

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

Product Name: Anti-HCV ELISA 4.0

Catalog #: KAPG4NAE3
KAPG4NAE12Kit Components: Microtiterplate
Concentrate conjugate
Controls
Conjugate Diluent
Chromogenic TMB
Substrate Buffer
Wash Solution
Stop Solution**1.2 Intended Use**

In-Vitro Diagnostics for professional use only

This kit is is a fourth generation enzyme immunoassay diagnostic kit for in-vitro qualitative detection and screening assay of Antibody to Hepatitis C virus (anti-HCV) in human serum or plasma.

1.3 CompanyDIAsource ImmunoAssays S.A.
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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 HAZARDS IDENTIFICATION**

This kit must be operated by qualified personnel trained in laboratory procedures and familiar with its potential hazards. The warnings during operation are given in the instruction for use.

2.1 Classification of the mixture

Components	Classification
Chromogenic TMB	Reproductive toxicity [Category 1B]
	Specific target organ toxicity - Single exposure [Category 2] Visual system, Central nervous system
	Specific target organ toxicity - Repeated exposure [Category 2] Visual system, Central nervous system
	Flammable liquid [Category 3]
Stop Solution	Corrosive to metals [Category 1]
	Skin corrosion [Category 1A]

The other kit components are not classified as hazardous mixture or substance according to GHS / CLP.

2.2 Label elements

2.2.1 Chromogenic TMB



Danger

Warning

Label Hazard Statement:	H226: Flammable liquid and vapour H340: May cause genetic defects H371: May cause damage to organs H373: May cause damage to organs
Supplemental Hazard – Statement:	None Specified
Precautionary Statement – Prevention:	P202: Do not handle until all safety precautions have been read and understood. P210: Keep away from heat/sparks/open flames/hot surfaces. – No smoking. P260: Do not breathe dust/ fume/ gas/ mist/ vapours/ spray. P280: Wear protective gloves/protective clothing/eye protection/ face protection.
Precautionary Statement – Response:	P308 + P313: IF exposed or concerned: Get medical advice / attention.
Precautionary Statement – Storage:	P405: Store locked up.
Precautionary Statement – Disposal:	P501: This material and its container must be disposed of as hazardous waste.

2.2.2 Stop Solution


Danger

Label Hazard Statement:	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage.
Supplemental Hazard – Statement:	None Specified
Precautionary Statement – Prevention:	P260: Do not breathe mist / vapours / spray. P280: Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement – Response:	P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P309 + P313: If exposed or if you feel unwell: get medical advice/attention.
Precautionary Statement – Storage:	P405: Store locked up.
Precautionary Statement – Disposal:	P501: This material and its container must be disposed of as hazardous waste.

 2.2.3 Microtiterplate

Each well can only be used once


2.3 Other hazards

 2.3.1 Microtiterplate, Concentrate Conjugate, Controls, CONjugate Diluent

Biological ingredient _ Potential Biohazard

Human/ animal sourced mixture in these components, handle as potentially infectious. Patient specimens analyzed with the kit represent an unknown, heightened biohazard, too.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Component	Ingredient	CAS No.	Classification (100%)	Conc. (w/w)
Concentrate Conjugate	Human/Animal sourced mixture	N/A	N/A	20%
	Sodium azide	26628-22-8	Acute toxicity, Oral (Category 2)H300 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410	0.005 %
Anti-HCV Positive Control	Human/Animal sourced Preparation	N/A	N/A	100%
	Sodium azide	26628-22-8	Acute toxicity, Oral (Category 2)H300 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410	0.099%
HC Negative Control	Human/Animal sourced mixture	N/A	N/A	100%
	Sodium azide	26628-22-8	Acute toxicity, Oral (Category 2)H300 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410	0.099%
Conjugate Diluent	Human/Animal sourced mixture	N/A	N/A	20%
	Sodium azide	26628-22-8	Acute toxicity, Oral (Category 2)H300 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410	0.005%
Chromogenic TMB	3,3',5,5'-tetramethyl Benzidine.	54827-17-7	Skin irritation (Category 2), H315 Eye irritation (Category 2), H319 Specific target organ toxicity - single exposure (Category 3), H335	< 0.04 %
	N,N-dimethyl formamide	68-12-2	Reproductive toxicity (Category 1B), H360D Acute toxicity, Inhalation (Category 4), H332 Acute toxicity, Dermal (Category 4), H312 Eye irritation (Category 2), H319	~0.2 %
	Methanol	67-56-1	Flammable liquids (Category 2), H225 Acute toxicity (Oral) (Category 5), H303 Serious eye damage/eye irritation (Category 2A), H319 Reproductive toxicity (Category 1B), H340 Specific target organ toxicity - Single exposure (Category 1) Visual system, Central nervous system, H370 Specific target organ toxicity- Single exposure (Category 3) Respiratory tract irritation, Narcotic effects,H335/H336 Specific target organ toxicity- Repeated exposure (Category 1) Visual system, Central nervous system H372	~4 %

