

1. Identification of the substance/preparation and of the company/undertaking

 Gc-globulin (Actin-free) ELISA Kit (KIT 034) (for *in vitro* diagnostic use)

Catalog No: KIT 034

The Gc-globulin (Actin-free) ELISA Kit (KIT 034) is intended by BioPorto Diagnostics to measure Gc-globulin (Actin-free) in human serum or plasma to aid the diagnosis of organ damage and the prognosis of critically ill patients, especially those with acute liver failure including acute liver failure after acetaminophen (paracetamol) overdose, and patients with multiple trauma.


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2. Hazards identification

None of the hazardous reagents are present in an amount that qualifies the products as hazardous according to Directive 67/548/EC.

However exposure to large amounts and/or ingestion can potentially be hazardous.

| Hazard to man | Kit component | 12x8 coated Microwells + Frame ① | 3x Sample Diluent Conc. ② | Gc-globulin Calibrator 1-8 ③a-h | 25x Wash Solution Conc. ④ | HRP-conjugated Gc-globulin (Actin-free) Antibody ⑤ | TMB Substrate ⑥ | Stop Solution ⑦ | Polypropylene U-microwell plate ⑧ |
|--|---------------|-------------------------------------|------------------------------|------------------------------------|------------------------------|---|--------------------|--------------------|--------------------------------------|
| Harmful by inhalation | | | | | X | | | | |
| Harmful in contact with skin and if swallowed | | | | | X | | | | |
| Danger of cumulative effects | | | | | X | | | | |
| Risk of percutaneous absorption. | | | X | X | X | X | | | |
| Risk of sensitization of skin. | | | X | X | X | X | X | X | X |
| Biological risks | | | | X | | | | | |
| Hazard to the environment | | | | | | | | | |
| Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment | | | (X) | (X) | X | (X) | | | |

3. Composition/information on ingredients

The kit contains the following components: 12x8 coated Microwells + Frame, 3x Sample Diluent Conc., Gc-globulin Calibrators 1-8, 25x Wash Solution Conc., HRP-conjugated Gc-globulin (Actin-free) Antibody, TMB Substrate, Stop Solution and Polypropylene U-microwell plate.

No single component contains a hazardous ingredient in an amount that requires labeling. The contents in the components of ingredients listed as hazardous are given below:

| | Component | Ingredient | Concentration | CAS# | EC# | Classification (pure ingredient) | Classification (kit component) |
|------|--|--|----------------------------------|------------|-----------|--|--------------------------------|
| ② | 3x Sample Diluent | Bronidox L (5-bromo-5-nitro-1,3-dioxane 10% in propylene glycol) | 0.06% (w/v) | 30007-47-7 | 250-001-7 | Xn; R22,R38 | NA |
| ③a-h | Gc-globulin Calibrator 1-8 | | 0.02% (w/v) | | | | NA |
| ⑤ | HRP-conjugated Gc-globulin (Actin-free) Antibody | | 0.2% (w/v) | | | | NA |
| ③a-h | Gc-globulin Calibrator 1-8 | Gc-globulin purified from human plasma* | 0-0.00001% (w/v) | - | - | NA, non-reactive for relevant infectious agents* | NA |
| ④ | 25x Wash Solution Conc. | Thimerosal | 0.038% | 54-64-8 | 200-210-4 | Tx; R26/27/28, R33 N; R50/53 | NA |
| ⑥ | TMB Substrate | 3,3',5,5'-tetramethylbenzidine | <0.05% (w/v) in H ₂ O | 54827-17-7 | 259-364-6 | Xn; R22 N; R51/53 | NA |
| ⑦ | Stop Solution | Sulfuric acid | 0.5 mol/L | 7664-93-97 | 231-639-5 | C; R35 | NA |

* The Gc-globulin preparation purified from human plasma has been found to be nonreactive for hepatitis B surface antigen (HBsAg) and antibodies against human immunodeficiency virus (HIV) 1 and 2, and hepatitis C virus (HCV). However, as no test method can offer complete security that infectious agents are absent, the calibrators and patient specimens should be

handled as potentially infectious.

