

Liquid AT Substrate - 0020002600

Intended use

Chromogenic substrate to be used in combination with the Liquid Antithrombin kit (Cat. No. 0020002500) for the quantitative determination of Antithrombin in human citrated plasma on the IL Coagulation Systems.

Summary and principle

Antithrombin (AT) or Heparin Cofactor I is the major inhibitor of blood coagulation and is essential for effective heparin therapy. By inhibiting the coagulation proteases, especially thrombin, FXa and FIXa, AT prevents uncontrolled coagulation. Antithrombin deficiency is associated with a high risk of thromboembolic disorders.^{1,2,3}

The Liquid AT Substrate kit, in conjunction with the Liquid Antithrombin kit, can be used to exclude or diagnose hereditary deficiency^{4,5} in patients with a tendency toward thromboembolism, in pre-operative stages, before prescription of oral contraceptives, DIC⁶, nephrotic syndrome, liver diseases,⁷ and in therapy with heparin or antithrombin concentrates.^{8,9}

Composition

The **Liquid AT Substrate** kit consists of:

- S** **Chromogenic substrate** (Cat. No. 0020002520): 6 x 2 mL vials of the chromogenic substrate S-2765, N- α -Z-D-Arg-Gly-Arg-pNA:2HCl (6 mg/vial), surfactant and buffer.

PRECAUTIONS AND WARNINGS:

Avoid contact with skin and eyes (S 24/25). Do not empty into drains (S 29). Wear suitable protective clothing (S 36).

This product is For *in vitro* Diagnostic Use.

Preparation

Invert to mix before use.

Reagent storage and stability

Unopened reagent is stable until the expiration date shown on the vial when stored at 2-8°C.

Opened reagent is stable: 5 weeks at 2-8°C in the original vial, 48 hours at 15-25°C on the ACL® 8000/9000/10000, 8 hours at 15-25°C on the ACL Classic or 48 hours at 15°C on the ACL Futura® and ACL Advance Systems. Do not freeze.

For optimal stability remove reagent from the system and store it at 2-8°C in the original vial.

Instrument/test procedures

Refer to the appropriate IL instrument's Operator's Manual, Application Manual and/or the Liquid Antithrombin kit (Cat. No. 0020002500) insert for the complete assay procedure instructions.

Specimen collection and preparation

Nine parts of freshly drawn venous blood are collected into one part trisodium citrate. Refer to NCCLS Document H21-A4 for further instructions on specimen collection, handling and storage.¹⁰

Additional reagents and control plasmas

The following are not supplied with the kit and must be purchased separately.

	Americas and Pacific Rim Cat. No.	Europe Cat. No.
Liquid Antithrombin	0020002500	0020002500
Calibration plasma	0020000000	0008467300
Normal Control	0020003120	0020003110
Special Test Control Level 1	0020010100	0020010100
Special Test Control Level 2	0020010200	0020010200
Low Abnormal Control	0020003220	0020003210
High Abnormal Control	0020003320	0020003310
Factor diluent	0009757600	0009757600
Cleaning solution	0009831700	0009831700
Cleaning agent	0009832700	0009832700

Quality Control/Results/Limitations/Expected Values/
Performance characteristics

Refer to the Liquid Antithrombin kit insert for performance characteristics.






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

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3. Harper PL, Luddington RJ, Daly M. The Incidence of Dysfunctional Antithrombin Variants: Four Cases in 210 Patients with Thromboembolic Disease, Br. J. Haematol. 1991; 77: 360-364.
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7. Knot E, Ten Cate JW, Drijfhout HR, Kahlé LH, Tytgat GN. Antithrombin III Metabolism in Patients with Liver Disease, J. Clin. Pathol. 1984; 37: 523-530.
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9. Schwartz RS, Bauer KA, Rosenberg RD, Kavanaugh EJ, Davies DC, Bogdanoff DA. Clinical Experience with Antithrombin III Concentrate in treatment of Congenital and Acquired Deficiency of Antithrombin, Am. J. Med. 1989; 87 (sup 3B): 53-60.
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Issued December 2004

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 Número 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 Festgelegte Temperatur Temperatura de Almacenamiento Températures limites de conservation Limiti di temperatura Limite de temperatura Temperatur begrænsninger Temperatur gräns Περιορισμοί θερμοκρασίας</p>	<p></p> <p>Consult instructions for use Beilage beachten 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 Prodotto 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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