Celltrion USA
DiaTrust™ COVID-19 Products

CELLTRION USA
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DiaTrust™ COVID-19 Test Kit Portfolio

Name	DiaTrust™ COVID-19 Ag Rapid Test	DiaTrust™ COVID-19 Ag Home Test	DiaTrust™ COVID-19 Ag Home Test
Picture			
FDA EUA #	EUA210190	EUA210501	EUA210501
Authorized Settings	Point of Care Testing (H,M,W[1)])	Non-Prescription Home Use (Over the Counter)	Non-Prescription Home Use (Over the Counter)
Category	Lateral Flow Immunoassay (No additional instrument required)	Lateral Flow Immunoassay	Lateral Flow Immunoassay
Time	Read results at 15 mins	Read results at 15 mins	Read results at 10 mins
Sample type	Nasopharyngeal Swab (NPS)	Mid-Turbinate Nasal Swab (NS)	Mid-Turbinate Nasal Swab (NS)
Intended Use	Detection of Antigen from SARS-CoV-2	Detection of Antigen from SARS-CoV-2	Detection of Antigen from SARS-CoV-2
Tests per kit box	25	2	25
Contents	 25 test devices 25 swabs 25 test tubes filled with extraction buffer 25 filter caps 1 positive control swab 1 negative control swab 1 Quick Reference Instruction	 2 test devices 2 test tubes 2 filter caps 2 swabs 1 Instructions for Use	 25 test devices 25 test tubes 25 filter caps 25 swabs 1 Instructions for Use
Sensitivity **Specificity**	**SARS-CoV-2** 93.3% 99%	**SARS-CoV-2** 86.7% 99.8%	**SARS-CoV-2** 86.7% 99.8%
Serial Screening Testing[2)]	Y	Y	Y
Shelf Life	12 months	12 months	12 months
Manufactured in	Republic of Korea (South Korea, TAA Compliant)	Republic of Korea (South Korea, TAA Compliant)	Republic of Korea (South Korea, TAA Compliant)
Sales Inquiry	DiaTrust@celltrion.com	DiaTrust@celltrion.com	DiaTrust@celltrion.com

1) **Authorized settings include the following:**
H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet requirements to perform high complexity tests.
M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet requirements to perform moderate complexity tests.
W - Patient care settings operating under a CLIA Certificate of Waiver.
(source: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)

2) **Screening testing:** Screening testing looks for individual infections in a group even if there is no reason to suspect those individuals are infected. Screening involves testing asymptomatic individuals who do not have known or suspected exposure to COVID-19 in order to make individual decisions based on the test results. The FDA has authorized some tests for screening.
(source: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/screening-covid-19-deciding-which-test-use-when-establishing-testing-programs)

Celltrion DiaTrust™ COVID-19 Ag Rapid Test

25 TESTS/KIT

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 buffers
25 Filter Caps
1 Positive Control Swab
1 Negative Control Swab
1 Quick Reference Instruction

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

· 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.

Celltrion DiaTrust™ COVID-19 Ag Home Test

2 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	· 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)

Contents

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

Package Configuration

BASIC INFORMATION	
Tests per Kit	2 tests
Weight of the Kit (with 25 tests)	0.26 lb
Kit Dimension (L x W x H)	4.37 x 1.46 x 8.62 (inch)

SHIPPER DIMENSION & ARRANGEMENT	
Kits per Shipper	60 kits (120 tests)
Weight of the Shipper	15.43 lb
Shipper Dimension (L x W x H)	23.50 x 18.43 x 9.53 (inch)
Arrangement in Shipper	10 x 6

PALLET DIMENSION & ARRANGEMENT	
Shippers per Pallet	16 shippers (960 kits = 1,920 tests)
Weight of the Pallet	250 lb
Pallet Dimension	43.31 x 43.31 x 44.50 (inch)
Arrangement in Pallet	4 x 4

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Kit Dimension (L x W x H)	7.67 x 5.70 x 3.93 (inch)

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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

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