Cepheid
A better way.

Xpert® Xpress Flu/RSV



Fast, accurate and reliable detection of Flu A, Flu B and/or RSV in one test

The Need

Influenza and RSV are leading causes of hospitalizations of both adults and children.[1]

- Influenza and RSV often present with **similar symptoms,** making it difficult to differentiate between the two infections[2]
- Sensitivities of rapid antigen detection tests (RADTs) for influenza range from 50–70%[3]
- The average sensitivity of RADTs for RSV is 29% in adults[4]
- **Manufacturers of RADTs recommend confirming Flu negative results with RT-PCR or culture**[3]
- Rapid RSV tests may have age limitations in their claims[5]

The Solution

- **Accurate and reliable detection of Flu A, Flu B and RSV in as soon as 20 minutes* for patients of all ages**
- Enables healthcare providers to **quickly deliver targeted therapies** and develop management plans related to isolation, vaccination and protecting staff
- Streamlines laboratory operations[6]

The Impact

Single-test confidence can potentially accelerate your laboratory's workflow with on-demand, random-access flexibility. Combine performance with the capability to run other Xpert® tests on Cepheid's GeneXpert® system may support productivity increases in overall laboratory service.

Be Proactive

- **Achieve fast results and improve patient management**
- Early assay termination option: deliver positive results for Flu or RSV only reporting in as soon as approx. 20 minutes* and negative results in approx. 30 minutes
- **Quickly deliver targeted therapies and increase peace of mind for patients**

1 Hanage WP, Schaffner W. Burden of Acute Respiratory Infections Caused by Influenza Virus, Respiratory Syncytial Virus, and SARS-CoV-2 with Consideration of Older Adults: A Narrative Review. Infect Dis Ther. 2025;14(S1):5-37. doi:10.1007/s40121-024-01080-4

2 Falsey AR, Walsh EE. Respiratory Syncytial Virus Infection in Adults. Clin Microbiol Rev. 2000 Jul; 13.

3 CDC. Guidance for Clinicians on the Use of Rapid Influenza Diagnostic Tests. Accessed May 2025. https://www.cdc.gov/flu/hcp/testing-methods/clinician_guidance_ridt.html?CDC_AAref_Val=https://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm

4 Chartrand C, et al. Diagnostic Accuracy of Rapid Antigen Detection Tests for Respiratory Syncytial Virus Infection: Systematic Review and Meta-analysis. J Clin Microbiol. 2015 Dec;53(12):3738-49.

5 https://www.accessdata.fda.gov/cdrh_docs/pdf10/K101918.pdf

6 Hernandez, D. R., Pellitteri, G. P., Kimmich, D. J., Heiter, B. J., Smeal, K., & Wolk, D. M. (2019). Near point-of-care adoption of Cepheid Xpert® Flu/RSV XC testing within an integrated healthcare delivery network. Diagnostic microbiology and infectious disease, 94(1), 28–29.

Xpert® Xpress Flu/RSV

Product Reference Sheet — FDA Cleared Moderate Complexity and CLIA Waived

Test Reagent Kit	Xpert **Xpress** Flu/RSV		
Catalog Number	XPRSFLU/RSV-10		
Technology	Real-time RT-PCR		
Targets	**Flu A** Genes encoding matrix protein, PB2 and PA	**Flu B** Genes encoding matrix protein and non-structural protein	**RSV** Genes encoding nucleocapsid of RSV A and RSV B
Batch or On Demand	On Demand		
Minimum Batch Size	1		
Sample Types	Nasopharyngeal Swab and Nasal Swab		
Sample Extraction	Automated/integrated		
Precision Pipetting	Not required		
TAT	As early as approx. 20 minutes for positives* and about 30 minutes for negatives		
Controls: Process	Sample Processing Control		
Controls: Probe Function/Detection	Probe Check Control		

Clinical Performance	**Moderate Complexity Environment** (GeneXpert® DX, GeneXpert Infinity, GeneXpert System with Touchscreen)			**CLIA Waived Environment** (GeneXpert **Xpress**)		
Nasopharyngeal (NP) Swab	**Flu A**	**Flu B**	**RSV**	**Flu A**	**Flu B**	**RSV**
Positive Percent Agreement	98.1% (93.3%–99.5%)	100% (95.3%–100%)	98.4% (91.7%–99.7%)	97.6% (94.4%–99%)	97.3% (90.6%–99.2%)	98.2% (95.9%–99.2%)
Negative Percent Agreement	98.8% (98.2%–99.2%)	99.1% (98.6%–99.4%)	99.3% (98.9%–99.6%)	98.2% (97.4%–98.8%)	99.6% (99.1%–99.8%)	98.5% (97.7%–99%)
Nasal (NS) Swab	**Flu A**	**Flu B**	**RSV**	**Flu A**	**Flu B**	**RSV**
Positive Percent Agreement	98.9% (96.2%–99.7%)	98.4% (91.7%–99.7%)	98.2% (95.8%–99.2%)	98.9% (96.2%–99.7%)	98.4% (91.7%–99.7%)	98.2% (95.8%–99.2%)
Negative Percent Agreement	97.5% (96.6%–98.2%)	99.3% (98.7%–99.6%)	99.1% (98.4%–99.5%)	97.5% (96.6%–98.2%)	99.3% (98.7%–99.6%)	99.0% (98.4%–99.5%)

Sample Storage	15–30 °C for up to 24 hours or 2–8 °C for up to 7 days in transport medium
Kit Storage	2–28 °C until the expiration date provided on the label
Commercial Controls	Refer to Package Insert or Contact Cepheid Technical Support

SPECIMEN KITS REQUIRED FOR PRIMARY SAMPLE COLLECTION AND TREATMENT		**CATALOG INFORMATION**
Nasopharyngeal Swab & UTM Collection Kits	50 test kits	305C
Nasal Collection Kits	50 test kits	346C

* With early assay termination (EAT) for positive Flu or for positive RSV only. Reporting negatives and combined Flu and RSV results in approximately 30 minutes.

US-IVD. *In Vitro* Diagnostic Medical Device.

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