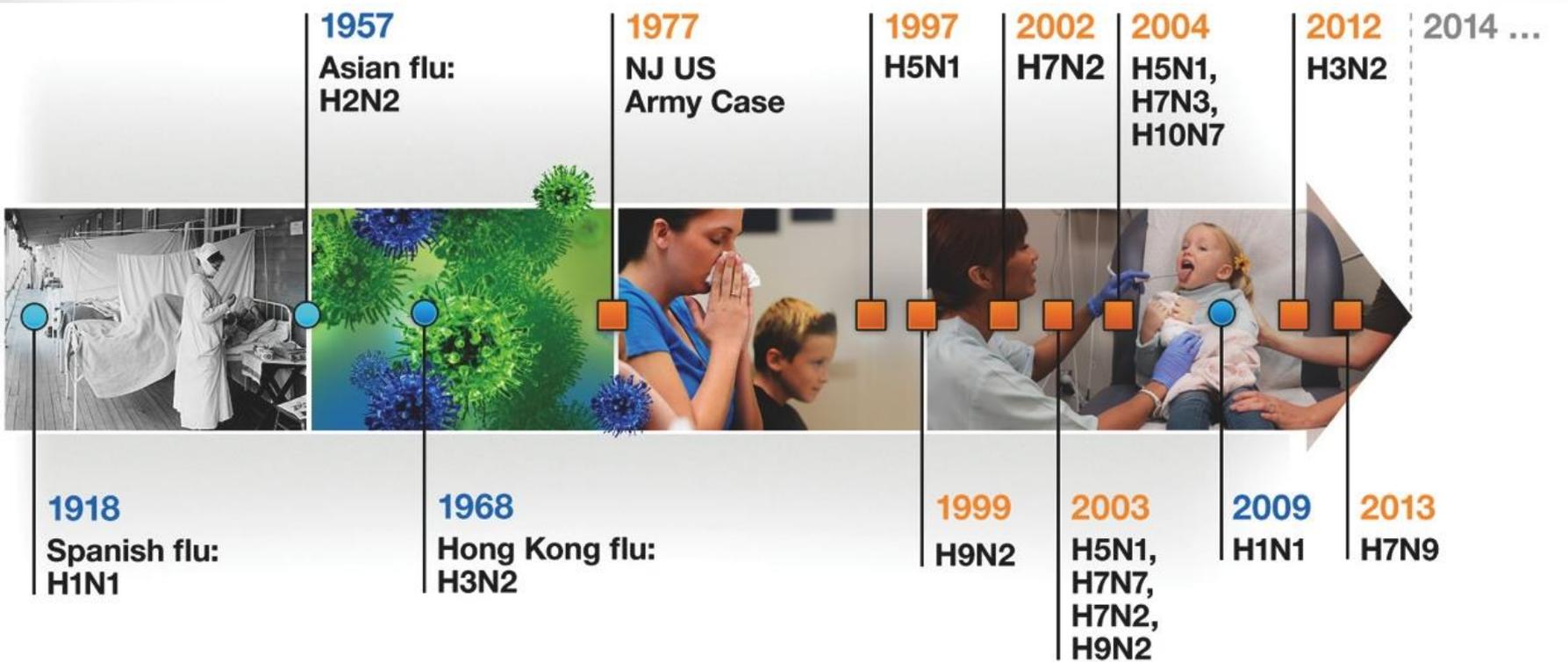
- RSV accounts for 42-45% of hospital admissions for lower respiratory tract infections in children  $\leq 2$  years<sup>3</sup>

1. [http://ecdc.europa.eu/en/healthtopics/seasonal\\_influenza/basic\\_facts/pages/factsheet\\_professionals\\_seasonal\\_influenza.aspx](http://ecdc.europa.eu/en/healthtopics/seasonal_influenza/basic_facts/pages/factsheet_professionals_seasonal_influenza.aspx)

2. <http://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-14-813>

3. <http://www.nivel.nl/sites/default/files/bestanden/Proefschrift-Tamara-Meerhoff.pdf>

