High Precision

SARS-CoV-2 Antigen Rapid Test Kit

eastwest ew medico

Fast and reliable assistance in identifying SARS-CoV-2 infection

The SARS-CoV-2 Antigen Rapid Test is a reliable, rapid chromatopgraphic immunoassay for the qualitative detection of specific antigens of SARS-CoV-2 present in the human nasopharynx.

This test is an aid in detecting antigen from the SARS-CoV-2 virus in individuals suspected of COVID-19.

The box contains 25 test cards individually packed and 2 bottles of dilution fluid.

This product is intended for professional use in laboratory and Point of Care environment.

Product Name: SARS-CoV-2 Antigen Rapid Test Kit
Product SKU: EWA251020
Certification: CE

Certificates

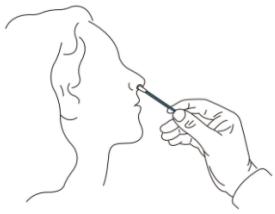
CE

For more information please contact
Eastwest Medico Ltd
by phone Tel.: +45 70 70 17 11
or email: **info@ewmedico.com**
www.ewmedico.com

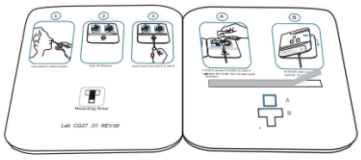
eastwest ew medico

HOW TO USE THE TEST

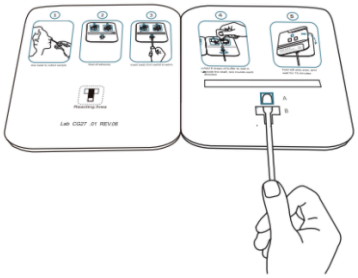
Instruction



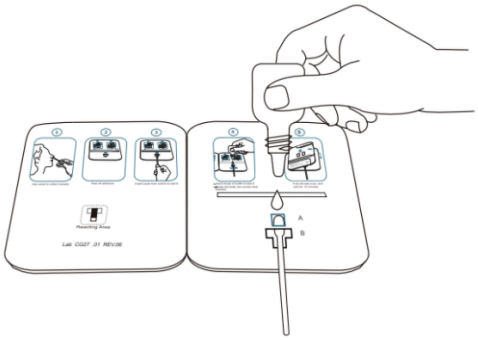
Step 1: Use swab to collect sample.



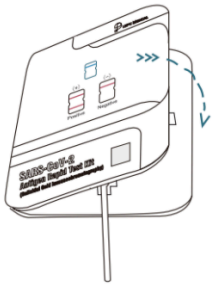
Step 2: Peel off adhesive.



Step 3: Insert swab from well B to well A.



Step 4: a. Add 6 drops of buffer to well A
b. Rotate the shaft, two rounds each direction.



Step 5: Fold left side over, and wait for 15 minutes.

Result Interpretation

eastwest ew medico

DECLARATION OF CONFORMITY

LEPU MEDICAL

Document No.: CE-DOC-CG27
Rev.: 1/0

Declaration of Conformity

Manufacture Address:	Beijing Lepu Medical Technology Co., Ltd. Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China
European Representative:	Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
Product information:	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) Model: 1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 50 tests/kit
Classification:	Others (not in List A and List B)
Conformity Assessment Route:	Section 2 to 5 in annex III of IVDD 98/79/EC We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premise of the manufacturer.
General Applicable Directive:	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on *in vitro* diagnostic medical devices
Standards Applied:	All applicable harmonized standards (published in the official journal of the European Communities on 25th March 2020). The applicable standards are listed in Annex 1.
Place, date of issue	Beijing, P.R. China, 3th, Sept., 2020
Signature of Management Representative	Zhao Changjue

Beijing Lepu Medical Technology Co., Ltd.
Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China

CE

eastwest ew medico

DECLARATION OF CONFORMITY

Annex 1

EN ISO 13485:2016 Medical devices – quality management systems - requirements for regulatory purposes

EN ISO 14971:2019 Medical devices – application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices

EN ISO 18113-1:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 1: terms, definitions and general requirements

EN ISO 18113-2:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 2: in vitro diagnostic reagents for professional use

EN ISO 23640:2015 In vitro diagnostic medical devices – evaluation of stability of in vitro diagnostic regents

EN 13612:2002/AC: 2002 Performance evaluation of in vitro diagnostic medical devices

IEC 62366-1:2015 Application of usability engineering to medical devices