



杭州隆基生物技术有限公司

Hangzhou Clongene Biotech Co., Ltd.

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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

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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.

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### SECTION 3 HEALTH HAZARDS

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**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).

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### SECTION 4 FIRE FIGHTING MEASURES

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**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.

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### SECTION 5 ACCIDENTAL RELEASE MEASURES

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**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.

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### SECTION 6 HANDLING AND STORAGE

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**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.

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### SECTION 7 EXPOSURE CONTROL/PERSONAL PROTECTION

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**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

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**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

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## SECTION 9 STABILITY AND REACTIVITY

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**Stability:** Stable under recommended storage conditions.

**Hazardous Decomposition Products:** Oxides of carbon and nitrogen.

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

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## SECTION 10 TOXICOLOGICAL INFORMATION

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**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.

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## SECTION 11 ECOLOGICAL INFORMATION

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**Persistence and Degradability:** no data available

**Ecotoxicity effects:** no data available

**Further Information on Ecology:** no data available

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## SECTION 12 DISPOSAL CONSIDERATIONS

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

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## SECTION 13 TRANSPORT INFORMATION

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**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

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

**EEC Classification and Labeling:** None required.

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#### SECTION 15 OTHER INFORMATION

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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.