CELLTRION

Celltrion DiaTrust™

COVID-19 Ag Rapid Test

NASOPHARYNGEAL SWAB SAMPLE(NPS)

FOR USE UNDER THE EMERGENCY USE AUTHORIZATION (EUA) ONLY
FOR *IN VITRO* DIAGNOSTIC USE
FOR PRESCRIPTION USE ONLY

FAST AND PRECISE RESULT IN 15 MINS

Celltrion DiaTrust™ COVID-19 Ag Rapid Test is a rapid test based on lateral flow immunoassay intended for the qualitative detection of nucleocapsid and receptor binding domains (RBDs) from the SARS-CoV-2 spike proteins in human nasopharyngeal swab specimen. Results are for the identification of SARS-CoV-2 nucleocapsid and RBD protein antigen.

Product Specifications

Sample type

NASOPHARYNGEAL SWAB SAMPLE (NPS)

Storage Temperature

2 - 30°C (36 - 86°F)

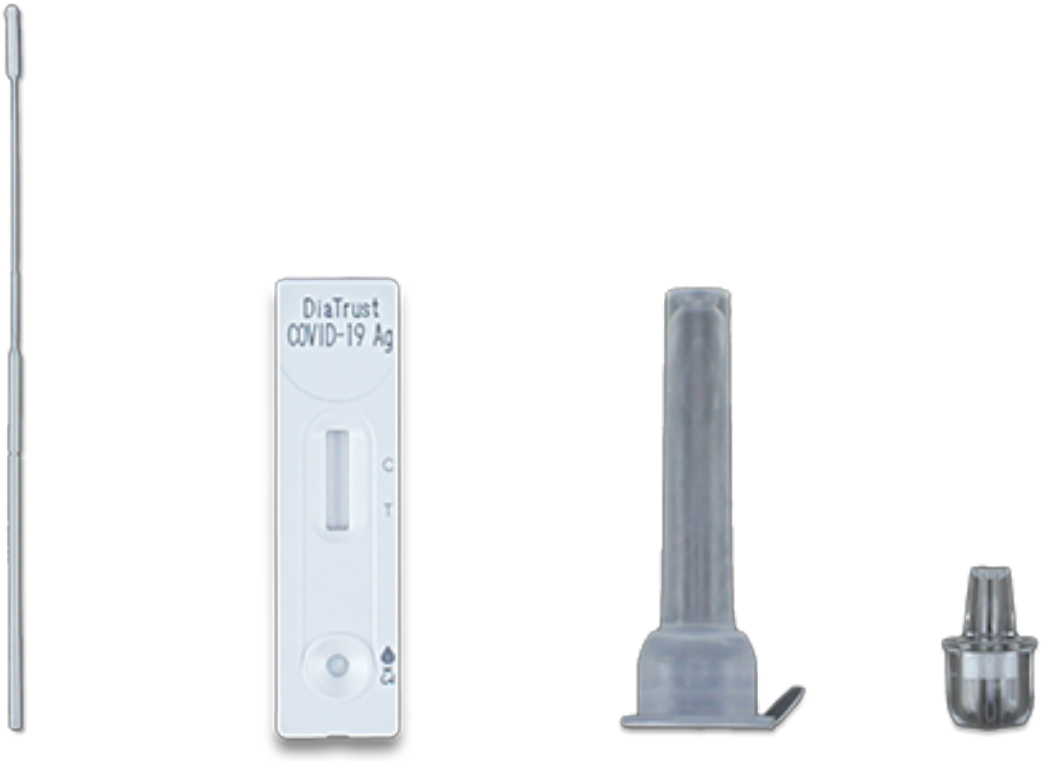
Sample-to-answer time

15 mins

Prospective Study

- Clinical sensitivity: 93.33% (28/30) (95% CI: 78.7%-98.2%)
- Clinical specificity: 99.03% (102/103) (95% CI: 94.7%-99.8%)
- Positive predictive value: 96.55% (28/29) (95% CI: 82.8%-99.4%)
- Negative predictive value: 98.08% (102/104) (95% CI: 93.3%-99.5%)
- Prevalence: 22.56%