# Constant Change: 100 Years of Influenza



 Pandemic  Appearance

# The Need to Test for Flu and RSV

1

Rapid EIA tests not sensitive enough—Negative result confirmation by culture is required<sup>1</sup>

2

Influenza and RSV seasons often overlap—Challenging to differentiate from each other

3

Antiviral treatment—Available for Influenza but not for RSV

4

Empirical Treatment and Resistance to Antivirals/Antibiotics<sup>2</sup>

5

High RSV hospitalization costs—Mean admission cost for infants <1 year was \$3915 and cost of palivizumab prophylaxis was \$162,551 per admission avoided<sup>3</sup>

1. [http://www.idsociety.org/uploadedFiles/IDSA/Guidelines-Patient\\_Care/PDF\\_Library/Influenza.pdf](http://www.idsociety.org/uploadedFiles/IDSA/Guidelines-Patient_Care/PDF_Library/Influenza.pdf)

2. <http://www.cdc.gov/mmwr/pdf/rr/rr6001.pdf>

3. Banerji, et al. Comparison of the cost of hospitalization for respiratory syncytial virus disease versus palivizumab prophylaxis in Canadian Inuit infants. *Pediatr Infect Dis J.* 2009 Aug;28(8):702-6.

# Xpert<sup>®</sup> Xpress Flu/RSV

## Intended Use

The Cepheid Xpert **Xpress** Flu/RSV test, performed on the GeneXpert<sup>®</sup> System, is an automated, multiplex real-time, reverse transcriptase polymerase chain reaction (RT-PCR) test intended for the *in vitro* **qualitative** detection and differentiation of **influenza A, influenza B, and respiratory syncytial virus (RSV)**. The Xpert **Xpress** Flu/RSV test uses **nasopharyngeal (NP) swab specimens** collected from patients with signs and symptoms of respiratory infection. Xpert **Xpress** Flu/RSV is intended as an aid in the diagnosis of influenza and respiratory syncytial virus infections in conjunction with clinical and epidemiological risk factors.

# Xpert<sup>®</sup> Xpress Flu/RSV:

*The Best of Both Worlds—Fast and Accurate*

- Next-generation test design for dramatically faster results
  - On-demand ACTIONABLE results in as early as 20 minutes\*
- Allows for fast diagnosis when it matters most
- Enables healthcare providers to quickly deliver targeted therapies and increase piece of mind for patients
- Suitable for patient triage and high risk patient management during outbreaks

