Cepheid
A better way.

Xpert® Xpress CoV-2 *plus*

Designed with three gene targets for a rapid, robust 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]
- SARS-CoV-2 **variants continue to emerge,** resulting in the risk of **new surge in cases and death.**[2]
- Accurate testing is required to identify the breakthrough infections and inform patient care, especially for the **high-risk population.**[3]

The Solution

The **Xpert Xpress CoV-2 *plus*** test is a fast, real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and anterior nasal swab specimens collected from individuals with signs and symptoms of respiratory tract infection by their healthcare provider. The **Xpert Xpress CoV-2 *plus*** test provides actionable results in as early as **19 minutes**.* **The test was designed with three gene targets** for the detection of SARS-CoV-2, providing target redundancy that mitigates impact of **genetic mutations.**

The Impact

- Support clinicians with **broad coverage** for SARS-CoV-2 variants with a **three-gene target design,** minimizing the possibility of false negatives.
- **Significant reduction in time-to-results reduces isolation time and total costs while optimizing capacity.**[4]
- **Rapid decision-making for cost-effective patient management** and isolation practices.[5]

1 Silva S, Goosby E, Reid MJA. Assessing the impact of one million COVID-19 deaths in America: economic and life expectancy losses. Sci Rep. 2023 Feb 22;13(1):3065

2 https://news.un.org/en/story/2023/05/1136367. Accessed Jan 2024.

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 Shah MM, Joyce B, Plumb ID, et al. Paxlovid Associated with Decreased Hospitalization Rate Among Adults with COVID-19 — United States, April–September 2022. MMWR Morb Mortal Wkly Rep 2022;71:1531–1537.

5 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 30 minutes.

Xpert® Xpress CoV-2 *plus*

Product Reference Sheet — FDA Cleared Moderate Complexity and CLIA Waived

Test Reagent Kit	Xpert **Xpress** CoV-2 ***plus***
Catalog Number	XPRS-COV2-10
Technology	Real-time RT-PCR
Targets	**RdRP:** RNA-dependent RNA polymerase gene **N2:** nucleocapsid gene **E:** envelope protein gene
Batch or On-Demand	On-Demand
Minimum Batch Size	1
Sample Types	**Specimen Collection:** Nasopharyngeal, Anterior nasal swabs **Transport Media**[1]**:** 3 mL of Universal/Viral Transport Media (UTM/VTM) and 2 mL eNAT
Sample Extraction	Automated/integrated
Precision Pipetting	Not required
TAT	Approximately 30 minutes. 19 minutes with early assay termination for positive results.
Hands-on Time	< 1 minute
Controls: Process	Sample Processing Control
Controls: Probe Function/Detection	Probe Check Control

Clinical Performance

	PPA	NPA
Moderate Complexity Environment (GeneXpert Dx or Infinity)		
Overall	98.1% (96.7%–98.9%)	98.3% (97.7%–98.7%)
Nasopharyngeal	97.0% (94.4%–98.4%)	98.2% (97.4%–98.8%)
Anterior Nasal	99.3% (97.5%–99.8%)	98.3% (97.5%–98.8%)
CLIA Waived Environment (GeneXpert **Xpress**)		
Overall	98.6% (96.0%–99.5%)	99.1% (98.5%–99.5%)
Nasopharyngeal	98.2% (93.8%–99.5%)	99.1% (98.1%–99.6%)
Anterior Nasal	99.0% (94.8%–99.8%)	99.1% (98.2%–99.6%)

Sample Storage	15–30 °C for up to 48 hours until testing is performed in VTM/UTM or eNAT 2–8 °C for up to 7 days until testing is performed in VTM/UTM or eNAT Nasopharyngeal and anterior nasal swab specimens collected in VTM/UTM or eNAT can be frozen at -80 °C and undergo 1 freeze/thaw cycle.
Kit Storage	2–28 °C
Commercial Controls	Refer to Xpert **Xpress** CoV-2 ***plus*** Package Insert or contact Cepheid Technical Support

1 Specimen transport media, other than eNAT, that contains guanidine thiocyanate (GTC) may interfere with the test causing false negative results. Refer to most current package insert for complete details.

US-IVD. *In Vitro* Diagnostic Medical Device.

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