

1.01 / Item

SARS-CoV-2 Antigen rapid self-Test "AllTest"

COD. EG26AST

1.02 / Imported by
Kimesta d.o.o.

1.03 / Origin
China

1.04 / CE Certification
Disponibile a richiesta

1.05 / Intended use
The SARS-CoV-2 Antigen Rapid Test Cassette (Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in swab specimens from individuals with suspected SARS-CoV-2 infection.

1.06 / EU Regulation
Directive IVDD 98/79/CE

1.07 / Standards
EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14791:2012, EN ISO 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 13612:2002/AC:2002, EN ISO 17511:2020, EN ISO 23640:2015, EN ISO 13641:2002, EN ISO 15223-1:2016, EN ISO 13532:2002

1.08 / REF n.
INCP-502H

1.09 / RDM n.
2148009

1.10 / Description
The COVID-19 Rapid Antigen Test (Nasal Swab) is a single-use test kit intended to detect SARS-CoV-2 that causes COVID-19 with self-collected nasal swab specimens from symptomatic individuals suspected of being infected with COVID-19. This test is designed for home use with self-collected nasal swab specimens from individuals suspected of having COVID-19. The rapid COVID-19 antigen test (nasal swab) only obtains preliminary results, final confirmation should be based on clinical diagnostic results.

1.11 / Instruction for use and storage
Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.



2.01/ Primary packaging

Quantity	1 piece
Dimension	n.d.
Weight-material	n.d. – Cardboard

2.02 / Secondary packaging

Quantity	400 pcs
Dimension	n.d.
Weight-material	n.d.. – Carrugated cardb.
Pallet	n.d.