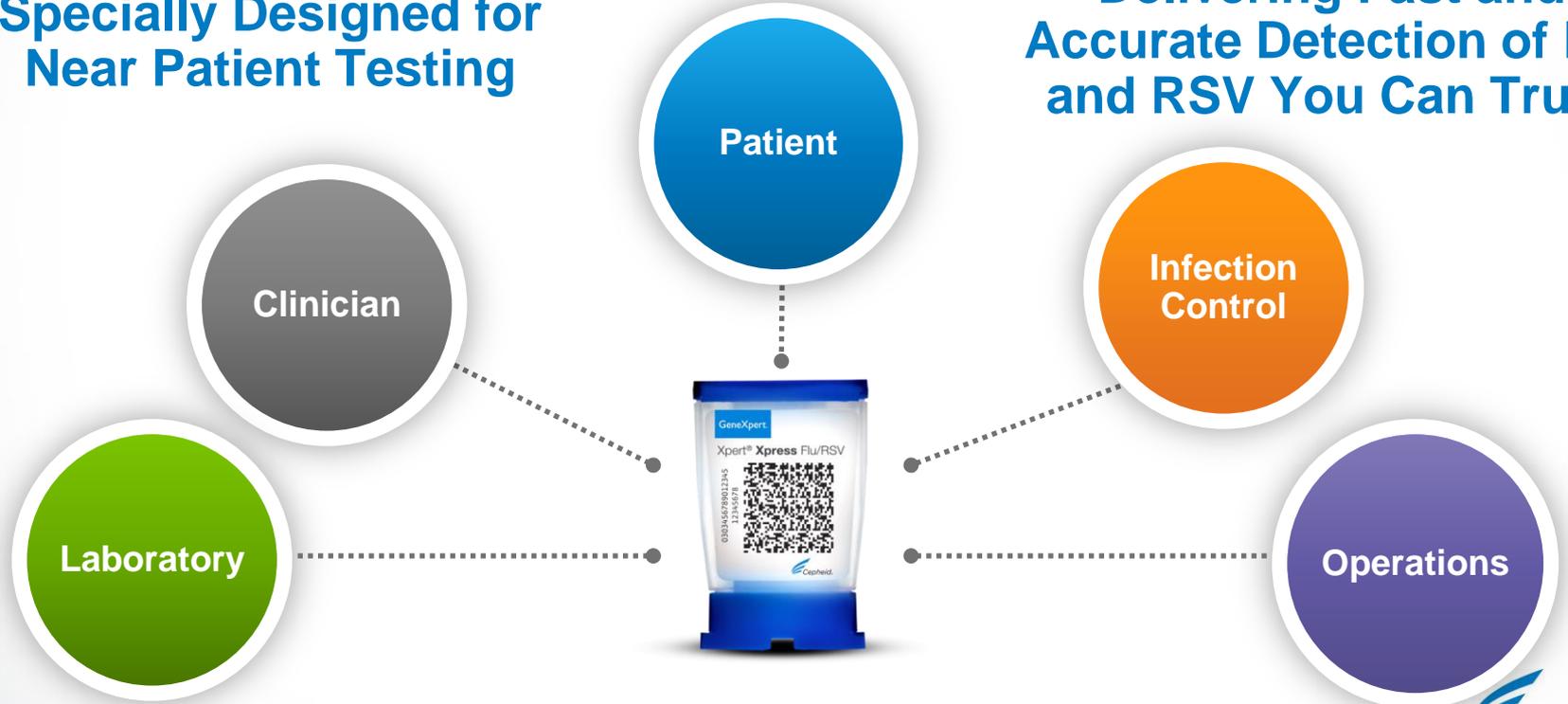


\*With Early Assay Termination (EAT) for positive results when running in Flu only or RSV only mode.

# Xpert® Xpress Flu/RSV Value Statement

**Specially Designed for  
Near Patient Testing**

**Delivering Fast and  
Accurate Detection of Flu  
and RSV You Can Trust**



# Product Specification

Specification	Target
Target	Flu A, Flu B and RSV
Time to Result	20 minutes with EAT*, ~30 minutes without EAT
Hands on Time	< 1 minute with no more than one specimen manipulation step
Sample Type	Nasopharyngeal (NP) Swab, and Nasal swab transported in Universal Transfer Medium (UTM)/Viral Transport Medium (VTM)
Reportable on Software	Qualitative Separate call outs for Flu A, Flu B and RSV
Internal Controls	Included Sample Processing Control (SPC) and Probe Check Control (PCC)
Sensitivity	≥95% (Lower confidence level: ≥85%)
Specificity	≥92% (Lower confidence level: ≥82%)
Regulatory Requirements	CE-IVD, US IVD and other based on local requirements

\* For positive result when running Flu or RSV alone

# Xpert<sup>®</sup> Xpress Flu/RSV

## Clinical Performance—NP Swab Specimens

Specimen Type	Target	n	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
Combined	Flu A	2167	111	42	2012	2	98.2% (95% CI: 93.8–99.5)	98.0% (95% CI: 97.2–98.5 )
	Flu B	2167	89	31	2047	0	100.0% (95% CI: 95.9–100.0 )	98.5% (95% CI: 97.9–98.9 )
	RSV	2167	97	28	2041	1	99.0% (95% CI: 94.4–99.8)	98.6% (95% CI: 98.1–99.1 )

Of the Xpert Xpress Flu/RSV Test runs performed with eligible specimens, 98.3% (2136/2174) of these specimens were successful on the first attempt.

After retesting of indeterminate cases, the overall rate of test success was 99.7% (2167/2174). The overall indeterminate rate was 0.3%.

