Cepheid®
A better way.

PCR in Primary Care

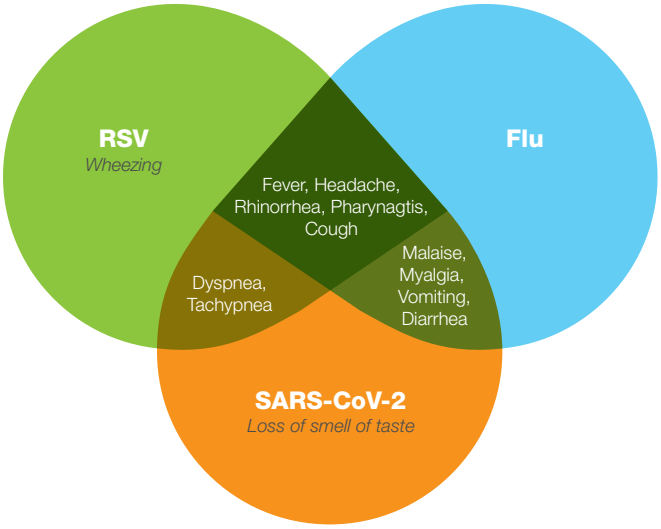
Test with Confidence

A wife and mother of two returns home from work with a sore throat and fever. She visits her primary care physician. Is it COVID-19 or flu?

How confident are you with your testing methodology, corresponding results, and ability to treat and send patients home to their families?

The Impact of COVID-19 on Respiratory Testing

- Like the flu, SARS-CoV-2 *(the virus that causes COVID-19)* may have peak seasonality in the fall/winter/spring
- Clinical signs and symptoms of respiratory viral infection for SARS-CoV-2, flu, and RSV can be similar



Highly Sensitive Tests will be Important

Co-testing for SARS-CoV-2, flu, and RSV will be critical to detect and differentiate between disease states, enabling accurate patient diagnosis and treatment

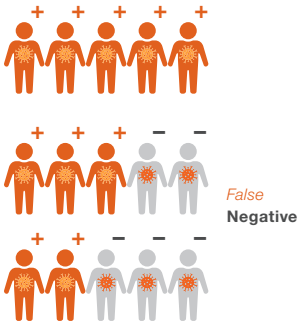
How Test Methods Work Functionally

1	**PCR** *Polymerase Chain Reaction*	Amplifies nucleic acid exponentially using a temperature-cycling method. Capable of detecting genetic targets with high sensitivity and specificity.[1]
2	**Isothermal Amplification**	Amplifies nucleic acids exponentially at a constant temperature. Has limitations on multiplexing and some methods have poor reported sensitivity.[1,2]
3	**Antigen Testing**	Detects specific viral proteins, called antigens. The sample is added to a surface coated with antibodies that bind to the viral proteins, which is used to create a signal that detects the virus. False positives can occur.[3]

How the Sensitivity of SARS-CoV-2 Test Methods Compare

RT-PCR

Antigen Testing



- **High sensitivity for detection** of the SARS-CoV-2 virus[1]
- Detects low viral loads, especially in the absence of symptoms[5]

- **Much lower sensitivity** than RT-PCR. False negatives are common when viral loads are moderate or low. In one study, **64% sensitivity** in symptomatic cases, meaning 36% (~2 in 5) positive cases receive a false negative[5]

  36% sensitivity in asymptomatic cases, meaning 64% (~3 in 5) of positive cases receive a false negative[5]

Why RT-PCR is the Gold Standard

- Higher sensitivity and specificity than other test methods; **yields accurate results** for actionable clinical diagnosis
- Provides an **early detection** window for SARS-CoV-2 infections.[4]
- Drives **same-day patient diagnosis and appropriate treatment**, thereby improving patient satisfaction, loyalty, and clinical outcomes[6,7,8]
- Does not require negative confirmatory tests[9]

Build Your Primary Care with a Single Solution: Cepheid's GeneXpert® Xpress & CLIA Waived Test Menu

Test with the Confidence of PCR

- **Easy-to-use CLIA waived molecular tests** for your practice
- **Accurate, on-demand, actionable results** in as soon as 18 minutes for Xpert **Xpress** Strep A^
- No negative confirmatory tests necessary
- 1 sample, 1 swab, 1 cartridge for 4 test results: COVID-19, Flu A, Flu B, and RSV

Xpert® **Xpress** Strep A

Xpert® **Xpress** SARS-CoV-2*

Xpert® **Xpress** CoV-2/Flu/RSV ***plus***

Simplify Your Workflow with Less than One Minute Hands-on Time

- Single, compact, scalable instrument
- Intuitive software and easy-to-use technology reduces training for all staff levels
- Self-contained cartridge reduces waste and risk of contamination
- **Integrated quality control** in every cartridge
- Ability to standardize inventory management
- Run up to **48 tests per day**#