4. First aid measures

First aid personnel should ensure self protection.

After inhalation: Immediately remove the casualty from exposure and move to fresh air. If breathing stops, immediately apply mechanical ventilation and apply an oxygen mask if available. Arrange medical treatment.

After skin contact: Wash off with plenty of water. Remove contaminated clothing. If necessary arrange medical treatment.

After eye contact: Rinse out with plenty of water with the eyelids held wide open. Arrange medical treatment.

After swallowing: Immediately make casualty drink plenty of water, induce vomiting (not if acid is ingested and never in an unconscious patient). Immediately arrange medical treatment.

5. Fire-fighting measures

Data for kit component solutions. Not for individual ingredients.

Suitable extinguishing media

Use water spray, carbon dioxide or foam depending on the surrounding materials and equipment.

Special risks

Non-combustible. Ambient fire may liberate hazardous vapors. The following may develop in event of fire: sulfur oxides or mercury vapors.

6. Accidental release measures

Person-related precautionary measures

Do not inhale aerosols. Immediately change contaminated clothing.

Environmental-precautionary measures

Do not allow to enter sewerage system. Contain spill.

Procedures for cleaning/absorption

Take up with liquid-absorbent material. Forward for disposal. Clean up and disinfect affected area.

7. Handling and storage

Handling

Cannot be stored indefinitely. Expiry date is printed on labels.

General good laboratory practice should be maintained. Handle calibrators and unknown samples as potentially infectious.

Take care to keep workplace clean and dry. The substances used should not be present at the place of work in quantities above those required for carrying out the work. Do not leave containers open. Avoid general contact by handling. Compatible materials: glass, plastic.

Storage

Store components in the box with the lids tightly closed. Store all components at 2-8°C.

Specific use

The product is intended for *in vitro* diagnostic or research use only.

Intended for professional use only.

8. Exposure controls/personal protection

Data for kit components solutions (not for individual ingredients).

Personal protective clothing

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled.

Respiratory protection

Required only in unintentional release of the substance.

Eye protection

Required.

Skin protection

Required. Wear laboratory coat and protective gloves. The glove material must be sufficient impermeable and resistant to the substance. Check the tightness before wear. Protect the skin. The following material is suitable for protective gloves: Nitrile rubber.

General protective and hygienic measures

Foods and beverages should not be consumed in the vicinity of the work area. Wash hands before work breaks and on finishing the work.

9. Physical and chemical properties

Data for kit component solutions (not for individual ingredients)

| | |
|------------------------|--|
| Appearance: | Clear to yellow solutions, odorless |
| pH: | Neutral except for Stop Solution (pH ~0.6) |
| Boiling point: | NA |
| Flash point: | NA |
| Flammability: | NA |
| Explosive properties: | NA |
| Oxidizing properties: | NA |
| Vapor pressure: | NA |
| Relative density: | NA |
| Solubility: | Soluble in water |
| Viscosity: | NA |
| Vapor density: | NA |
| Evaporation rate: | NA |
| Additional parameters: | NA |

10. Stability and reactivity

Stability: Stable. However note expiry date printed on labels. Store at 2-8°C and replace the components at this temperature at the end of the working procedure.

Conditions to avoid: Heating above room temperature, freezing.

Materials to avoid: Generally use only clean glass and plastic suitable for laboratory use for handling the kit components.

Note that individual ingredients are incompatible with strong oxidizing agents, alkaline metals, alkaline compounds, ammonia, alkaline earth metals, (strong) acids, strong bases, metals, metal alloys, combustible compounds, organic solvents, halogenates, permanganates, reducing agents.

Dangerous reactions: In the case of fire see chapter 5.

Further information: Note that Stop Solution contains sulfuric acid (H₂SO₄) and has a corrosive effect.

11. Toxicological information

Because of the small size of the containers and the low concentrations of hazardous ingredients, the toxicological risks are minor.

