

Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR Test (BT-SCV2-UHTP-EP)

Product Information Card

The information provided in this document applies to the BT-SCV2-UHTP-EP, including its following components:

EpiScript™ RNase H-Reverse transcriptase	Biosearch Technologies, ERT12925K-ENZ
	Biosearch Technologies, ERT12925K-1.25ML
	Biosearch Technologies, ERT12925K-12ML
RapiDxFire™ qPCR 5X Master Mix GF, 1 mL, 2 mL, 100 mL	Biosearch Technologies, 30050-1
	Biosearch Technologies, 30050-2
	Biosearch Technologies 30050-100ML
SuperROX™ Reference Dye, 15 µM 1 mL, 10 mL	Biosearch Technologies, SR-1000-1
	Biosearch Technologies, SR-1000-10
UltraDx SARS-CoV-2 N1/N2/RnP Assay, 100X, 1010 µL	Biosearch Technologies, N1N2RNP-RES-1010
Positive Control Material for SARS-COV-2	SeraCare AccuPlex™ 0505-0268
Negative Control Material RNase P only	SeraCare AccuPlex 0505-0269



Test Name: Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR Test (BT-SCV2-UHTP-EP)

- . The complete Instructions for Use (IFU) as well as customer ordering information for the BT-SCV2-UHTP-EP test may be found at the following link: <https://www.biosearchtech.com/ultra-high-throughput-pcr-testing-system-for-sars-cov-2-detection-na>
- . A free paper copy of the complete IFU may also be requested by sending an email to techsupport@lgcgroup.com.

Warnings and Precautions

- . For Prescription Use Only
- . For In Vitro Diagnostic Use
- . For Use under Emergency Use Authorization Only
- . This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- . This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- . The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

