CELLTRION USA
CELLTRION

Celltrion DiaTrust™

COVID-19 Ag Home Test

- RESULTS IN 15 MINUTES
- NON-PRESCRIPTION HOME USE (OTC) IN VITRO DIAGNOSTIC USE ONLY
- MID-TURBINATE SWAB SAMPLES
- SERIAL TESTING AUTHORIZED

Please read the instructions carefully before use!

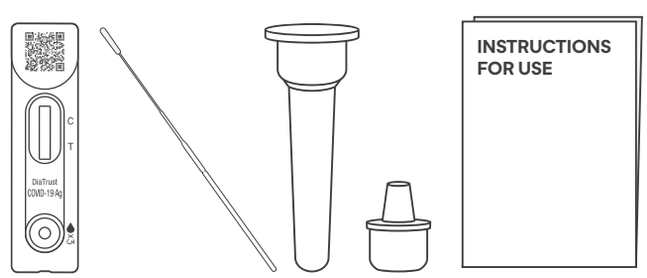
01 INTENDED USE

Celltrion DiaTrust™ COVID-19 Ag Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein and receptor binding domain (RBD) of the SARS-CoV-2 spike proteins in mid-turbinate swabs from the SARS-CoV-2. This test is authorized for non-prescription home use with self-collected and adult-collected direct mid-turbinate swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first seven days of symptom onset.

This test is also authorized for non-prescription home use with self-collected and adult-collected mid-turbinate swab samples from individual 14 years or older with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

- *For Emergency Use Authorization only*
- *For in vitro diagnostic use only*

02 MATERIALS SUPPLIED



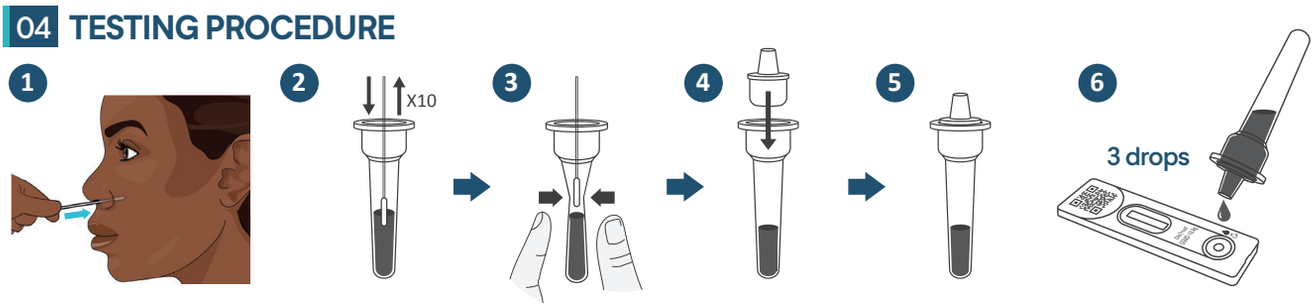
1. Test Device (2 ea.)
2. Test tube filled with extraction buffer and filter cap (2 ea.)
3. Swab (2 ea)
4. Instructions for Use manual (1 ea.)

- *The actual size of the test device may differ from the image*

03 PERFORMANCE DATA (Data including symptomatic and asymptomatic subjects)

Parameters	Positive Percentage Agreement	Negative Percentage Agreement	Accuracy
Results	**86.7%** (95% CI: 73.8%-93.7%)	**99.8%** (95% CI: 98.7%-100.0%)	**98.6%** (95% CI : 97.1 – 99.3%)

04 TESTING PROCEDURE



- The Celltrion DiaTrust™ COVID-19 Ag Home Test is for use under Emergency Use Authorization (EUA) only.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
- This product has been authorized only for the detection of proteins 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.

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