

# Xpert® Xpress SARS-CoV-2

<b>Test Reagent Kit</b>	Xpert Xpress SARS-CoV-2	
<b>Catalog Number</b>	XPRSARS-COV2-10	
<b>Technology</b>	Real-time RT-PCR	
<b>Targets</b>	N2 – nucleocapsid gene E – envelope protein gene	
<b>Batch or On-Demand</b>	On-Demand	
<b>Minimum Batch Size</b>	1	
<b>Sample Types</b>	<p><b>Specimen Collection:</b> Nasopharyngeal, nasal, mid-turbinate, or oropharyngeal swabs and nasal wash/aspirates*</p> <p><b>Transport Media:</b> UTM/VTM or Saline</p>	
<b>Sample Extraction</b>	Automated/integrated	
<b>Precision Pipetting</b>	Not required	
<b>TAT</b>	As soon as 30 minutes for positives <sup>^</sup> and approximately 45 minutes for negatives	
<b>Hands-on Time</b>	< 1 minute	
<b>Controls: Process</b>	Sample Processing Control	
<b>Controls: Probe Function/Detection</b>	Probe Check Control	
	<b>Positive Percent Agreement</b>	<b>Negative Percent Agreement</b>
<b>Clinical Evaluation</b>	97.8% (95% CI: 88.4%–99.6%)	95.6% (95% CI: 85.2%–98.8%)
	<i>Testing performed with 45 positives and 45 negatives</i>	
<b>Sample Storage</b>	15-30 °C for up to 8 hours or 2-8 °C for up to 7 days until testing is performed	
<b>Kit Storage</b>	2-28 °C	
<b>Commercial Controls</b>	Refer to Xpert SARS-CoV-2 Package Insert or contact Cepheid Technical Support	

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

<sup>^</sup> With Early Assay Termination (EAT) for positive results.

Refer to most current package insert 302-3562 (for GeneXpert Dx and GeneXpert Infinity Systems) or 302-3750 (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 detection of nucleic acid from SARS-CoV-2, and not for any other viruses or pathogens. 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.

**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 0780-02

www.Cepheid.com