



**BIOLABO**  
 www.biolabo.fr  
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# BIO-CK APTT Kaolin

Reagent for the determination of activated partial thromboplastin time (APTT) in human plasmas

REF	13560	R1	6 x 3 mL
REF	13570	R1	6 x 10 mL



**Made In France**

## TECHNICAL SUPPORT AND ORDERS

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Latest revision: www.biolabo.fr

I: corresponds to significant modifications

## INTENDED USE

I This reagent is designated for professional use in laboratory (semi-automated or automated method). It allows the determination of activated partial thromboplastin time (APTT) in human plasmas.

## GENERALITIES (1)

BIO-CK Reagent is a basic coagulation screening test, useful to investigate the intrinsic coagulation pathway (factors XII, XI, IX, VIII, X, V, II and I) except the platelets.

The main application of the APTT is to monitor heparin therapy. APTT is also used to detect congenital and acquired deficiencies related to the factors mentioned above.

Prolonged APTT may require further investigations related to congenital or acquired deficiencies.

## PRINCIPLE (4)

The BIO CK reagent involves recalcification of plasma in the presence of standardised amount of cephalin (platelet substitute) and a factor XII activator (Kaolin). The use of Kaolin minimizes reading time and optimizes the optical detection.

## REAGENTS (3)

**R1** **BIO-CK** Freeze dried Reagent

Cephalin (Rabbit cerebral tissues)

Kaolin

According to 1272/2008 regulation, this reagent is not classified as dangerous.

## SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

## REAGENTS PREPARATION

Vial R1: Use a non-sharp instrument to remove the cap.

Transfer immediately the volume of demineralized water indicated in vial R1.

Mix gently until complete dissolution

## STABILITY AND STORAGE

**Stored away from light, well capped in the original vial at 2-8°C, and used as described, reagents are stable:**

Unopened:

- Until expiry date stated on the label of the kit

Once opened:

- Reconstitute immediately the contents of vial R1.
- Transfer requested quantity, well recap vials and store at 2-8°C
- Working reagent is stable for:
  - ✓ 8 hours at room temperature
  - ✓ 30 days at 2-8°C

Don't use working reagent after expiry date.

## SPECIMEN COLLECTION AND HANDLING (1) (6)

- Careful venipuncture:
- Blood/anticoagulant ratio: 4.5 mL of blood for 0.5 mL of trisodium citrate 2 H<sub>2</sub>O 0.109 M.
- Avoid blood drawing with a syringe that could result in the formation of micro-clots.
- Centrifuge for 10 minutes at 2500 g as soon as possible and run the assay within 3 hours following the blood collection.
- Use plastic disposable test tubes to store plasmas refrigerated before testing.
- Patient's specimen on heparin therapy: centrifuge and run the assay within 1 hour following the blood collection.
- Simultaneously prepare a pool of at least 2 freshly drawn normal plasmas as reference.

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Medical analysis laboratory equipment
2. Automated or semi-automated coagulation analyzer
3. Demineralised water for preparation of reagent
4. REF 13565: Calcium chloride 0.025 M

## LIMITS (2) (4) (5)

- Heparin, depending on its origin and composition (calcium or sodium salt) has a different influence on the sensitivity of reagent.
- Mishrahi and al. indicate an easy procedure to determine the sensitivity of the method used in each laboratory and to inform the clinician in order to optimize the posology.

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with