Xpert® Xpress Respiratory Test Menu Overview

CPT Code: 87635

Xpert Xpress SARS-CoV-2*

*Positive results in as soon as 30 minutes^*

Sample Type: Nasopharyngeal or Nasal Swabs

Positive Percent Agreement	Negative Percent Agreement
97.8%	95.6%

PLA Code: 02420U or 0241U

Xpert Xpress CoV-2/Flu/RSV *plus**

*Positive results in as soon as 25 minutes^*

Sample Type: Nasopharyngeal or Anterior Nasal Swab

	Positive Percent Agreement	Negative Percent Agreement
SARS-CoV-2	100%	100%
Flu A	100%	100%
Flu B	100%	100%
RSV	100%	100%

CPT Code: 87651

Xpert Xpress Strep A

*Positive results in as soon as 18 minutes^*

Sample Type: Throat Swab

Sensitivity	99.4%
Specificity	94.1%
Positive Predictive Value	85.3%
Negative Predictive Value	99.8%

XPERT XPRESS MENU		CATALOG NUMBER
Xpert **Xpress** Strep A	10 tests	XPRSTREPA-10
	120 tests	XPRSTREPA-120
Collection and Transport Device Kit	50 ESwab™ Liquid Amies Collection & Transport Devices	480CFA
Xpert **Xpress** SARS-CoV-2	10 tests	XPRSARS-COV2-10
Xpert **Xpress** CoV-2/Flu/RSV ***plus***	10 tests	XP3COV2/FLU/RSV-10
Cepheid Nasopharyngeal Collection Kits	100 kit	SWAB/M-100
	100 kit	SWAB/B-100
Cepheid Nasal Collection Kits	100 kit	SWAB/F-100

SYSTEMS	DESCRIPTION	INSTRUMENT DIMENSIONS	CATALOG NUMBER
GeneXpert® **Xpress** IV-2	2-module system	11.5" W x 18" H x 16" D	GXIV-2-CLIA
GeneXpert **Xpress** IV-4	4-module system	11.5" W x 18" H x 16" D	GXIV-4-CLIA

US-IVD. For *In Vitro* Diagnostic Use.

Consult individual Cepheid tests' package inserts for complete product information.

* For use under an Emergency Use Authorization in the United States.

^ For Xpert **Xpress** Strep A, early assay termination (EAT) for positive results, otherwise the full run time is 24 mins. For Xpert **Xpress** SARS-CoV-2, early assay termination (EAT) for positive results, otherwise the full run time is 45 mins. For Xpert **Xpress** SARS-CoV-2/Flu/RSV early assay termination (EAT) for positive results when running SARS-CoV-2 only, otherwise the full run time is 36 mins.

\# Assuming 40 minute test results and using 4 modules

1 Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. Dinnes J, Deeks JJ, Adriano A, Berhane S, Davenport C, Dittrich S, Emperador D, Takwoingi Y, Cunningham J, Beese S, Dretzke J, Ferrante di Ruffano L, Harris IM, Price MJ, Taylor-Phillips S, Hooft L, Leeflang MM, Spijker R, Van den Bruel A; Cochrane COVID-19 Diagnostic Test Accuracy Group.Cochrane Database Syst Rev. 2020 Aug 26;8(8):CD013705. doi: 10.1002/14651858.CD013705. PMID: 32845525

2 Some methods have poor reported sensitivity compared to RT-PCR (Zhen et al.) Zhen W, Smith E, Manji R, Schron D, Berry GJ. Clinical Evaluation of Three Sample-to-Answer Platforms for Detection of SARS-CoV-2. J Clin Microbiol. 2020;58(8):e00783-00720. doi: 00710.01128/JCM.00783-00720. Print 02020 Jul 00723.

3 False-positive results in SARS-CoV-2 antigen test with rhinovirus-A infection. Otake S, et al. Pediatr Int. 2021. PMID: 3396363

4 Virological assessment of hospitalized patients with COVID-2019.Wölfel R, Corman VM, Guggemos W, Seilmaier M, Zange S, Müller MA, Niemeyer D, Jones TC, Vollmar P, Rothe C, Hoelscher M, Bleicker T, Brünink S, Schneider J, Ehmann R, Zwirglmaier K, Drosten C, Wendtner C.Nature. 2020 May;581(7809):465-469. doi: 10.1038/s41586-020-2196-x. Epub 2020 Apr 1.PMID: 32235945

5 CDC. Evaluation of Abbott BinaxNOW Rapid Antigen Test for SARS-CoV-2 Infection at Two Community-Based Testing Sites — Pima County, Arizona, November 3–17, 2020. Accessed July 2021. https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e3.htm Per BINAXNOW COVID-19 AG CARD (PN 195-000) Instructions for Use, PPA (sensitivity) is 84.6% in symptomatic patients.

6 Prakash, Bhanu. "Patient satisfaction." Journal of cutaneous and aesthetic surgery vol. 3,3 (2010): 151-5.

7 Buhlman, Nell and Matthes, Nikolas. "The Time to Prepare for Value-based Purchasing is Now: Calculating Risk and Strategizing for Improvement as a New Payment Methodology Hits Home." Press Ganey. 2011.

8 Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. BMJ Open 2013;3:e001570.

9 Follow-up testing by culture is required if the Xpert **Xpress** Strep A test result is negative and clinical symptoms persist, or there is an outbreak of acute rheumatic fever (ARF).

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