

Celltrion DiaTrust™ COVID-19 Ag Home Test

25
TESTS/KIT



FDA EUA #	EUA210501
Authorized Settings	Non-Prescription Home Use (Over the Counter)
Category	Lateral Flow Immunoassay
Time for Result	Read results at 15 mins
Sample type	Mid-Turbinate Nasal Swab (NS)
Intended Use	Detection of Antigen from SARS-CoV-2
Prospective Study	<ul style="list-style-type: none"> Clinical Sensitivity: 86.7 % (95% CI: 73.8%-93.7%) Clinical Specificity: 99.8 % (95% CI: 98.7%-100.0%)
Serial Screening	Y
Variants	Anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation
Shelf Life	12 months
Manufactured in	Republic of Korea (South Korea)



Package Configuration

BASIC INFORMATION	
Tests per Kit	25 tests
Weight of the Kit (with 25 tests)	0.79 lb
Kit Dimension (L x W x H)	7.67 x 5.70 x 3.93 (inch)
SHIPPER DIMENSION & ARRANGEMENT	
Kits per Shipper	24 kits (600 tests)
Weight of the Shipper	22.68 lb
Shipper Dimension (L x W x H)	18.5 x 15.74 x 16.73 (inch)
Arrangement in Shipper	2 x 3 x 4
PALLET DIMENSION & ARRANGEMENT	
Shippers per Pallet	8 shippers (192 kits = 4,800 tests)
Weight of the Pallet	180 lb
Pallet Dimension	40 x 40 x 40 (inch)
Arrangement in Pallet	4 x 2



Contents

25 Test Devices
25 Test Tubes
25 Filter Caps
25 Swabs
1 Instruction For Use

- 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.