



Xpert Xpress CE-IVD SARS-CoV-2 Test manufactured by **Cepheid** is available for procurement through UNICEF Supply Division and offered at EXW-based* price US\$14.90 per test. The product is available as a kit of 10 tests.

Technical and commercial description of the product is presented in Table 1 below.

Table 1: Xpert Xpress CE-IVD SARS-CoV-2 Test

UNICEF Material Number	Product Description	Product Code	Pack Size	Price* per Pack, USD	FCA* Lead Time, <i>indicative</i>	FCA* Delivery Port
S0003892	Xpert Xpress CE-IVD SARS-CoV-2 kit/10T Kit content: 10 x Xpert Xpress SARS-CoV-2 Cartridges with Integrated Reaction Tubes 12 x Disposable Transfer Pipettes 1 x CD 1 x IFU	XPRSARS-COV2-CE-10	10 tests	149.00	2 – 4 weeks	SCHIPHOL AMSTERDAM, NL

* The price indicated in this note is EXW however all deliveries are FCA-based and additional 3rd party charges apply for orders. The 3rd party charges depend on the size of an order and must be consulted with UNICEF prior to placing an order.

Intended use:

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

- Results are for the identification of SARS-CoV-2 RNA. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

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- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
- The Xpert Xpress CE-IVD SARS-CoV-2 Test is intended to be performed by trained users in both laboratory and near patient testing settings

The **Instructions for Use** for the test can be found in the following link: [IFU](#)

Please note that the following are not provided with the kit but are required to run the test:

1) System and software:

GeneXpert Dx or GeneXpert Infinity systems (catalog number varies by configuration):
GeneXpert instrument, computer, barcode scanner, operator manual.

- For GeneXpert Dx System: GeneXpert Dx software version 4.7b or higher
- For GeneXpert Infinity-80 and Infinity-48s systems: Xpertise software version 6.4b or higher

2) Consumables:

- Nylon flocked swab (Copan P/N 502CS01, 503CS01) or equivalent
- Viral transport medium, 3 mL (Copan P/N 330C) or equivalent
- 0.85% (w/v) saline, 3 mL
- Sample Collection Kit for Viruses (Cepheid P/N SWAB/B-100, SWAB/F-100)

Storage and stability conditions:

Store at 2-28°C

Shelf life:

6 months

Should you have any questions regards to ordering please contact Tatsiana Ptashnik tptashnik@unicef.org

Should you have any technical questions regards to the test please contact Wandani Sebonego wsebonego@unicef.org

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