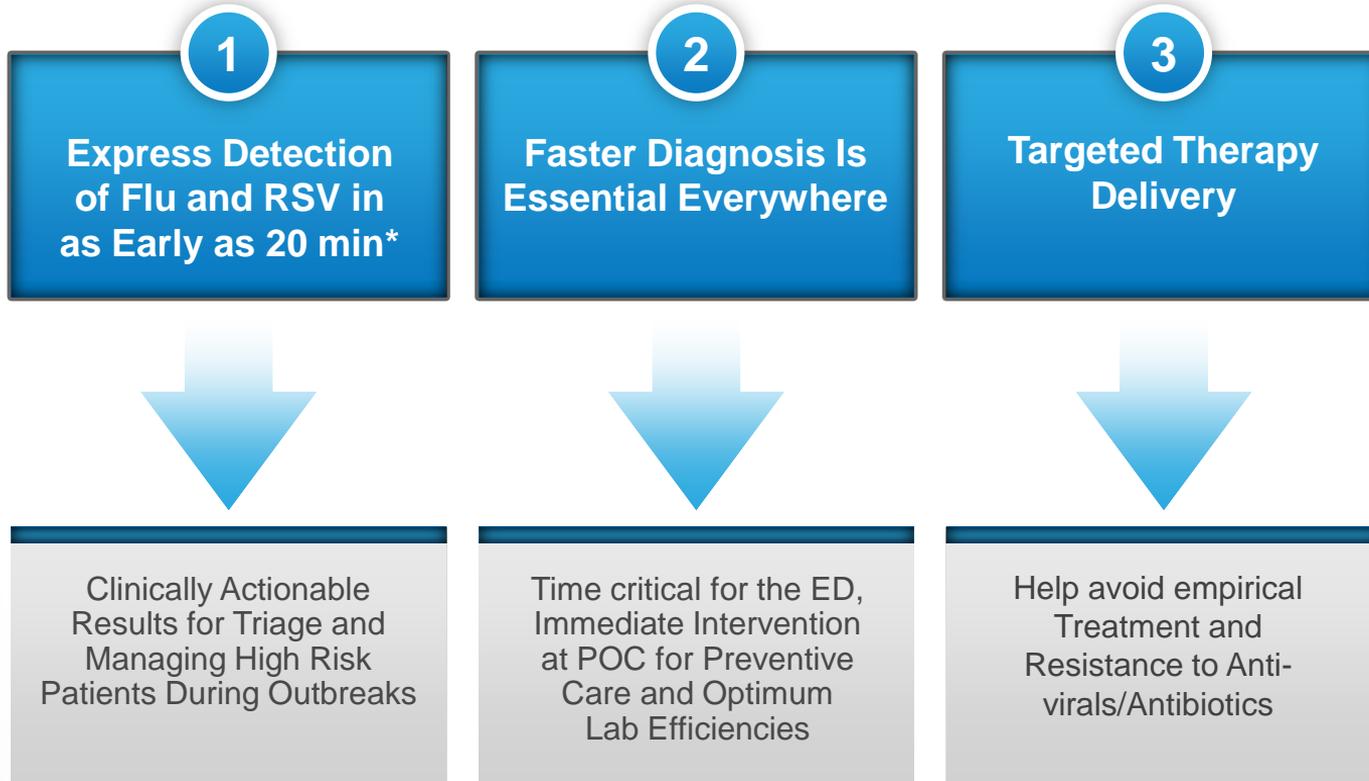
# Xpert® Xpress Flu/RSV

## Kit Components

	Xpert® Xpress Flu/RSV
Catalog Number	XPRSFLU/RSV-CE-10
Tests per Kit	10
Contents per Test Cartridge	Reagent beads (freeze-dried)
	Lysis reagent (1.5mL)
	Binding reagent (1.5mL)
	Elution reagent (3mL)
Regulatory Requirements	Assay Definition File (ADF)—.gxa
	Instructions to import ADF
	Package insert (multi-languages)
Transfer Pipettes	1 bag of 12 (300µl volume)
Storage	2-28° C
Shelf life	12 months



# Conclusions





Thank You.



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