

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

 NGAL Rapid ELISA Kit (KIT 037) (for *in vitro* diagnostic use)

Catalog No: KIT 037

The NGAL Rapid ELISA Kit (KIT 037) is intended by BioPorto Diagnostics to measure human NGAL in urine, plasma or serum as a marker of acute renal injury which may lead to acute renal failure.


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2. Hazards identification

Only the kit component ② 5x Sample Diluent Conc. contains a hazardous reagents present in an amount that qualifies the products as hazardous according to Directive 67/548/EC. This component is labeled harmful (Xn). This pertains to contact with skin and if swallowed. The 5x Sample Diluent Conc. is harmful to aquatic organisms and may cause long-term adverse effects in the aquatic environment.

According to EU regulations, no danger labeling is necessary for the diluted solution or all other kit components. However exposure to large amounts and/or ingestion can potentially be hazardous.

Kit component	① 12x8 coated Microwells + Frame	② 5x Sample Diluent Conc.	③a-f NGAL Rapid Calibrator 1-6	④ 25x Wash Solution Conc.	⑤ HRP-conjugated NGAL Antibody	⑥ TMB Substrate	⑦ Stop Solution	⑧ Polypropylene U-Microwell Plate
Hazard to man								
Harmful by inhalation		X	X	X				
Harmful in contact with skin and if swallowed		X	X	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	
Hazard to the environment								
Harmful to aquatic organisms, may cause long-term adverse effects		X	X	X	(X)			

3. Composition/information on ingredients

The kit contains the following components: 12x8 coated Microwells + Frame, 5x Sample Diluent Conc., NGAL Rapid Calibrators 1-6, 25x Wash Solution Conc., HRP-conjugated NGAL Antibody, TMB Substrate, Stop Solution and Polypropylene U-Microwell Plate.

Only the kit component ② 5x Sample Diluent Conc. contains a hazardous reagent 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	5x Sample Diluent Conc.	Sodium azide	0.25% (W/v)	26628-22-8	247-852-1	Tx; R28, R38 N; R50/53	Xn; R21/22, R52/53
③a-f	NGAL Rapid Calibrator 1-6		0.05% (w/v)				NA
③a-h	NGAL Rapid Calibrator 1-6	Recombinant NGAL produced in non-hazardous <i>E. coli</i> bacteria and subsequently purified	0-0.000002% (w/v)	-	-	NA, Biologic	NA
④	25x Wash Solution Conc.	Thimerosal	0.038%	54-64-8	200-210-4	Tx; R26/27/28, R33 N; R50/53	NA
⑤	HRP-conjugated NGAL Antibody	Bronidox L (5-bromo-5-nitro-1,3-dioxane 10% in propylene glycol)	0.2% (w/v)	30007-47-7	250-001-7	Xn; R22,R38	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

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, dry sand, 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, mercury vapors, nitrous gases or nitrogen oxides.

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, heavy metals, metallic salts, dimethylsulfate/acid, dichloromethane, carbon disulfide.

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:

Sodium azide (ingredient in 5x Sample Diluent Conc. and NGAL Rapid Calibrators)

Sodium azide is a cytochrome oxidase inhibitor which is a nitridizing agent and an inhibitor of terminal oxidation (Merck Index, 12th ed). Sodium azide acts as a fungicide, bactericide, herbicide, insecticide and nematocide.

Acute toxicity

After inhalation: Severe irritation of mucous membranes, respiratory tract. Possible damages: pulmonary edema. Latency time until onset of action.
After swallowing: Irritations of mucous membranes in the mouth, pharynx, esophagus and gastrointestinal tract.
After skin contact: Slight irritations. Danger of skin absorption.
After eye contact: Eye irritation test (rabbit): Slight irritation of the eye.

Systemic effects of azide exposure: CNS disorders (tremor on long-term exposure), cardiovascular failure, tachycardia, drop in blood pressure, coughing, dyspnea, spasms, headache, dizziness, nausea, vomiting, collapse, unconsciousness.

Animal toxicity data: LD₅₀ (dermal, rabbit): 20 mg/kg, LD₅₀ (oral, rat): 27 mg/kg.

Human toxicity data: An oral dose of 0.71 mg/kg caused general anesthetic effect and depressed activity as well as changed activity in the kidney, ureter and bladder.

An oral dose of 29 mg/kg caused increased intracranial pressure, change in pulse rate and acute pulmonary edema.

An oral dose of 129 mg/kg caused coma and death within 4 hours.

Further toxicological information: No teratogenic effect in animal experiments.

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 HRP-conjugated NGAL 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

Sodium azide

Highly toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment. Forms toxic mixtures in water, dilution measures notwithstanding. Herbicidal effect. Nematocidal effect.

NCLASS data:

Toxicity: Proposed 0.1 mg/L < L(E)C50 < 1 mg/L

Degradation: Readily degradable = No

Bioaccumulation: Log Pow = NA, BCF = NA

ECOTOX data

Algal toxicity: *Dunaliella tertiolecta* (green algae) EC₅₀: 2 mg/L (24 h), *Macrocystis pyrifera* (giant kelp) EC₅₀: 1.1 mg/L (24 h)

Crustacean toxicity: *Daphnia pulex* (water flea) EC₅₀: 4.2 mg/L (48 h)

Fish toxicity: *Lepomis macrochirus* (bluegill) LC₅₀: 0.7 mg/L (96 h)

Plant toxicity: *Lemna minor* (duckweed): 64 µg/L (24 h)

Insect toxicity: *Pteronarcys californicus* (stonefly) LC₅₀: 9 mg/L (96 h)

Invertebrate toxicity: *Microregma* sp. (ciliated protozoa): 3 mg/L

Mollusc toxicity: *Mytilus californianus* (mussel): EC₅₀: 13.2 mg/L (96 h)

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 < 1 mg/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
Classification:

② 5x Sample Diluent Conc.



Xn = Harmful

No danger labeling is required for the diluted solution

Risk phrases:

R21/22: Harmful in contact with skin and if swallowed.

R52/53: Harmful to aquatic organisms and may cause long-term adverse effects in the aquatic environment.

Safety Phrases:

S35: Dispose of containers and unused contents in a safe way

S45: In case of accident or if you feel unwell, seek medical advice immediately (show the labeling where possible)

S61.: Avoid release into the environment.


No other kit 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, Canada and India 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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