

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

APC-PCI ELISA Kit (KIT 040)

Catalog No: KIT 040

The APC-PCI ELISA Kit (KIT 040) is intended by BioPorto Diagnostics for the measurement of activated protein C – protein C inhibitor complex in human plasma. For Research Use Only. Not for use in diagnostic procedures.


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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.

Kit component	① 12x8 coated Microwells + Frame	② Sample Diluent	③ APC-PCI Calibrator	④ 25x Wash Solution Conc.	⑤ Biotinylated Protein C Antibody	⑥ HRP-Streptavidin	⑦ TMB Substrate	⑧ Stop Solution
<b>Hazard to man</b>								
Harmful by inhalation, in contact with skin and if swallowed		X	X	X	X	X	X	
Danger of cumulative effects		X	X		X			
Causes burns						X		X
May cause sensitization or irritation by skin contact				X				
Biological risks		X	X		X			
<b>Hazard to the environment</b>								
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.		X	X		X	X	X	

**3. Composition/information on ingredients**

The kit contains the following components: 12x8 coated Microwells + Frame, Sample Diluent, 2 vials of freeze-dried APC-PCI Calibrator, 25x Wash Solution Conc., Biotinylated Protein C Antibody, HRP-Streptavidin, TMB Substrate and Stop Solution.

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	Sample Diluent	Thimerosal	0.02% (w/v)	54-64-8	200-210-4	Tx; R26/27/28, R33 N; R50/53	NA
③	APC-PCI Calibrator						
⑤	Biotinylated Protein C Antibody						
③	APC-PCI Calibrator	Recombinant APC PCI purified from human plasma	0.0000001% (w/v)	-	-	NA,	Handle at Biosafety level 2*
④	25X Wash Solution Conc.	Bronidox (5-bromo-5-nitro-1,3-dioxane)	0.01% (w/v)	30007-47-7	250-001-7	Xn; R22,R38	NA
⑥	HRP-Streptavidin	Kathon (3:1 mixture of: 5-chloro-2-methyl-thiazol-3-one 2-methylthiazol-3-one)	0.00012% (w/v)	55965-84-9	-	T; R23/24/25 C; R34-43 N; R50/53	NA
②	Sample Diluent	Bovine Serum Albumin or bovine IgG	-	-	-	NA, US Origin	NA
③	APC-PCI Calibrator						
⑤	Biotinylated Protein C Antibody						
⑥	HRP-Streptavidin						
⑦	TMB Substrate	3,3',5,5'-tetramethylbenzidine	<0.05% (w/v) in H <sub>2</sub> O	54827-17-7	259-364-6	Xn; R22 N; R51/53	NA
⑧	Stop Solution	Sulfuric acid	0.5 mol/L	7664-93-97	231-639-5	C; R35	NA

\* CDC/NIH manual "Biosafety in Microbiological and Biomedical Laboratories", current Edition.

#### 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. 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, mercury vapors, carbon oxides, nitrogen oxides or hydrogen chloride gas.

#### 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 research use only. Not for use in diagnostic procedures.

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 in aerosol form.

**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 or yellow to red 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. Reconstituted calibrator material remains stable for 24 hours at 2-8°C. If longer storage is wanted, it can be frozen at -20°C. Will stand up to 5 freeze-thaw cycles.

**Conditions to avoid:** Heating above room temperature, freezing (for freezing of calibrator material, see above).

**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, (strong) acids, strong bases, reducing agents and aluminum.

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

**Further information:** Note that Stop Solution contains sulfuric acid (H<sub>2</sub>SO<sub>4</sub>) 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 Sample Diluent, APC-PCI Calibrator and Biotinylated PC Antibody)**

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:** LD<sub>50</sub> (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 25x Wash Solution Concentrate):**

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:** LD<sub>50</sub> (oral, mouse): 590 mg/kg, LD<sub>50</sub> (oral, rat): 455 mg/kg.

**Human toxicological data:** No data available.

**Kathon (ingredient in HRP-Streptavidin):**

Kathon is a broad spectrum biocide and used in cosmetic preservative formulation, particularly in rinse-off products such as shampoos and conditioners.

**Acute toxicity**

After inhalation: Destructive to the mucous membranes of respiratory tract.  
After swallowing: May be harmful if swallowed.  
After skin contact: Causes burns. Danger of skin absorption.  
After eye contact: Causes burns.

**Systemic effects of thimerosal exposure**

Spasm, inflammation and edema of the bronchi, chemical pneumonitis and pulmonary edema. Burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea and vomiting.

**Animal toxicological data:** LD<sub>50</sub> (oral, mouse): 60 mg/kg, LD<sub>50</sub> (oral, rat): 53 mg/kg.

**Human toxicological data:** No data available.

**12. Ecological information****Thimerosal**

Very toxic to 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) LC<sub>50</sub>: 110 mg/L (24 h)

**Bronidox L**

No data available

**Kathon**

Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

Very few data available.

*NCLASS data*

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

Degradation: Readily degradable = NA

Bioaccumulation: Log Pow = NA, BCF = NA

*ECOTOX data*

Invertebrate toxicity: *Acanthamoeba hatchetti* (Amoeba) LOEC: 16.5 mg/L (24 h)

**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 research use only. Not for use in diagnostic procedures.

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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