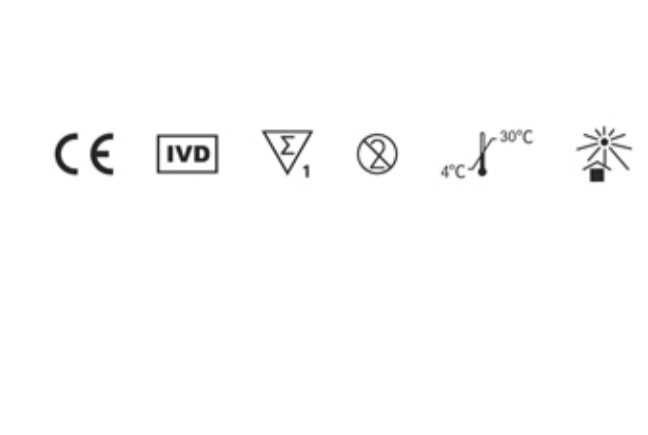


Covid? or just a snotty nose...? Diagnose now!

LOMINA COVID-19 + INFLUENZA A/B ANTIGEN TEST

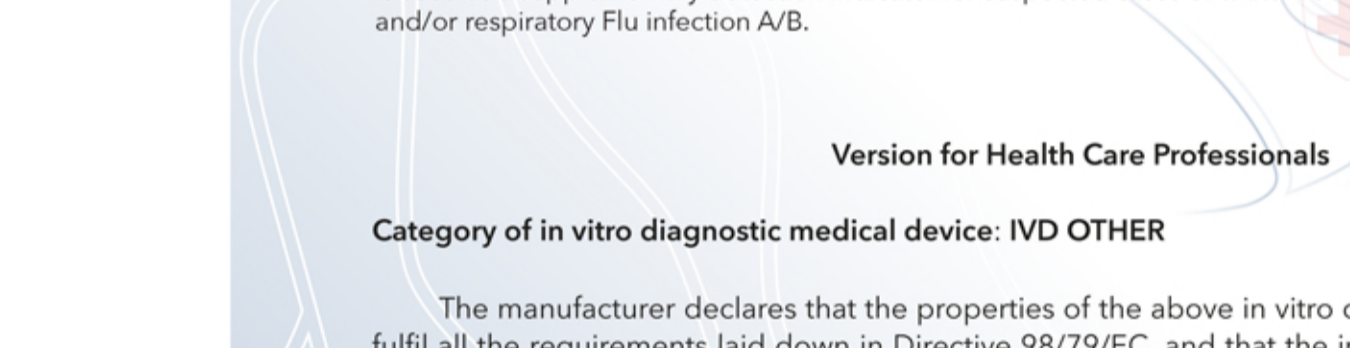


PERFORMANCE EVALUATION REPORT (Nov. 10, 2022)  
Overall sensitivity and specificity were determined from the results of all the above tests. The resulting values were determined by summing the individual positive and negative samples for the same reference method:  
Reference method:  
PCR (780 samples - positive samples (307 COVID-19 positive, 284 influenza A positive, 189 influenza B positive = 520 negative samples).  
Reference material:  
- Comparative PCR: samples taken with a nasal swab  
- Nasal swab - 1300 samples for LOMINA SARS-CoV-2+influenza A/B Antigen Test  
Number of samples for sensitivity determination (number of PCR positive samples): 780  
Number of samples for specificity determination (number of PCR negative samples): 520

Tables showing test results for SARS-CoV-2 virus and Influenza A virus. Both tables show Positive and Negative results for both the test and the reference method, with associated sensitivity and specificity percentages.

Terms & Conditions  
Direct contact: With the manufacturer Lomina Superbio a.s., Czech Republic.  
Representative of LOMINA A.O., Oberer Garschitz 1, 9050 Appenzel (AI), Switzerland.  
Delivery terms: EXW, Czech Republic (negotiable)  
Certificates and standards: EMEA, ISO, CE, Declaration of Conformity

Product details:  
Origin: Czech Republic  
Brand: Lomina  
Type: COVID-19 + Influenza A/B  
Packaging Collection: Nasal swab  
Packaging: Box of 1/5/25/50 Italian  
IFU Language: English / German / Italian / French / Spanish / Dutch / Portuguese / Dansk / Czech / Slovak  
... other available by OEM



In accordance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.

