

杭州博拓生物科技股份有限公司 Hangzhou Biotest Biotech Co., Ltd.	文件编号 Document No.: MSDS-0284
MSDS for COVID-19 Rapid Test	第 1 页共 3 页 Page 1 of 3

MSDS for COVID-19 IgG/IgM Rapid Test

I.1. Identification of the product

Product Name: COVID-19 IgG/IgM Rapid Test Cassette

Brand: Lumiratek

I.2. Use of the preparation

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary COVID-19 infections.

I.3. Company Identification

Company: Hangzhou Biotest Biotech Co., Ltd.

Address: #17 Futai Road, Zhongtai Street, Yuhang District, Hangzhou, P.R.China.
311121

Tel: 0086-571-89058016

Fax: 0086-571-88633388

E-mail: info@biotests.com.cn

I.4. Emergency telephone No.

Emergency telephone: 0086-571-89058016

II Information of Ingredients

Sodium Azide Concentration: = <0.02% (7.5ng/test)

CAS#: 26628-22-8

III Hazards Identification

Not dangerous preparation

IV First aid measures

First-aid personnel: N/A

After inhalation: N/A

After skin contact: N/A

After eye contact: N/A

After swallowing: N/A

V. Fire-fighting measures

Inflammable in contact with flames, not explosive.

Extinguishing media: water or foam

VI Accidental release measure

N/A

版本号 Version: 02	修订号 Revision: 00
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VII. 1. Handling

Good Laboratory Practices(disposal gloves)

VII. 2. Storage

Store in a dry place at +2°C to +30°C

Avoid storage near to heat sources

Accessible only for authorized persons

VIII. Exposure controls/personal protection

Specimen collection and preparation : all the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

Use disposal gloves.

IX. Physical and chemical properties

Form: Solid reaction strip that could be placed into a plastic cassette depending on the format used.

Colour: White solid with red lines.

Odour: N/A

pH value: N/A

Melting point: N/A

Ignition temperature: N/A

Flash point: N/A

Explosion limits: N/A

Density: N/A

X. Stability and reactivity

1. Stable
2. Conditions to be avoided: Strong heating, direct contact with flames.
3. Substances to be avoided: only use provided diluent for sample dilution

XI. Toxicological information

N/A

XII. Ecological information

The COVID-19 Rapid Test should be discarded in a proper biohazard container after testing.

XIII. Disposal considerations

After testing, the COVID-19 Rapid Test must be disposed of compliance with the respective national regulations.

XIV. Transport information

Not dangerous preparations, not required transport regulation.

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MSDS for COVID-19 Rapid Test	第 3页共 3 页 Page 3 of 3

XV. Regulatory information

This product does not require special labeling, in accordance with the appropriate EC directives.

This product is for in vitro diagnostic use therefore must comply with the European Directive 98/79/EC bearing the CE label prior to the placing on the market.

XVI. Other information

For professional in vitro Diagnostic use only. Consult instructions for use.

References:

1. REGULATION (EC) No 1907/2006
2. REGULATION (EC) No 1272/2008
3. IVDD 98/79/EC
4. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020.
5. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
6. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
7. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.