

KIT**1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY****1.1 Product identifier**

Product Name: COVID-19 IgG-IgM Rapid Test

Catalog #: RAPU08COVID19

Kit Components: Test device
Disposable sample droppers
Buffer**1.2 Intended Use**

Rapid Test kit for In vitro Diagnostic

1.3 Company

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

Belgium

Tel. Nr. +32 (0)10/84.99.11

E-mail: tech.support@diasource.be**1.4 Emergency telephone**

DIAsource (only office hours): +32 (0)10/84.99.23

Centre Anti-Poisons (BE) 070 245 245

Please refer to your local Anti-Poison Center!

2 OTHER INFORMATION

No data available.

TEST DEVICE

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Test device

Catalog #: Component of the kit mentioned on the first page

1.2 Intended Use

Rapid Test kit for In vitro Diagnostic.

1.3 Company

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Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII:
Not applicable

2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008

The product does not need to be labelled in accordance with EC directives or respective national laws.

Hazard picograms and Signal word: No

Hazardous components for labeling: No

Hazard statements: No

Precautionary statements: No

2.3 Other hazards

This biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit). ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317].

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Hazardous Ingredients	CAS No.	EINECS No.	REACH Registration No.	Classification: Category Codes / Hazard Statements	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H - isothiazol-3-one (3:1)	55965-84-9	N/A	Not available	Acute Tox. 3: H301-H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	0,001 %
Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1 Lowest specific concentration limits according to Table 3.1 Annex VI: Skin Corr. 1B; H314 $C \geq 0.6 \%$ Skin Irrit. 2; H315: $0,06 \% \leq C < 0.6 \%$ Eye Irrit. 2; H319: $0,06 \% \leq C < 0.6 \%$ Skin Sens. 1; H317: $C \geq 0.0015 \%$					

4 FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
After skin contact	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

4.2 Most important symptoms and effects, both acute and delayed

Not applicable.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:

The common fire extinguish media can be used

Unsuitable extinguishing media:

Not investigated

5.2 Special hazards arising from the substance or mixture

Not find yet

5.3 Additional information

Advice for fire-fighters: dry-chemical fire extinguisher

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

6.2 Environmental Precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning-up

Clean up with broom.

6.4 Reference to other sections

Collect material and dispose of waste according to section 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

General hygiene measures: Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use.

Contaminated clothing and protective equipment must remove before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Information about storage conditions: Note the storage conditions on product packaging.

Requirements for storage rooms and containers: Store in a cool dry place.

7.3 Specific Use(s)

Lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019-nCov in human whole blood, serum or plasma specimen.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Personal protective equipment

General protective and hygienic measures:	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
Respiratory protection	Not required
Protective gloves	Disposable gloves
Material of gloves	Latex/natural rubber
Penetration time of glove material	Gloves resistance is not critical when the product is handled according to the instruction for use.
Eye Protection	Safety glasses
Body protection	Lab coat

8.2.3 Environmental exposure controls

There are no special precautions and measures. See section 6 and 7!

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Solid
Colour	White appearance and some content of the test strip is purple
Odour	odourless
Odour threshold	Not established
Flash point	Not established
Self-igniting	Product is not known to be self-igniting
Danger of explosion	There is no substances in the kit could lead to the danger of explosion
Self ignition temperature	Product is not self-igniting.
Danger of explosion	Product does not present an explosion hazard.
Melting point	Not established
Boiling point	Not established
Vapour pressure	Not established
Density (20°C)	Not established
pH-value at 20°C:	Not established
Solubility in water	The product almost could not solute in the water

9.2 Other information

No

10 STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable in accordance with the recommended storage conditions.

10.2 Chemical Stability

All the chemicals in the test kits are stable.

10.3 Possibility of hazardous reactions

Almost impossible

10.4 Conditions to Avoid

High humidity and the temperature out of 2-30°C

10.5 Incompatible materials

No

10.6 Hazardous Decomposition Products

No

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
Irritation:	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity:	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.
Sensitization:	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
Repeated dose toxicity:	Not yet investigated
Carcinogenicity:	Not yet investigated
Mutagenicity:	Not yet investigated
Toxicity for reproduction:	No reproductive toxic effect known.

12 ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulation

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

No data available

13 DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Product:	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
European waste catalogue:	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
Packaging:	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further information.

