

V-DEF Plasma

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ENGLISH - Insert revision 05/2002



Intended use

As a prediluent of plasma samples in connection with the use of Coatest APC Resistance V/V-S. Predilution allows for determination of resistance to activated protein C, caused by the factor V:Q506 (factor V Leiden) mutation, in plasma from untreated individuals and from patients on oral anti-coagulant (OAC) or heparin therapy.

Reagent

V-DEF Plasma 5 vials

Stabilized, lyophilized human plasma, with a low level of FV activity, containing the heparin antagonist Polybrene®. Reconstitute with 4.0 mL of deionized water, filtered through 0.22 µm or NCCLS type II water.¹ Allow to stand for 30 minutes at 20-25°C. Swirl gently before use.

CAUTION: Each donor unit used in the preparation of human source reagent has been tested by FDA approved methods for the presence of Hepatitis B surface antigen and antibodies to HIV 1 and 2 and Hepatitis C and found to be negative. However, since no test can completely rule out the presence of these blood borne diseases, the handling and disposal of human source reagents from this product should be made with care.

Avoid contact with skin and eyes (S24/25).

Do not empty into drains (S29).

Wear suitable protective clothing (S36).

This product is for *in vitro* diagnostic use.

Storage conditions and stability

The sealed, lyophilized reagent is stable at 2-8°C until the expiry date printed on the label. Avoid contamination of the reconstituted reagent by microorganisms.

The reconstituted reagent is stable for 8 hours at 15-25°C, 24 hours at 2-8°C and for 3 months at -20°C or below.






The frozen reagent should be thawed at 37°C and gently mixed before use. Do not refreeze.

Bibliography / Literatur / Bibliografía / Bibliographie / Bibliografia / Bibliografia / Litteratur / Litteraturförteckning / Βιβλιογραφία

1. National Committee for Clinical Laboratory Standards. Specifications for reagent water used in the clinical laboratory, NCCLS Approved Standard: ASC-3

EP 0 690 991; Australia 690 535; New Zealand 261 190.
Additional patents pending.

Symbols used / Verwendete Symbole / Símbolos utilizados / Symboles utilisés / Simboli impiegati / Símbolos utilizados / Anvendte symboler / Använda Symboler / Χρησιμοποιηθέντα σύμβολα

<p>IVD</p> <p><i>In vitro</i> diagnostic medical device <i>In-vitro</i> Diagnostikum De uso diagnóstico <i>in vitro</i> Dispositif médical de diagnostic <i>in vitro</i> Per uso diagnostico <i>in vitro</i> Dispositivo médico para utilização em diagnóstico <i>in vitro</i> "in vitro" diagnostisk udstyr <i>In vitro</i> diagnostisk medicinsk produkt Προϊόν για διαγνωστική χρήση <i>In vitro</i></p>	<p>LOT</p> <p>Batch code Chargen-Bezeichnung Identificación número de lote Désignation du lot Numero del lotto Número de lote Batch nr. Tillverkningskod Αρ. Παρτίδας</p>	<p></p> <p>Use by Verwendbar bis Caducidad Utilisable jusqu'à Da utilizzare prima del Data limite de utilização Anvendelse Användning Χρήση έως</p>	<p></p> <p>Temperature limitation Beilage beachten Temperatur Consultar la metódica Lire le mode d'emploi Vedere istruzioni per l'uso Consultar as instruções de utilização Se vejledning for anvendelse Ta del av instruktionen före användning Συμβουλευτείτε τις οδηγίες χρήσης</p>	<p></p> <p>Consult instructions for use Beilage beachten Temperatur Consultar la metódica Lire le mode d'emploi Vedere istruzioni per l'uso Consultar as instruções de utilização Se vejledning for anvendelse Ta del av instruktionen före användning Συμβουλευτείτε τις οδηγίες χρήσης</p>	<p>CONTROL</p> <p>Control Kontrollen Control Contrôle Controllo Controlo Kontrol Kontroll Υλικό ποιοτικού ελέγχου</p>	<p></p> <p>Biological risks Biologisches Risiko Riesgo biológico Risque biologique Rischio biologico Risco biológico Miljø oplysninger Biologiska risker Βιολογικοί κίνδυνοι</p>	<p></p> <p>Manufacturer Hergestellt von Fabricado por Fabricant Produto da Fabricado por Producent Tillverkare Κατασκευαστής</p>	<p>EC REP</p> <p>Authorised representative Bevollmächtigter Representante autorizado Mandataire Rappresentanza autorizzata Representante autorizado Leverandør Auktoriserad representant Εξουσιοδοτημένος αντιπρόσωπος</p>
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