Celltrion USA COVID-19 Rapid Test Kit Product Catalog

CELLTRION USA
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Celltrion DiaTrust™ COVID-19 Ag Rapid Test

FDA EUA #	EUA210190
Authorized Settings	Point of Care Testing (H,M,W)
Category	Lateral Flow Immunoassay (No additional instrument required)
Time for Result	Read results at 15 mins
Sample type	Nasopharyngeal Swab (NPS)
Intended Use	Detection of Antigen from SARS-CoV-2
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%)
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)

Contents

25 test devices
25 swabs
25 extraction buffer
25 filter caps
1 positive control swab
1 negative control swab
1 Quick Reference Instruction

Package Configuration

BASIC INFORMATION	
Tests per Kit box	25 tests
Weight of the Kit box (with 25 tests)	0.79 lb
Kit Dimension (L x W x H)	7.67 x 5.70 x 3.93 (inch)

CARTON (SHIPPER) DIMENSION & ARRANGEMENT	
Arrangement in shipper	2 x 3 x 4
Number of Kits in shipper	24 kits (600 tests)
Weight of the Shipper (Full case)	22.68 lb
Shipper Dimension (L x W x H)	18.5 x 15.74 x 16.73 (inch)

PALLET DIMENSION & ARRANGEMENT	
Shipper arrangement on pallet	4 boxes x 2
Number of shipper per pallet	8 boxes
Number of Kits per pallet	192 kits (24 kits x 8 boxes)
Number of tests per pallet	4,800 tests (600 tests x 8 boxes)
Weight of the pallet	190 lb
Pallet dimension US standard pallet	40 x 40 x 40 (inch)

This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;
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.

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