



杭州隆基生物技术有限公司
Hangzhou Clongene Biotech Co., Ltd.

No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, Hangzhou, 311121, China
Tel: +86-571-88262120 Web: www.clongene.com
Fax: +86-571-88261752 Email: marketing@clongene.com

MATERIAL SAFETY DATA SHEET

SECTION 1 IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

Product name: COVID-19 IgG/IgM Rapid Test cassette

Brand: CLUNGENE

Manufacturer: Hangzhou Clongene Biotech Co., Ltd.

NO.1 YICHUANG ROAD, YUHANG SUB-DISTRICT,
YUHANG DISTRICT, HANGZHOU, 311121, CHINA

Telephone: 0086-571-88262120

FAX: 0086-571-88261752

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SECTION 2 COMPOSITION

List of ingredients

1. Nitrocellulose membrane coated with a control line and a test line

Component	CAS #	% W/V
Nitrocellulose	9004-70-0	≤100%
Antibody	N/A	<3%
Disodium hydrogen phosphate	10039-32-4	< 0.5%
Sodium dihydrogen phosphate	13472-35-0	<0.1%
NaCl	7647-14-5	< 1%
Water	7732-18-5	> 95%

2. Absorbent Paper

Component	CAS #	% W/V
Cellulose microcrystalline	113669-95-7	≤100%

3. Fiberglass membrane

Component	CAS #	% W/V
Fiberglass	65997-17-3	≤100%

4. Desiccant

Component	CAS #	% W/V
Silica gel	112945-52-5	≤100%

5. Foil pouch and label

Component	CAS #
Poly(Ethylene Terephthalate)	25038-59-9
Aluminium	7429-90-5
Polypropylene	N/A

6. Buffer

Component	CAS #	% W/V
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NaCl	7647-14-5	< 1%
Water	7732-18-5	> 95%

The unit does not contain any human source material.

SECTION 3 HEALTH HAZARDS

WARNING STATEMENT: For in vitro diagnostic use only.

Potential Routes of Exposure: No hazardous exposures anticipated under conditions of use as described in other product literature.

Eye: None

Skin: None

Inhalation: None

Ingestion: None

Chronic Toxicity: None known.

Reproductive and Developmental Toxicity: The components of this product are not considered reproductive or developmental toxins.

Carcinogenicity: None of the components of this product is listed by NTP, IARC, or OSHA as a carcinogen.

Medical Conditions Aggravated by Exposure: Skin and eye conditions (e.g., dermatitis, conjunctivitis).

SECTION 4 FIRE FIGHTING MEASURES

Unusual Fire and Explosion Hazards: The nitrocellulose membrane is classified as a flammable solid. Keep away from excessive heat, fire or flame.

Extinguishing Media: Water, carbon dioxide, multipurpose dry chemical or halon-fire extinguisher.

Special Protective Equipment for Fire-fighter: Wear self-contained breathing apparatus for fire fighting if necessary.

SECTION 5 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Take proper precautions to minimize exposure by using appropriate personal protective equipment. Shut off all sources of ignition.

Environmental Precautions: Place in container for disposal according to local/ national regulations for handling of bio-hazardous waste.

SECTION 6 HANDLING AND STORAGE

Handling: Avoid contact between test area and skin, eyes or clothing. Wash thoroughly after handling.

Storage: Store at 4- 30°C in original sealed package.

SECTION 7 EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational Exposure Limits: There are no established exposure limits for this product, nor indicated for any ingredients.

Eye Protection: Face shield and safety glasses

Respiratory Protection: Inhalation not anticipated in intended use. Respiratory protection not necessary.

Skin Protection: Wear protective clothing and gloves.

Engineering Controls: Minimize any anticipated skin and eye contact with test strip.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.



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SECTION 8 PHYSICAL AND CHEMICAL PROPERTIES

Appearance, Color, Odor: Flat, white plastic housing containing white, narrow membrane test strip; odorless.

pH: no data available

Boiling Point: no data available

Melting Point: no data available

Flash Point: 200° C (nitrocellulose membrane)

Low Explosion Limit: no data available

High Explosion Limit: no data available

Water Solubility: Nitrocellulose: insoluble.

Reagents: soluble

SECTION 9 STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Hazardous Decomposition Products: Oxides of carbon and nitrogen.

Conditions to Avoid: Excessive heat, direct sunlight (nitrocellulose)

SECTION 10 TOXICOLOGICAL INFORMATION

Acute Toxicity: no data available

Irritancy and Corrosion: no data available

Sensitisation: no data available

Chronic Toxicity (Target Organ Effects): no data available

Reproductive and Developmental Toxicity: no data available

Carcinogenicity: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Potential Health Effects:

Inhalation: no data available

Ingestion: Toxic if swallowed.

Skin: Toxic if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

SECTION 11 ECOLOGICAL INFORMATION

Persistence and Degradability: no data available

Ecotoxicity effects: no data available

Further Information on Ecology: no data available

SECTION 12 DISPOSAL CONSIDERATIONS

Dispose of waste materials according to prescribed national and local regulations.

SECTION 13 TRANSPORT INFORMATION

Land Transport (ADR/RID): Not dangerous goods.

Air Transport (ICAO/IATA): Not dangerous goods.

Maritime Transport (IMO-IMDG): Not dangerous goods.



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SECTION 14 REGULATORY INFORMATION

EINECS Status: This product does not contain any hazardous ingredients above trigger levels.

EEC Classification and Labeling: None required.

SECTION 15 OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Hangzhou Clongene Biotech Co., Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product.