



Xpert® Xpress SARS-CoV-2/Flu/RSV*

Actionable Rapid Respiratory Results to Meet the Challenges of the Ongoing Pandemic



The Need

- Detection and differentiation of SARS-CoV-2, flu, and RSV which all present with similar symptoms
- Insights for effective triage and patient management
- Risk assessment for patients and staff while resuming traditional healthcare procedures
- Identify potential cases of co-infections during respiratory season
- Current flu and SARS-CoV-2 therapies need definitive diagnosis for each pathogen



The Solution

- Actionable detection of SARS-CoV-2, Flu A, Flu B, and RSV in as little as 25 minutes[^]
- Actionable on-demand results with 1 sample collection
- Optimizes GeneXpert® System module capacity by combining 2 Xpress test cartridges into 1
- Standardization of results between the central lab and near patient testing sites



The Impact

- Empower patients with rapid results to help keep their loved ones and the community safe
- Assist hospitals to effectively manage limited resources
- Provide labs with single-test confidence to accelerate workflows
- Support clinicians with on-demand, timely, and accurate results

* This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; this test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens; and this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



Simple Implementation into Existing Workflows

As Simple as 1, 2, 3 – Minimal Hands-on Time

1

Obtain specimen stored in appropriate transport medium



2

Transfer sample to cartridge



3

Scan and insert cartridge



Xpert® Xpress SARS-CoV-2/Flu/RSV is a qualitative real-time PCR test that provides accurate detection and differentiation of SARS-CoV-2, Flu A, Flu B, and RSV in as little as 25 minutes.[^]

CATALOG INFORMATION

Xpert® Xpress SARS-CoV-2/Flu/RSV	10 tests	XPCOV2/FLU/RSV-10
----------------------------------	----------	-------------------

COLLECTION KITS#

CATALOG INFORMATION

Cepheid Nasopharyngeal Collection Kits	100 kits	SWAB/M-100
	100 kits	SWAB/B-100
Cepheid Nasal Collection Kits	100 kits	SWAB/F-100

Nasal or Nasopharyngeal swabs in 3mL of UTM are supported for use with this test.

EXTERNAL CONTROLS#

AVAILABLE FROM ZEPTOMETRIX

ZeptoMetrix NATtrol Flu/RSV/SARS-CoV-2 Positive Control Kit	6 vials	NATFRC-6C
ZeptoMetrix NATtrol Flu/RSV/SARS-CoV-2 Negative Control Kit	6 vials	NATCV9-6C

* This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; this test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens; and this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

[^] For positives when running SARS-CoV-2 only on Xpress SARS-CoV-2/Flu/RSV; otherwise, the test will have a runtime of approximately 36 minutes.

Recommended but not required materials, please see package insert 302-4421 (for GeneXpert Dx and GeneXpert Infinity Systems) or 302-4419 (for GeneXpert Xpress Systems) for complete details.

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.Cepheid.com