

COAMATIC® Protein C - 82 2098 63

**Intended use**

This kit is for the quantitative determination of Protein C activity in human citrated plasma.

Background and summary

Protein C is a vitamin K dependent plasma protein which plays an important role in the anticoagulant regulatory mechanisms. It circulates as a zymogen and is converted to an active serine protease, activated Protein C (APC), by the action of thrombin in presence of thrombomodulin. APC regulates the coagulation system by proteolytic cleavage and inactivation of activated factors V and VIII. Hereditary and/or acquired Protein C deficiency has been shown to be a risk factor for development of venous thrombosis.

Measurement principle

Protein C in plasma is activated by a specific enzyme from Southern Copperhead Snake venom. The amount of activated protein C is determined by the rate of hydrolysis of the chromogenic substrate S-2366. The pNA release measured at 405 nm is proportional to the Protein C level in the range from 0-120% of normal plasma.

**Reagents**

1. S-2366 6 mg 2 vials
Lyophilized chromogenic substrate pyroGlu-Pro-Arg-pNA-HCl.

2. Protein C activator 1.2 U 2 vials
Lyophilized venom enzyme from Southern Copperhead Snake (Agkistrodon Contortrix Contortrix), with bovine serum albumin (stabilizer) and Ciprofloxacin® (preservative).

PRECAUTION AND WARNINGS

S-2366:

- Hazard class: **none**
 - Risk phrases: **none**
 - Safety phrases: **none**
- Protein C Activator:
- Hazard class: **Xn** (Harmful)
 - Risk phrases: **May cause sensitization by inhalation and skin contact (R42/43)**
 - Safety phrases: **Do not breathe dust (S22)**
Wear suitable protective clothing and gloves (S36/37)
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible) (S45)
In case of accident by inhalation: remove casualty to fresh air and keep at rest (S63)

Protein C activator 1.2 U contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.
This product is for *in vitro* diagnostic use.

Reagent preparation

For microplate and test tube techniques reconstitute each reagent with 7.2 mL of water (see REAGENTS 3.) Replace the stopper and swirl gently. Make sure of the complete reconstitution of the product. Keep reagent at 15-25°C for 10-30 min and invert before use.

NOTE: Other reagent reconstitution volumes may apply for automated methods. Reagents are not interchangeable between lots.

Reagents required but not provided

3. Deionized water, filtered through 0.22 µm or NCCLS type II water^a.

4. Human normal plasma with a Protein C activity of 100%.

Different standard dilutions are obtained by diluting normal plasma with water (see REAGENTS 3). A lyophilized preparation of human normal plasma, calibrated against International standard for Protein C is recommended.

5. Acetic acid 20% or citric acid 2%.

Materials required but not provided:

— Spectrophotometer 405 nm (405 nm and 490 nm for microplate procedure)

— Incubator 37°C ± 0.2°C

— Microplates[®] or semi-micro cuvettes

— Centrifuge, 2000 x g

— Plastic test tubes

— Stopwatch

— Vortex mixer

— Calibrated pipettes

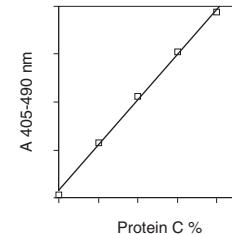
— Linear graph paper

*NOTE: Do not use microplates intended for coating!

ENGLISH - Insert revision 08/2011

Calculation

Plot the absorbance (A) for the standard samples against their protein C activity on linear graph paper. Plot A on the Y axis and % protein C on the X axis. Connect the standard points with the best fitting straight line. Samples are evaluated based on this standard curve. An example of a typical standard curve (microplate method) is shown below.



Protein C %

Performance Characteristics**Limitations/interfering factors**

Addition of anti-human Protein C antibodies to normal plasma inhibits >98% of the amidolytic activity. Heparin levels ≤ 3 IU/mL do not interfere in the assay. Aprotinin inhibits activated Protein C. A low Protein C activity in aprotinin treated patients is thus expected.