Contents



25 test devices

25 swabs

25 extraction buffer

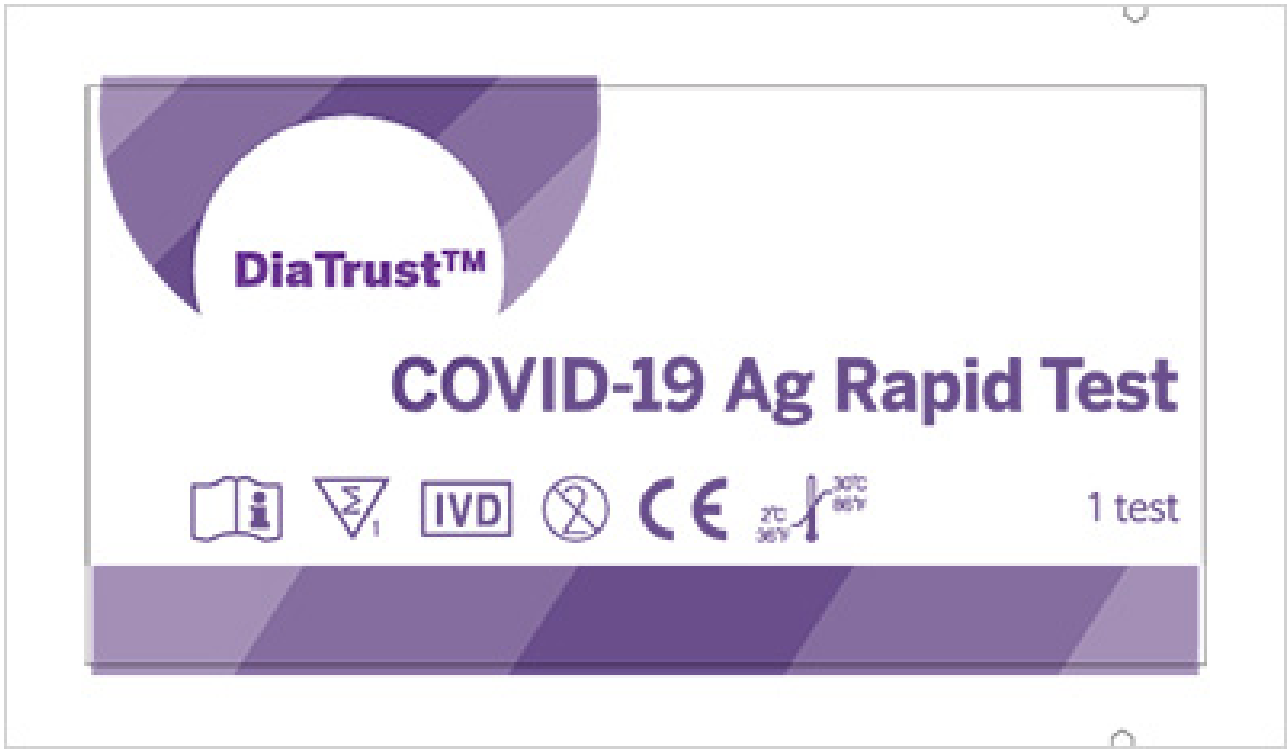
25 filter caps

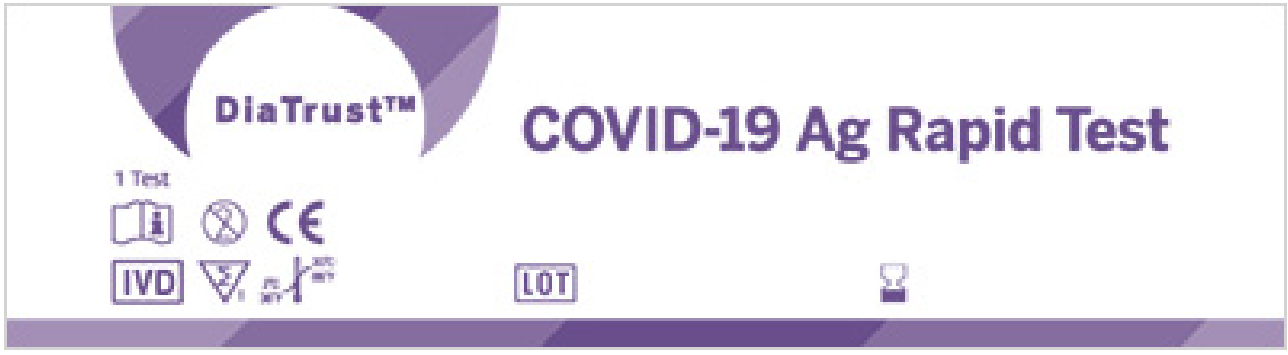
1 positive control swab

1 negative control swab

1 Quick Reference Instruction

POC test device package





Test Device Pouch for Point of Care Use

(By laboratories certified under the CLIA that meet the requirements to perform high or moderate complexity, or waived tests)

DiaTrust COVID-19 Ag Rapid Test IFU VIEW | DOWN

Quick Reference Instruction VIEW | DOWN

Privacy policy VIEW | DOWN

Terms of use	VIEW DOWN
Authorized Distributor list	VIEW DOWN

PRECAUTIONS AND WARNINGS

- For use under Emergency Use Authorization Only.
- For *in vitro* diagnostic use only.
- For prescription use only.
- Read all instructions completely and carefully and follow all instructions. Failure to follow all instructions may result in inaccurate test results.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the CLIA that meet the requirements to perform high or moderate complexity, or waived tests. This product 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.
- 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 diagnostic tests 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 the authorization is revoked sooner.
- Use appropriate precautions in the collection, handling and storage of patient samples. Refer to CDC Interim Guidelines for Collection, Handling and Transportation of clinical specimens from persons with Coronavirus Disease 2019 (COVID-19) at https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html, and to WHO's Interim guidance for Laboratory testing for coronavirus disease (COVID-19) in suspected human cases at http://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117, as amended and supplemented. Refer to the WHO website for additional publications.
- Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).

- Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Do not use the test device beyond the expiration date.
- Keep sealed until usage, and once opened use immediately.
- Do not use the test device if the pouch is damaged or the device is seriously broken.
- Do not re-use the device.