Toxicological experiments have not been done on the kit components.

The following toxicological information is for the hazardous ingredients in pure form from ChemIdplus:

Thimerosal (ingredient in 25x Wash Solution Conc.)

Thimerosal is a topical antiseptic used on skin and mucous membranes. It is also used as a preservative in pharmaceuticals. Thimerosal acts as an anti-infective agent, fungicide, bactericide, disinfectant, wood preservative, and germicide.

Acute toxicity

After inhalation: Irritation and/or damage of the mucous membranes of respiratory tract.
After swallowing: Irritation of the mouth, throat, and other tissues of the gastrointestinal system can occur.
After skin contact: Irritation of the skin. Danger of skin absorption.
After eye contact: Eye irritation test (rabbit): Slight irritation of the eye.

Systemic effects of thimerosal exposure

Acute: Metallic taste, nausea, vomiting, abdominal pain, bloody diarrhea, intestinal burns, glottal edema, aspiration pneumonia, drop in blood pressure, cardiac arrhythmia, circulatory collapse and renal failure.

Chronic: Inflammation of the mouth with loss of teeth and mercurial line. The principal signs manifest themselves in the CNS (impaired speech, vision, hearing and sensitivity, loss of memory, irritability, hallucinations, delirium).

Animal toxicological data: LD₅₀ (oral, rat): 75 mg/kg.

Human toxicological data: An oral dose of 29 mg/kg caused degenerative changes in the brain, anorexia and changes in motor activity.

An oral dose of 83 mg/kg caused coma, gastritis, renal tubular failure, dermatitis, gingivitis, delirium, polyneuropathy and respiratory failure.

Further toxicological information: Danger of cumulative effects. Long-term exposure leads to damage of the nervous system.

Bronidox L (ingredient in 3x Sample Diluent Conc, Gc-globulin Calibrators and HRP-conjugated Gc-globulin (Actin-free) Antibody):

Few data are available.

Acute toxicity

After inhalation: May be harmful after inhalation and irritate the respiratory tract.
After swallowing: Harmful if swallowed
After skin contact: Irritation of the skin. Danger of skin absorption.
After eye contact: May cause eye irritation.

Effects of Bronidox L exposure: Behavioral (tremor), behavioral (convulsions or effect on seizure threshold), behavioral (excitement), skin and appendages (after systemic exposure: dermatitis, other)

Animal toxicological data: LD₅₀ (oral, mouse): 590 mg/kg, LD₅₀ (oral, rat): 455 mg/kg.

Human toxicological data: No data available.

12. Ecological information**Thimerosal**

Highly toxic for aquatic organisms. May cause long-term adverse effects in the aquatic environment. Hazard for drinking water supplies.

NCLASS data

Toxicity: L(E)C50 < 1mg/L

Degradation: Readily degradable = No

Bioaccumulation: Log Pow = NA, BCF = NA

ECOTOX data

Fish toxicity: *Lepomis macrochirus* (Bluegill) LC₅₀: 110 mg/L (24 h)

Bronidox L

No data available

Further ecological information

Do not allow to enter waters, waste water or soil.

Due to the small size of the containers and the low concentrations of hazardous ingredients, ecological risks are minor.

13. Disposal considerations

Product: Must be disposed in compliance with the respective national regulations.

Packaging: Must be disposed in compliance with the respective national regulations.

14. Transport information

No special transport regulations

ADR (road)/ RID (rail): NA

IMDG (sea): NA

ICAO / IATA (air): NA

15. Regulatory information


No single component contains a hazardous ingredient in an amount that requires identification and labeling according to EC directives.

16. Other information

For in vitro diagnostic use in the European Union only. For research use only in the rest of the world.

Read instructions for use before using the product. Observe the general safety regulations when handling chemicals. Good laboratory practice is the best preventive measure to avoid hazards.

The information above is believed to be accurate and represents the best information currently available to us. Data are predominantly from the NCLASS, Ecotox and ChemIdplus databases and the Merck Index.

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