Manufacturer: LOMINA Superbio a.s.  
No. Radosty 184/59, v. p. s., Lomina 5, 158 00, Czech Republic  
ID: CZ07420099, www.lomina.cz, IVD, CE, CE Mark, CE Mark, CE Mark, CE Mark

Medical Device (Product) Identification Data.  
Name: LOMINA SARS-CoV-2 + Influenza A/B Antigen Test  
REF: La-CAB-Pro

Intended use: LOMINA SARS-CoV-2 + Influenza A/B Antigen Test is an antigen test kit designed for simultaneous qualitative detection of SARS-CoV-2 infection (human nasal swab) and/or as a supplementary detection indicator for suspected cases of SARS-CoV-2 causing disease COVID-19 and/or respiratory flu infection A/B.

Version for Health Care Professionals  
Category of in vitro diagnostic medical device: IVD OTHER

The manufacturer declares that the properties of the above in vitro diagnostic medical device fulfill all the requirements laid down in Directive 98/79/EC, and that in the vitro diagnostic medical device will be taken in accordance with its intended purpose. The manufacturer further declares that he has performed measures to ensure compliance of the medical device produced on the market with the essential requirements and the manufacturer's technical documentation pursuant to Annex II of Directive 98/79/EC.

Harmonized standards table with columns for standard number and title.

Name: CEO Mrkacek  
Position: CEO  
Valid from: 2022/05/05  
Signature: [Handwritten signature]

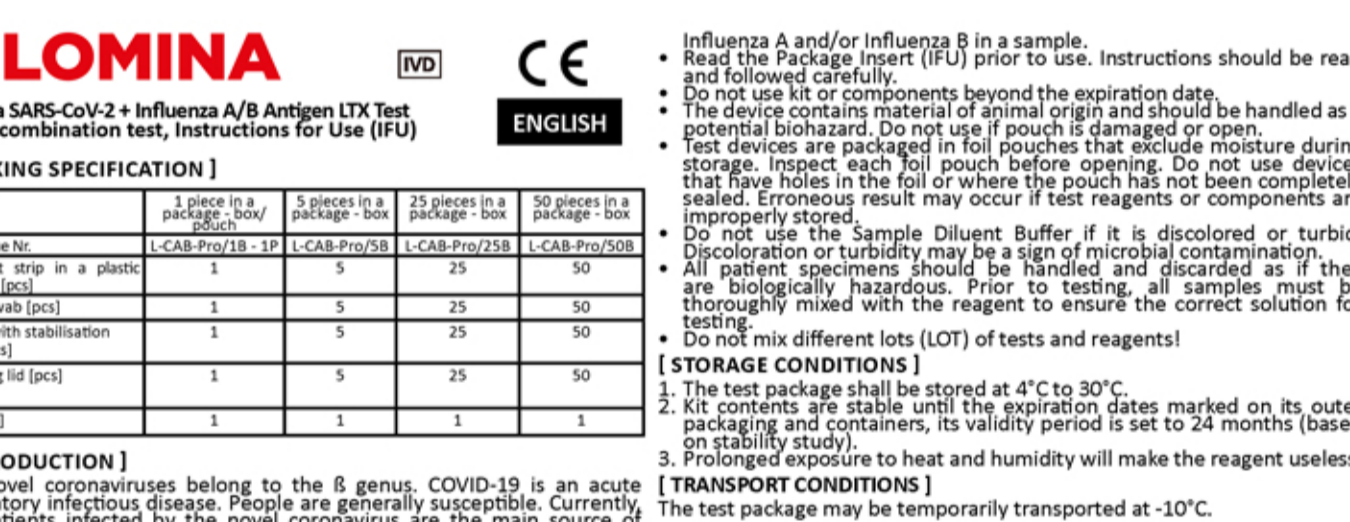
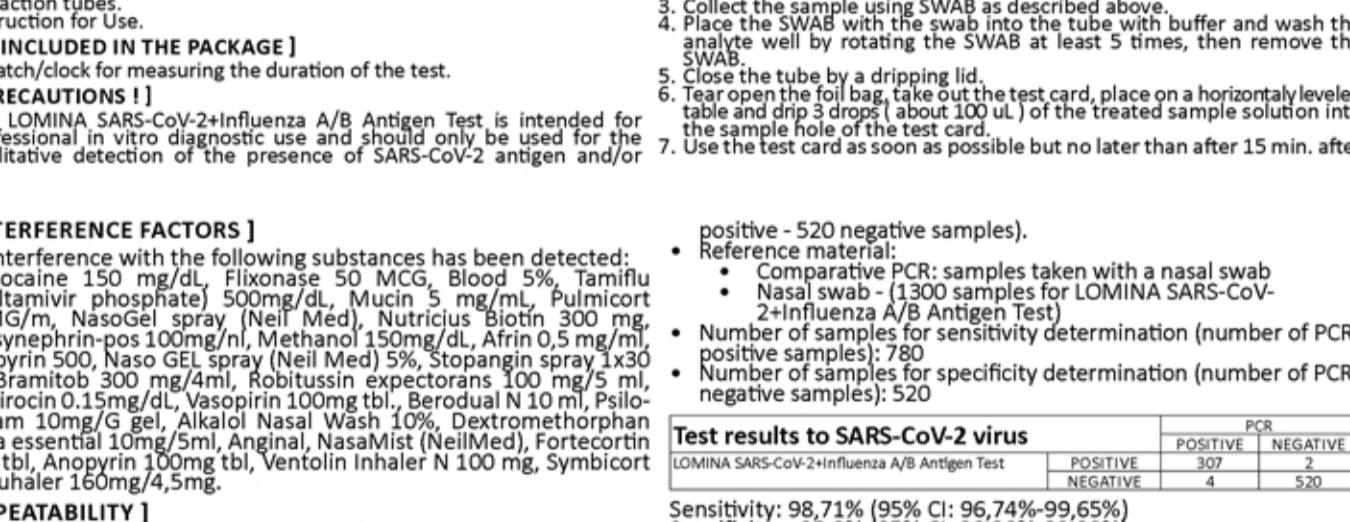


