Cepheid
A better way.

Xpert® Xpress SARS-CoV-2

Rapid, accurate detection of SARS-CoV-2

The Need

- SARS-CoV-2 infections are associated with increased **morbidity, mortality, cost** and pose an ever-present **threat to public health** globally.[1,2]
- Prior emergence of SARS-CoV-2 **variants caused new surges in cases and death**.[2]
- Testing required to identify the breakthrough infections and inform patient care, especially for the **high-risk population**.[3]

The Solution

The Xpert **Xpress** SARS-CoV-2 test is a real-time PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swab, nasal swab, or specimen collected from individuals who are suspected of COVID-19 infection.

The Xpert **Xpress** SARS-CoV-2 test provides:

- Fast, accurate results in as early as 30 minutes.*
- Two gene targets for the detection of SARS-CoV-2.
- Rapid sample-to-answer testing with actionable results from a single sample.

The Impact

- Support clinicians with on-demand, timely, and accurate results.
- Significant reduction in time-to-results reduces isolation time and total costs while optimizing capacity.[4]
- Enable patients to receive timely and appropriate treatment.

1 WHO Coronavirus (COVID-19) Dashboard –Last accessed 22nd Sep 2023

2 https://news.un.org/en/story/2023/05/1136367

3 Peeling RW, Heymann DL, Teo YY, Garcia PJ. Diagnostics for COVID-19: moving from pandemic response to control. Lancet. 2022 Feb 19;399(10326):757-768. doi: 10.1016/S0140-6736(21)02346-1. Epub 2021 Dec 20. PMID: 34942102; PMCID: PMC8687671

4 Fistera D, Kikull K, Risse J, Herrmann A, Brachmann M, Kill C. Point-of-care PCR testing of SARS-CoV-2 in the emergency department: Influence on workflow and efficiency. PLoS One. 2023 Aug 3;18(8) https://pubmed.ncbi.nlm.nih.gov/37535577

* With early assay termination for positives, otherwise, the full test runtime is 45 minutes.

Xpert® Xpress SARS-CoV-2

Product Reference Sheet — CE-IVD

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 swab, nasal swab **Transport Media:** UTM/VTM or Saline
Sample Extraction	Automated/integrated
Precision Pipetting	Not required
Turnaround Time	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 **Xpress** SARS-CoV-2 Package Insert or contact Cepheid Technical Support

* With Early Assay Termination (EAT) for positive results.
Refer to current package insert for complete details.

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries.

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