Component	Ingredient	CAS No.	Classification (100%)	Conc. (w/w)
	Sodium metabisulfite	7681-57-4	Acute toxicity, Oral (Category 4), H302 Serious eye damage (Category 1), H318	<0.01 %
Substrate Buffer	Urea Hydrogen Peroxide	124-43-6	Oxidizing solids (Category 3), H272 Skin corrosion (Category 1B), H314	~0.05 %
	Gentamycin	1405-41-0	Respiratory sensitisation (Category 1), H334 Skin sensitisation (Category 1), H317	< 0.1%
Stop Solution	Sulfuric Acid	7664-93-9	Corrosive to metals (Category 1), H290 Skin corrosion (Category 1A), H314	4.94%

4 FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Remove to fresh air. Seek medical advice.
Ingestion	Rinse out mouth thoroughly with water. Seek medical advice.
Eye contact	Flush with copious amounts of water. Seek medical advice.
Skin contact	Flush thoroughly with water. Seek medical advice.
Protection of First-aids	Wearing of protective gloves and avoiding the generation of aerosols.

4.2 Most important symptoms and effects, both acute and delayed

No data available

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

CO₂, powder or water spray.

Fight larger fires with water spray or alcohol resistant foam.

5.2 Hazardous combustion products

Components	Specific Hazards
1. Microtiterplate	CO
2. Concentrate Conjugate	CO, NO _x , SO _x , Hg.
3. Anti-HCV Positive Control	CO, NO _x , SO _x , N ₂ .
4. HC Negative Control	CO, NO _x , SO _x , N ₂ .
5. Conjugate Diluent	CO, NO _x , SO _x .
6. Chromogenic TMB	CO, NO _x , SO _x .
7. Substrate Buffer	CO
8. Wash Solution	CO
9. Stop Solution	SO _x .

5.3 Advice for firefighters

Wear self-contained breathing apparatus if necessary.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions

Wear protective gloves, lab coat and avoid the generation of aerosols. Keep unprotected persons away and ensure adequate ventilation.

6.2 Environmental Precautions

Treated (inactivated) as biological hazardous contamination.

6.3 Methods for Cleaning Up

Components	Methods for Cleaning Up
2. Concentrate Conjugate	Inactivated with Sodium Hypochlorite Solution prior to clean with plenty of water.
3. Anti-HCV Positive Control	
4. HC Negative Control	
5. Conjugate Diluent	
6. Chromogenic TMB	Clean with plenty of water.
7. Substrate Buffer	
8. Wash Solution	
9. Stop Solution	

7 HANDLING AND STORAGE

7.1 Handling

This kit must be operated by qualified personnel trained in laboratory procedures and familiar with its potential hazards. The warnings during operation are given in the instruction for use. Handled as biohazards and wear protective gloves and lab coat.
 Keep Chromogenic TMB away from fire sources.

7.2 Storage

Store according to product instruction for use and labels (generally at 2-8°C).

This kit is for in vitro diagnostic use, professional use only. Read and follow all warnings and precautions in product instruction for use and labels.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters

No special measures required.

8.2 Exposure controls

Respiratory protection: Ensure adequate ventilation.

Hand protection: Protective gloves.

Eye protection: Safety goggles or face shield.

Body protection: Lab coat.

9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Aqueous liquids, exception are the solid microwell plate
Color	Nearly colorless Exceptions : - Conc. Conjugate : dark red - Positive Control : light yellow - Negative Control : light yellow - Conjugate Diluent : Light Yellow
Odor	Nearly odorless
pH	Most of the liquid components are between pH 6~8 Exceptions are the following acidic solutions: Chromogenic TMB : pH~3 Substrate Buffer : pH~5 Stop Solution : pH<2.
Melting point	Not established
Boiling point	Not established
Flash point	Not established
Evaporation rate	Not established
Fire hazard	Keep Chromogenic TMB away from fire source
Vapor pressure	Not established
Vapor density	Not established
Density	Not established
Solubility	The liquid components are soluble in water.
Partition coefficient	Not established
Auto igniting	Not established
Decomposition temperature	Not established
Viscosity	Not established
Danger of explosion	Not established

10 STABILITY AND REACTIVITY
10.1 Chemical stability / reactivity

No data available

10.2 Conditions to avoid

None known when used as intended

10.3 Materials to avoid

None known when used as intended.

And don't let the acidic solutions in contact with strong bases, oxidizing agents and metals.