14 TRANSPORT INFORMATION**14.1 UN proper shipping name**

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.2 Transport hazard class

ADR/RID: - IMDG: - IATA: -

14.3 Packing group

ADR/RID: - IMDG: - IATA: -

14.4 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No

Marine Pollutant : No

14.5 Special precautions for user

See sections 6-8

14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Delivery will only be taken in suitable and regulatory approved packaging

15 REGULATORY INFORMATION**15.1 Safety, health and environmental regulation/legislation specific for the substance or mixture****EU regulations:**

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

The mixture was not subjected to security assessment.

16 OTHER INFORMATION**General information**

The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501].

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user`s responsibility to determine the suitability of the information for their particular purposes.

Notification:

English is acceptable for our MSDS as the following conditions are met:

- Medical specialists (users) are well educated in the English language

BUFFER

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Buffer

Catalog #: Component of the kit mentioned on the first page

1.2 Intended Use

Dilution the whole blood, serum or plasma specimen.

1.3 Company

DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
E-mail: tech.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.23
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Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII:
Not applicable

2.2 Label elements

Labelling according to regulation (EC) No. 1272/2008

The product does not need to be labelled in accordance with EC directives or respective national laws.

Hazard picograms and Signal word: No

Hazardous components for labeling: No

Hazard statements: No

Precautionary statements: No

2.3 Other hazards

No

3 COMPOSITION/INFORMATION ON INGREDIENTS
Mixture

Hazardous Ingredients	CAS No.	EINECS No.	REACH Registration No.	Classification: Category Codes / Hazard Statements	W/W %
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Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1 Lowest specific concentration limits according to Table 3.1 Annex VI: Skin Corr. 1B; H314 $C \geq 0.6 \%$ Skin Irrit. 2; H315: $0,06 \% \leq C < 0.6 \%$ Eye Irrit. 2; H319: $0,06 \% \leq C < 0.6 \%$ Skin Sens. 1; H317: $C \geq 0.0015 \%$					

4 FIRST AID MEASURES
4.1 Description of first aid measures

After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
After skin contact	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

4.2 Most important symptoms and effects, both acute and delayed

Not applicable.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:

The common fire extinguish media can be used

Unsuitable extinguishing media:

Not investigated

5.2 Special hazards arising from the substance or mixture

Not find yet

5.3 Additional information

Advice for fire-fighters: dry-chemical fire extinguisher

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, protective equipment and emergency procedures

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

6.2 Environmental Precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning-up

Absorb in vermiculite, dry sand or earth and place into containers. Flush with plenty of water to clean spillage area.

6.4 Reference to other sections

Collect material and dispose of waste according to section 13.

7 HANDLING AND STORAGE

7.1 Precautions for safe handling

General hygiene measures: Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use.

Contaminated clothing and protective equipment must remove before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Information about storage conditions: Note the storage conditions on product packaging.

Requirements for storage rooms and containers: Store in a cool dry place.

7.3 Specific Use(s)

Dilution the whole blood, serum or plasma specimen.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Personal protective equipment

General protective and hygienic measures:	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
Respiratory protection	Not required
Protective gloves	Disposable gloves
Material of gloves	Latex/natural rubber
Penetration time of glove material	Gloves resistance is not critical when the product is handled according to the instruction for use.
Eye Protection	Safety glasses
Body protection	Lab coat

8.2.3 Environmental exposure controls

There are no special precautions and measures. See section 6 and 7!

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	Colorless
Odour	odourless
Odour threshold	Not established
Flash point	Not established
Self-igniting	Product is not known to be self-igniting
Danger of explosion	There is no substances in the kit could lead to the danger of explosion
Self ignition temperature	Product is not self-igniting.
Danger of explosion	Product does not present an explosion hazard.
Melting point	Not established
Boiling point	Not established
Vapour pressure	Not established
Density (20°C)	Not established
pH-value at 20°C:	Not established
Solubility in water	The product is easily soluble in water

9.2 Other information

No

10 STABILITY AND REACTIVITY**10.1 Reactivity**

The product is stable in accordance with the recommended storage conditions.

10.2 Chemical Stability

All the chemicals in the test kits are stable.

10.3 Possibility of hazardous reactions

Almost impossible

10.4 Conditions to Avoid

Temperature out of 2-30°C

10.5 Incompatible materials

No

10.6 Hazardous Decomposition Products

No

11 TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects**

Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
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Carcinogenicity:	Not yet investigated
Mutagenicity:	Not yet investigated
Toxicity for reproduction:	No reproductive toxic effect known.

12 ECOLOGICAL INFORMATION**12.1 Toxicity**

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulation

No data available

12.4 Mobility in soil

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14.3 Packing group

ADR/RID: -

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14.4 Environmental hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No

Marine Pollutant : No

14.5 Special precautions for user

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MSDS established : 2020-03-27

Revision number : 0