Liquid Antithrombin - 0020300400, 0020030100

产品名称

通用名称：抗凝血酶测定试剂盒（发色底物法）
英文名称： HemosIL Liquid Antithrombin

包装规格

显色底物：2×2mL，因子Xa试剂：2×2mL；
显色底物：4×4.5mL，因子Xa试剂：4×4.5mL。

预期用途

本试剂盒用于定量检测人枸橼酸盐抗凝血浆中的抗凝血酶。

抗凝血酶（AT）或肝素辅因子 I 是主要的血凝凝血抑制剂，是有效的肝素治疗的关键。抗凝血酶通过抑制凝血蛋白酶，尤其是凝血酶FXa和 FIXa，防止不受控制的凝固和血栓形成。抗凝血酶缺乏症与高血栓栓塞性疾病风险相关。液态抗凝血酶可用于排除或诊断病人的遗传缺陷，主要有血栓前期、处于手术前阶段的、口服避孕药给药前的、弥漫性血管内凝血病、肾病综合征、肝病、用肝素或抗凝血酶浓缩液治疗的病人。

检验原理

液态抗凝血酶试剂盒是一种以合成显色底物和FXa灭活为基础的测定法，该方法具有特异性，结果不受肝素辅因子 II 的影响。

用IL凝血系统测定病人血浆的抗凝血酶水平，有以下2个阶段：

1. 在过量肝素的条件下，血浆和Xa因子反应物进行孵化；
2. 用合成显色底物对残留FXa因子活性进行定量测定。释放出的对硝基苯胺与样品中抗凝血酶水平呈反比，并在405nm下进行动力学监测。

主要组成成分

显色底物：每瓶分别为S-2765, N-α-Z-D-Arg-Gly-Arg-pNA•2HCl (6 mg/瓶或13.5 mg/瓶), 表面活性剂和缓冲液的显色底物。
Xa因子反应物：每瓶装有含牛Xa因子(20 nkat/瓶或45 nkat/瓶)、肝素、缓冲液、牛血清白蛋白和防腐剂的溶液。

产品名称	产品货号
校准品	0020003700
正常值血凝试剂质控品	0020003120
特殊实验质控水平1	0020011000
特殊实验质控水平2	0020012000
低值血凝试剂质控品	0020003220
高值血凝试剂质控品	0020003320
因子测定稀释液	0009757600
清洁液	0009831700
清洗剂	0009832700

储存条件及有效期

2~8°C保存，有效期为36个月。

未启封的试剂置于2~8°C环境时，可保存到标签所示的日期

显色底物--开封的试剂在以下条件是稳定的：原装瓶内2~8°C可保存5周或ACL TOP中15°C可保存48小时。禁止冷冻。

Xa因子反应物--开封的试剂在以下条件是稳定的：原装瓶内2~8°C可保存5周或ACL TOP中15°C可保存48小时。禁止冷冻。

为了保持最佳的稳定性，将反应物从仪器中取出，并在2~8°C下贮存于原装瓶内。

生产日期及失效日期见包装标签。

适用仪器

全自动凝血分析仪（Coagulation Instrument)，型号：ACL TOP。

样本要求

收集9份新鲜抽取的静脉血，加入1份枸橼酸钠。
适用于CLSI （以前为NCCLS）H21-A4文件—标本收集、处理和贮存的进一步说明。

检验方法

试剂准备：
显色底物：使用前颠倒混匀。
Xa因子反应物：使用前颠倒混匀。
质量控制：
正常和异常空白推荐用于全部质量控制方案中。正常值质控、低值质控、高值质控和特殊实验质控水平1和2设计用于本方案中。每个实验室应当建立自己的均值和标准偏差，并建立质量控制方案以监控实验室试验。质控应根据标准实验室规范的要求,至少每8小时测定一次。适用于仪器操作者手册的附加信息，也适用于Westgard等的失控情形的鉴别和分辨。

参考区间

健康人体内抗凝血酶活性水平约在83~128%范围内。新生儿或婴儿体内的抗凝血酶活性水平很低，约1岁时逐渐增强至成年水平；而至16岁时比成人水平稍微高一些。

由于存在很多可能影响结果的变量，每个实验室应该建立自己的正常值范围。

检验结果的解释

抗凝血酶的结果以活性（%）表示。请参阅仪器操作者手册的附加信息。

检验方法的局限性

用ACL TOP测定的抗凝血酶结果，不受肝素（普通肝素或低分子肝素）高达4 U/mL、α_1抗胰蛋白酶高达4 mg/mL、α_2巨球蛋白高达10 mg/mL、肝素辅因子 II 高达4 U/mL、血红蛋白高达500 mg/dL、胆红素高达40 mg/dL和甘油三酯高达2300 mg/dL的影响。