Sample blank activities should be determined and subtracted in plasmas from patients on Streptokinase therapy as well as in plasmas where contact factor activation is suspected, such as in plasmas from DIC patients or from individuals on oral contraceptives where cold activation may occur. The sample blank activity is determined by substituting the Protein C activator with the same volume of sterile water.

Precision

The repeatability of the method has been determined on Cobas Mira.

Mean activity	Within run CV (%)	Mean activity	Between runs CV (%)
99%	0.8% n=21	103%	1.7% n=5 N=7
47%	1.6% n=21	49%	2.8% n=5 N=7

n=number of replicates per series, N=number of series

These results have been obtained at Chromogenix laboratories and should be considered as examples only. Other laboratories are requested to establish their own precision data.

Correlation

The assays show a strong correlation with Coatest Protein C:

% PC (Coamatic) = 8.2 + 0.99x (Coatest) r=0.98 n=45

% PC (Cobas Mira) = 3.7 + 0.98x (Coatest) r=0.99 n=49

% PC (Cobat Mira) = 3.7 + 0.98x (Coatest) r=0.97 n=45

% PC (ACL) = 0.3 + 1.07x (Coatest) r= 0.97 n=45

Recommended measuring range

The relationship between released pNA, measured as absorbance at 405 nm, and the level of Protein C is linear in the 0-120% range of normal plasma.

Detection limit

The assays allow detection of at least 5% Protein C.

Sensitivity:**System:**

Cobas Mira ΔAbs per 1% Protein C activity: 0.0013 ΔAbs

Determinations/kit

Microplate method: 2 x 144 Test tube method: 2 x 36

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PORTEGUÉS - Revisão do folheto 08/2011



Para a revisão actual deste folheto informativo em Português, contacte o representante da Chromogenix da sua área.

PRECAUÇÕES E ADVERTÊNCIAS: S-2366:

- Classe de risco: **nenhuma**
- Frases de risco: **nenhuma**
- Frases de segurança: **nenhuma**

Protein C Activator:

- Classe de risco: **Xn (Nocivo)**
- Frases de risco: Pode causar sensibilização por inalação e em contacto com a pele (R42/43)
- Frases de segurança: Não respirar as poeiras (S22)
Usar vestuário de protecção e luvas adequadas (S36/37)
Em caso de acidente ou de indisposição, consultar imediatamente o médico (se possível mostrar-lhe o rótulo) (S45)
Em caso de acidente ou de indisposição, consultar imediatamente o médico (se possível mostrar-lhe o rótulo) (S45)
Em caso de acidente ou de indisposição, remover a vítima da zona contaminada e mantê-la em repouso (S63)

Protein C activator 1.2 U contém material bovino. Todos os dadores animais foram fornecidos a partir de manadas sem BSE. O gado recebeu uma inspecção de saúde ante- e post-mortem, efectuada por um veterinário, e aparentemente não tinham material infetioso e contagioso. Contudo, o material deve ser tratado como potencialmente infetioso.

Este reagente destina-se à utilização em diagnóstico *in vitro*.

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SVENSK - Instick revision 08/2011



För aktuell revision av detta insticksblad på svenska ber vi Er att kontakta Chromogenix distributör.

FÖRSIKTIGHETSÄTGÄRDER OCH VARNINGAR: S-2366:

- Faroklass: **Ingen**
- Riskfraser: **inga**
- Skyddsfrazer: **inga**

Protein C-aktivator:

- Faroklass: **Xn (Hälsovårdsfel)**
- Riskfraser: Kan ge allergi vid inandning och hudkontakt (R42/43)
- Skyddsfrazer: Undvik inandning av damm (S22)
Använd lämpliga skyddskläder och skyddshandskar (S36/37)
Vid olyckstillfall, illamående eller annan påverkan, kontakta ommedelbart läkare, Visa om möjligt etiketten (S45)
Vid olyckstillfall via inandning, flytta den drabbade till frisk luft och låt vila (S63)

Protein C-aktivator 1.2 U innehåller bovint material. Alla donatordjur kom från BSE-fria hjordar. Nötkreaturen hälsas kontrollerades ante och post mortem av en veterinär och de var uppbenbarligen fria från infektiöst och smittsamt material. Materialet skall dock betraktas som potentially infektiöst.