10.4 Dangerous decomposition products

Components	Specific Hazards
1. Microtiterplate	CO
2. Concentrate Conjugate	CO, NO _x , SO _x , Hg.
3. Anti-HCV Positive Control	CO, NO _x , SO _x , N ₂ .
4. HC Negative Control	CO, NO _x , SO _x , N ₂ .
5. Conjugate Diluent	CO, NO _x , SO _x .
6. Chromogenic TMB	CO, NO _x , SO _x .
7. Substrate Buffer	CO
8. Wash Solution	CO
9. Stop Solution	SO _x .

11 TOXICOLOGICAL INFORMATION

Refer to Sections 2 and 3 for the kit component concentrations. The composite toxicological information for this product is:

11.1 Acute Toxicity

Toxicity:	Acute toxicity will not occur if used and stored according to the product instruction for use.
Irritation:	May cause irritation to skin, mucous membranes and eyes.
Corrosivity:	Component stop solution may causes skin, eye damage and chemical burns to the respiratory tract.
STOT-Single Exposure:	No data available, chromogenic TMB may affects visual and central nervous system.
STOT-Repeated Exposure:	No data available, chromogenic TMB may affects visual and central nervous system.
Aspiration Hazard:	No data available

11.2 Chronic Toxicity or Long Term Toxicity

Sensitization:	May cause sensitization to mucous membranes and eyes.
Carcinogenicity/Mutagenicity:	Component Stop Solution , (Sulfuric acid, CAS# 7664-93-9: IARC Group 1, is carcinogenic to humans, which is diluted to 4.94% in Stop Solution)
Reproductive hazard:	No data available.

11.3 Biohazard Potential

Human/ animal sourced mixture should be handle as potentially infectious. Patient blood samples analyzed with the kit represent an unknown, heightened biohazard, too.

12 ECOLOGICAL INFORMATION

Components of this kit were not tested; the following data is according to the ingredients vendor safety data sheets.

12.1 Toxicity

Methanol	No data available
Sulfuric acid	No information available

12.2 Persistence and degradability

Methanol	92 % (by BOD), 99 % (by TOC), 100 % (by GC) *The substance was determined as "Ready biodegradability" under the Chemical Substances Control Law.
Sulfuric acid	No information available

12.3 Bioaccumulative potential

Methanol	BCF: 0.2
Sulfuric acid	No information available

12.4 Mobility in soil

Methanol	Mobility in soil Log Pow: -0.82/-0.66 Soil adsorption (Koc): No data available Henry's Law constant(PaM ₃ /mol): 0.4
Sulfuric acid	No information available

12.5 Results of PBT and vPvB assessment

Methanol	N/A
Sulfuric acid	PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Methanol	No data available
Sulfuric acid	Biological effects: Forms corrosive mixtures with water even if diluted. Harmful effect due to pH shift. Endangers drinking-water supplies if allowed to enter soil or water. Further information on ecology. Discharge into the environment must be avoided.

13 DISPOSAL CONSIDERATIONS

Prior to disposing patient specimens and kit components as general waste; it should be treated in accordance with the local practice of potential bio-hazardous waste or treated as follows: Both liquid and solid waste should be autoclaved at +121 °C for at least 30 minutes. Solid waste can also be incinerated.

Non-acidic liquid waste can be treated with sodium hypochlorite diluted to a final concentration of 1%.

Acidic liquid wastes must be neutralized before treatment with sodium hypochlorite as mentioned above and should stand for 30 minutes to obtain effective disinfection.

14 TRANSPORT INFORMATION**Land Transport ADR/RID:**

1N Sulfuric Acid: ADR/RID Class: 8 Corrosive Substances

UN Number: UN2796

Packaging Group: II

Shipping Name: Corrosive liquid, acidic, inorganic, n.o.s., sulfuric acid.

Other components: ADR/RID Class: None

Maritime Transport IMDG:

1N Sulfuric Acid: IMDG Class: 8

UN Number: UN2796

Packaging Group: II

Shipping Name: Corrosive liquid, acidic, inorganic, n.o.s., sulfuric acid.

Other components: IMDG Class: None

Air Transport ICAO-Ti and IATA DGR:

1N Sulfuric Acid: ICAO/IATA Class: 8

UN Number: UN2796

Packaging Group: II

Shipping Name: Corrosive liquid, acidic, inorganic, n.o.s., sulfuric acid.

Other components: ICAO/IATA Class: None

15 REGULATORY INFORMATION**Product Related Hazard Information:**

Observe the general safety regulations when handling the kit, its components and specimens.

Labeling and classification according to GLOBALLY HARMONISED SYSTEM (GHS), REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (CLP)**Information about limitation of use:**

The kit and its components are for in vitro diagnosis use and for professional use only.

16 OTHER INFORMATION

This MSDS is based on our present knowledge. However, it is intended only as a guide to the appropriate precautionary handling of the kit and its components for professional use. Individuals receiving this MSDS must exercise their independent judgment in determining its appropriateness for a particular purpose.

Notification:

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

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

MSDS established : 2020-01-15**Revision number** : 5