Datasheet
EUA

Xpert® Xpress SARS-CoV-2

Test Reagent Kit	Xpert **Xpress** SARS-CoV-2
Catalog Number	XPRSARS-COV2-10
Technology	Real-time RT-PCR
Targets	N2 – nucleocapsid gene E – envelope protein gene
Batch or On-Demand	On-Demand
Minimum Batch Size	1
Sample Types	**Specimen Collection:** Nasopharyngeal, nasal, mid-turbinate, or oropharyngeal swabs and nasal wash/aspirates* **Transport Media:** UTM/VTM or Saline
Sample Extraction	Automated/integrated
Precision Pipetting	Not required
TAT	As soon as 30 minutes for positives^ and approximately 45 minutes for negatives
Hands-on Time	< 1 minute
Controls: Process	Sample Processing Control
Controls: Probe Function/Detection	Probe Check Control

	Positive Percent Agreement	**Negative Percent Agreement**
Clinical Evaluation	97.8% (95% CI: 88.4%–99.6%)	95.6% (95% CI: 85.2%–98.8%)
	Testing performed with 45 positives and 45 negatives	

Sample Storage	15-30 °C for up to 8 hours or 2-8 °C for up to 7 days until testing is performed
Kit Storage	2-28 °C
Commercial Controls	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).

^ 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.

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