Denna produkt är för *in vitro* diagnostiskt användande

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DANSK - Metodeforskrift revision 08/2011



Venligst rekvirer den gældende udgave af metodeforskriften på dansk fra den lokale Chromogenix distributør.

ADVARSEL: S-2366:

- Hazard class: **Ingen**
- Risk phrases: **Ingen**
- Safety phrases: **Ingen**

Protein C Activator:

- Hazard class: **Xn (Sundhedsskadelig)**
- Risk phrases: Kan give overførsomhed ved indånding og ved kontakt med huden (R42/43)
- Safety phrases: Undgå indånding af stov (S22)
Brug særtilpassede arbejdstøj og egne beskyttelseshandsker (S36/37)
Ved ulykkesfaldelle der ved tilbedriften er omgående lægebehandling nødvendig; vis etiketten, hvis det er muligt (S45)
Ved ulykkesfaldelle ved indånding bringes tilskadekomne ud i frisk luft og holdes i ro (S63)

Protein C activator 1.2 U indeholder bovint materiale. Alle donor-dyr stammer fra BSE-frie besætninger. Hver kval undergik ante- og post mortem helbredsundersøgelser af en dyrlæge og blev fundet hverken infektiøse eller smitsomme. Dog bør materialet behandles som potentielt infektiøst. Dette produkt er til *in vitro* diagnostisk anvendelse.

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Symbols used / Verwendete Symbole / Símbolos utilizados / Symboles utilisés / Simboli impiegati / Símbolos utilizados / Χρηματοποιηθεντά σύμβολα

IVD

In Vitro Diagnostic Medical Device

In Vitro Diagnostikum

Dispositif medical de diagnostic in vitro

Producto sanitario para diagnóstico in vitro

Dispositivo medicodiagnóstico in vitro

Dispositivo médico para utilização em diagnóstico in vitro

Medicinsk udstyr til in-vitro-diagnostik

In vitro diagnostisk medicinsk produkt

Πρόϊστο για διαγνωστική

χρήσης

LOT

Batch code

Chargenbezeichnung

Código de lote

Code du lot

Codice del loto

Número de lote

Batchkoden

Tillverkningskod

Ap. Παρτίδας



Use by

Verwendbar bis

Fecha de

caducidad

Utiliser jusque

Utilizzare entro

Data límite de

utilização

Anwendungsdato

Anwendung

Χρήσης έως



Temperature limitation

Zulässiger

Temperaturbereich

Limite de temperatura

Limites de température

Limite di temperatura

Limite de temperatura

Temperaturbegrenzung

Temperatur gräns

Περιορισμός

Θερμοκρασίας



Consult instructions for use

Gebrauchsanweisung beachten

Consulte las instrucciones de uso

Consulter les instructions d'utilisation

Consultare le istruzioni per l'uso

Consultar as instruções de utilização

Se instruktion for bruk

Ta del av instruktioner före användning

Συμβουλεύεται τις οδηγίες

χρήσης

CONTROL

Control

Kontrollen

Control

Contrôle

Controllo

Control

Kontroll

Kontroll

Yliko ποιοτικού

ελέγχου



Manufacturer

Hersteller

Fabricante

Fabricant

Fabbricante

Fabrikant

Producent

Tillverkare

Kataskeusastής

EC REP

Authorised Representative in the European Community

Bevollmächtigter in der Europäischen Gemeinschaft

Representante autorizado en la Comunidad Europea

Mandatário dans la Communauté européenne

Mandatario nella Comunità Europea

Representante autorizado Representant i det

Europæiske Fællesskab

Auktorisera representant

Εξουσιοδοτημένος αντιπρόσωπος

CHROMOGENIX

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