

Liquid Antithrombin XL - 0020003800



Intended use

Automated chromogenic assay for the quantitative determination of Antithrombin in human citrated plasma on the ACL Futura/ACL Advance and ACL TOP 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 and thrombosis. Antithrombin deficiency is associated with a high risk of thromboembolic disorders.^{1,2,3} Liquid Antithrombin XL 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 syndromes, liver diseases⁷ and in therapy with heparin or antithrombin concentrates.^{8,9} The Liquid Antithrombin XL kit is an assay based on a synthetic chromogenic substrate and on FXa inactivation.^{10,11} As a consequence, the method is specific and not influenced by Heparin Cofactor II. Antithrombin levels in patient plasma are measured automatically on IL Coagulation Systems in two stages:

1. Incubation of the plasma with the Factor Xa reagent in the presence of an excess of heparin.
2. Quantification of the residual FXa activity with a synthetic chromogenic substrate. The paranitroaniline released is monitored kinetically at 405 nm and is inversely proportional to the Antithrombin level in the test sample.

Composition

The Liquid Antithrombin XL kit consists of:

S Chromogenic substrate (Cat. No. 0020003820): 4 x 2.5 mL vials of the chromogenic substrate S-2765, N- α -Z-D-Arg-Gly-Arg-pNA·2HCl (7.5 mg/vial), surfactant and buffer.

E Factor Xa reagent (Cat. No. 0020003810): 4 x 6 mL vials of a solution containing bovine Factor Xa (60 nkat/vial), heparin, buffer, bovine serum albumin and preservatives.

PRECAUTIONS AND WARNINGS:

All animal products should be treated as potentially infectious. 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

Chromogenic substrate: Invert to mix before use.

Factor Xa reagent: Invert to mix before use.

Reagent storage and stability

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

Chromogenic substrate - Opened reagent is stable: 5 weeks at 2-8°C in the original vial or 3 days at 15°C on the ACL Futura®, ACL Advance and ACL TOP™ Systems. Do not freeze.

Factor Xa reagent - Opened reagent is stable: 5 weeks at 2-8°C in the original vial or 3 days at 15°C on ACL Futura, ACL Advance and ACL TOP Systems. Do not freeze.

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

Instrument/test procedures

Refer to the IL instrument's Operator's Manual and/or Application Manual 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.¹²

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.
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

Normal and abnormal controls are recommended for a complete quality control program.¹³ Normal control, Low Abnormal Control, High Abnormal Control and Special Test Control Level 1 and 2 are designed for this program. Each laboratory should establish its own mean and standard deviation and should establish a quality control program to monitor laboratory testing. Controls should be analyzed at least once every 8 hour shift in accordance with good laboratory practice. Refer to the instrument's Operator's Manual for additional information. Refer to Westgard *et al* for identification and resolution of out-of-control situations.¹⁴

Results

Antithrombin results are reported in activity (%). Refer to the instrument's Operator's Manual for additional information.

Limitations/interfering substances

Antithrombin results on the ACL Futura/ACL Advance are not affected by heparin (UF heparin or LMW heparin) up to 4 U/mL, α_1 -antitrypsin up to 4 mg/mL, α_2 -macroglobulin up to 7 mg/mL, Heparin Cofactor II up to 4 U/mL, hemoglobin up to 275 mg/dL, bilirubin up to 30 mg/dL and triglycerides up to 900 mg/dL.

Antithrombin results on the ACL TOP are not affected by heparin (UF heparin or LMW heparin) up to 4 U/mL, α_1 -antitrypsin up to 4 mg/mL, α_2 -macroglobulin up to 7 mg/mL, Heparin Cofactor II up to 4 U/mL, hemoglobin up to 150 mg/dL, bilirubin up to 40 mg/dL and triglycerides up to 500 mg/dL.

Expected values

A normal range study was performed using the Liquid Antithrombin XL kit.

System	N	Range (units)
ACL Futura/ACL Advance	44	80 - 123 (% activity)
ACL TOP	127	81 - 137 (% activity)

Ranges were calculated as recommended by NCCLS document C28-A2.¹⁵ These results were obtained using a specific lot of reagent. Due to many variables which may affect results, each laboratory should establish its own normal range.

Performance characteristics

Precision:

Within run and total (run to run and day to day) precision was assessed over multiple runs using both normal and abnormal samples.

ACL Futura/ACL Advance	Mean (% activity)	CV % (Within run)	CV % (Total)
Normal Control	101	2.5	3.4
Low Abnormal Control	32.8	4.4	4.9
High Abnormal Control	21.8	6.4	7.4

ACL TOP	Mean (% activity)	CV % (Within run)	CV % (Total)
Normal Control	108.5	5.7	5.8
Low Abnormal Control	28.4	7.5	8.5
High Abnormal Control	16.9	6.7	10.4

Correlation:

System	n	slope	intercept	r	Comparative method
ACL Futura/ACL Advance	80	1.038	-1.039	0.993	HemosIL Antithrombin
ACL TOP	123	1.03	-1.42	0.966	HemosIL Antithrombin

The precision and correlation results were obtained using specific lots of reagents and controls.

Detection limit:

System	
ACL Futura/ACL Advance	10 (% activity)

Linearity:

System	
ACL Futura/ACL Advance	10 - 120 (% activity)
ACL TOP	10 - 150 (% activity)






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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 Caducidad 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 Número de lote Batch nr. Tillverkningskod Αρ. Παρτίδας</p>	<p></p> <p>Temperature limitation Festgelegte Temperatur Temperatura de Almacenamiento Températures limites de conservation Limiti di temperatura Limite de temperatura Temperatur 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 Συμβουλευτήτε τις οδηγίες χρήσης</p>	<p>CONTROL</p> <p>Control Kontrollen Control Contrôle Controllo Controllo 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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