Datasheet
EUA

Xpert® Xpress SARS-CoV-2/Flu/RSV

Test Reagent Kit	Xpert **Xpress** SARS-CoV-2/Flu/RSV
Catalog Number	XPCOV2/FLU/RSV-10
Technology	Real-time RT-PCR
Targets	**SARS-CoV-2** N2 – nucleocapsid gene E – envelope protein gene **Flu A** Genes encoding matrix protein, PB2, and PA **Flu B** Genes encoding matrix protein and non-structural protein **RSV** Gene encoding nucleocapsid of RSV A and RSV B
Batch or On-Demand	On-Demand
Minimum Batch Size	1
Sample Types	**Specimen Collection:** Nasopharyngeal or nasal swabs and nasal wash/aspirates* **Transport Media^:** UTM/VTM or saline
Sample Extraction	Automated/integrated
Precision Pipetting	Not required
TAT	Approximately 36 minutes When running SARS-CoV-2 alone, results in as soon as 25 minutes#
Hands-on Time	< 1 minute
Controls: Process	Sample Processing Control
Controls: Probe Function/Detection	Probe Check Control

	Positive Percent Agreement	**Negative Percent Agreement**
SARS-CoV-2	97.9% (95% CI: 88.9% – 99.6%)	100% (95% CI: 98.1% – 100%)
Flu A	100% (95% CI: 92.6% – 100%)	100% (95% CI: 98.0% – 100%)
Flu B	100% (95% CI: 92.3% – 100%)	99% (95% CI: 96.3% – 99.7%)
RSV	100% (95% CI: 92.4% – 100%)	100% (95% CI: 98.1% – 100%)

Sample Storage	15-30 °C for up to 24 hours or 2-8 °C for up to 7 days until testing is performed
Kit Storage	2-28 °C
Commercial Controls	Refer to Xpert **Xpress** SARS-CoV-2/Flu/RSV Package Insert or contact Cepheid Technical Support

* See package insert for details, sample types vary by system. Nasal wash/aspirate samples not available for use with GeneXpert Xpress Systems (Tablet and Hub Configurations).

^ Specimen transport media that contain guanidine thiocyanate (GTC) may interfere with the test causing false negative results

\# With Early Assay Termination (EAT) for positive results.

Refer to most current package insert 302-4421 (for GeneXpert and GeneXpert Infinity Systems) or 302-4419 (for GeneXpert Xpress Systems) for complete details.

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.

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