- Handle all specimens safely as potentially infectious.
- All samples, even after the extraction procedure, and reagents containing biological materials used for the assay must be considered as potentially able to transmit infectious agents; accordingly samples, reagents and the waste must be handled with utmost care and disposed of in compliance with the laboratory guidelines and the statutory provisions in force in each country.
- This test is intended for assessment of coronavirus infection by detecting COVID-19 antigen, but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other methods and clinical information (signs and symptoms) should be used and considered for diagnosis.
- Discard Celltrion DiaTrust™ COVID-19 Ag Rapid Test in accordance with local, state and federal regulations or accreditation requirements.

Safety Precautions

- Specimens may be infectious. Use Universal Precautions when performing this assay.
- Use routine laboratory precautions. Do not eat, drink, or smoke in the area where samples are being handled and testing is being conducted. Avoid any contact between hands, eyes or mouth during sample collection and testing.
- Wear personal protective equipment (PPE) in accordance with laboratory and institutional policies, such as laboratory coats, disposable gloves, and eye protection when handling patient samples.
- Wash hands thoroughly after handling specimens and used cartridge.
- Dispose of used test device in a biohazard waste container. Proper handling and disposal methods should be established according to local regulations.
- Avoid splashing or aerosolization of samples or reagents as droplets are a means of transmission of SARS-CoV-2 virus. All drops and spills must be wiped up with an appropriate disinfectant such as a sodium hypochlorite solution with 0.5% active chlorine, and all soiled materials must be disposed of as infectious waste.

※ This test has not been FDA cleared or approved. This webpage is intended for U.S. audiences only. This webpage may contain information on products that are targeted to U.S. audiences, and could

contain product details or information not approved in countries or regions outside U.S