CELLTRION USA
CELLTRION

Celltrion DiaTrust™

COVID-19 Ag Rapid Test

Please read the instructions carefully before use!

FAST AND PRECISE RESULT WITHIN 15 MINS

IN VITRO DIAGNOSTIC USE ONLY POINT OF CARE TESTING (POCT)

NASOPHARYNGEAL SWAB SAMPLE (NPS)

SERIAL TESTING AUTHORIZED

01 INTENDED USE

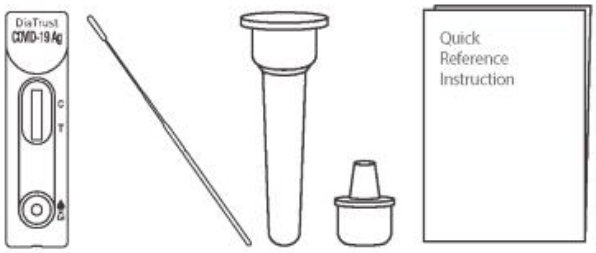
Patients who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset, or
Individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

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

02 US PERFORMANCE DATA

Parameter	Percentage (%)
Sensitivity	93.33%
Specificity	99.03%
Positive Predictive Value (PPV)	96.55%
Negative Predictive Value (NPV)	98.08%
Prevalence	22.56%

03 MATERIALS SUPPLIED



1. Test Device (25 ea)
2. Test tube filled with extraction buffer and filter cap (25 ea)
3. NPS swab (25 ea)
4. Quick refernce instruction (1 ea)
5. Positive control swab (1ea)
6. Negative control swab (1 ea)

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

04 TESTING PROCEDURE

- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- 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.
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.