Table with columns for Bulk packing, Carton, Palette, and 12 Cartons. Rows include Single box Test, Double box Test, 25 box Test, 50 box Test, and 100 box Test, listing pieces, weight, and price.

- Recycled ECO paper cartons – bearing
- 1. Manufacturers logo
- 2. Iso symbols (fragile, Protect from humidity, bottom up, IVD and CE)
- 3. Table for expedition control



### COVID-19 + Influenza A/B Instructions for use (IFU)

Intended use: LOMINA SARS-CoV-2 + Influenza A/B Antigen Test is an antigen test kit designed for simultaneous qualitative detection of SARS-CoV-2 infection (human nasal swab) and/or as a supplementary detection indicator for suspected cases of SARS-CoV-2 causing disease COVID-19 and/or respiratory flu infection A/B.  
Version for Health Care Professionals  
Category of in vitro diagnostic medical device: IVD OTHER  
The manufacturer declares that the properties of the above in vitro diagnostic medical device fulfill all the requirements laid down in Directive 98/79/EC, and that in the vitro diagnostic medical device will be taken in accordance with its intended purpose.

Table with columns for Bulk packing, Carton, Palette, and 12 Cartons. Rows include Single box Test, Double box Test, 25 box Test, 50 box Test, and 100 box Test, listing pieces, weight, and price.

Standard ISO palettes as used, showing a grid of boxes with dimensions 1200mm x 1000mm.

Table with columns for Bulk packing, Carton, Palette, and 12 Cartons. Rows include Single box Test, Double box Test, 25 box Test, 50 box Test, and 100 box Test, listing pieces, weight, and price.

Intended use: LOMINA SARS-CoV-2 + Influenza A/B Antigen Test is an antigen test kit designed for simultaneous qualitative detection of SARS-CoV-2 infection (human nasal swab) and/or as a supplementary detection indicator for suspected cases of SARS-CoV-2 causing disease COVID-19 and/or respiratory flu infection A/B.

Version for Health Care Professionals  
Category of in vitro diagnostic medical device: IVD OTHER  
The manufacturer declares that the properties of the above in vitro diagnostic medical device fulfill all the requirements laid down in Directive 98/79/EC, and that in the vitro diagnostic medical device will be taken in accordance with its intended purpose.

Manufacturer: LOMINA Superbio a.s.  
No. Radosty 184/59, v. p. s., Lomina 5, 158 00, Czech Republic  
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