产品性能指标

准确性：使用正常值血凝试剂质控品、特殊质控水平品1和特殊质控水平品2，检测抗凝血酶，所得结果应在质控品给定的靶值范围内。

重复性：使用正常值血凝试剂质控品、特殊质控水平品1和特殊质控水平品2，检测抗凝血酶，所得结果的变异系数（CV）应满足：CV≤10%

批间差：使用三个不同批号的试剂盒各测量正常值血凝试剂质控品、特殊质控水平品1和特殊质控水平品2，检测抗凝血酶，三批试剂盒的批间差应符合： 批间差：CV≤15%

线性：使用试剂盒对高值样本及其按比例稀释样本，检测抗凝血酶，计算线性相关系数应符合:$r^2 \geq 0.9850$。本试剂盒线性范围：10~150%。

注意事项

含有牛源材料。
所有供体动物均来自非BSE群体。兽医对牛死前和死后进行健康检查。它们显然不含有传染物质，不具有传染性。然而，材料应被视为潜在传染物质进行处置。
危险级别：无
风险术语：无
安全术语：无
本产品适用于体外诊断。

参考文献

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3. Zucker S, Cathey MH, West B. Preparation of Quality Control Specimens for Coagulation, Am J. Clin. Pathol. 1970; 53: 924-927.
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5. Holm HA, Abildgaard U, Kalvenes S. Heparin Assays and Bleeding Complications in Deep Venous Thrombosis with Particular Reference to Retroperitonal Bleeding, Thromb. Haemost. 1985; 53: 278-281.

基本信息

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Liquid Antithrombin - 0020300400

사용목적

본 제품은 사람 혈장 (Sodium citrate)에서 안티트롬빈(Antithrombin)을 Chromogenic assay로 검출하는 정량 검사용 체외진단분석기용 시약이다.

사용방법

1. 검체 준비 및 저장방법

- 3.2% Sodium citrate가 들어있는 용기에 정맥혈을 채집하여야 하며, 이때 혈액과 항응고제의 비율은 9:1로 해야 한다.
- 혈장을 얻기 위해 실온에서 1500g 15분간 원심 분리 한다. 이때 원심분리된 혈장의 기준은 platelet poor plasma(PPP)로 혈소판 10000/ul 이하여야 한다.
- 가능한 신선한 혈장을 사용하도록 한다.
- 검체 처리 시간은 가능한 4시간 이내에 원심분리, 검사를 시행해야 한다.
- 제한 시간 내에 검사가 실시되지 못할 때에는 혈장을 완전히 분리하여 -20°C에서 2주간 보관가능하며 -70°C에서 6개월까지 보관할 수 있다.
- 냉동된 혈장으로 검사를 시작할 때는 37°C에서 재빨리 녹여야 하며 즉시 검사를 시행하는 것이 좋다.

2. 검사 전 준비 과정

1) 해당 장비의 준비과정
   - 검사 전 준비는 장비 매뉴얼을 참고한다.

2) 시약
   - Chromogenic substrate : 사용 전 잘 섞어준다.
   - Factor Xa reagent : 사용 전 잘 섞어주도록 한다.

3. 추가 시약과 정도관리 물질

다음은 키트에 제공되지 않지만, 따로 구입할 수 있다.

- HemosIL Calibration Plasma (수허 13-3)
- HemosIL Normal Control (수허 13-3)
- HemosIL Low Abnormal Control (수허 13-3)
- HemosIL High Abnormal Control (수허 13-3)
- HemosIL Special Test Control Level 1 (수허 13-36)
- HemosIL Special Test Control Level 2 (수허 13-36)
- HemosIL Factor Diluent (수허 13-3)
- HemosIL Cleaning Solution (수허 13-3)
- HemosIL Cleaning Agent (수허 13-3)
- HemosIL Reference Emulsion (수허 13-3)
- HemosIL Wash-R Emulsion (수허 13-3)
- HemosIL Rinse Solution (수허 13-3)

4. 검사 과정

검사과정에 관한 자세한 사항은 아래에 나와 있는 장비의 작동매뉴얼을 참조한다.

- ACL TOP, ACL TOP 700 Base, ACL TOP 700 CTS, ACL TOP 700 LAS, ACL TOP 500 CTS, ACL TOP 300 CTS (1등급, 서울 수신 01-1724 호) : 405nm, Chromogenic assay
- ACL 7000 (1등급, 서울 수신 01-1815호) : 405nm, Chromogenic assay
- ACL 9000, ACL 8000, ACL 10000, ACL Elite, ACL Elite Pro (1등급, 서울 수신 01-2037호) : 405nm, Chromogenic assay

검사에 필요한 검체와 시약 량은 다음과 같다.

- ACL TOP, ACL TOP 700 Base, ACL TOP 700 CTS, ACL TOP 700 LAS, ACL TOP 500 CTS, ACL TOP 300 CTS (1등급, 서울 수신 01-1724 호), ACL 7000 (1등급, 서울 수신 01-1815호) : 검체 량은 50ul 이며, 시약 량은 Chromogenic substrate는 50ul, Factor Xa reagent 는 50ul 이다.
- ACL 9000, ACL 8000, ACL 10000, ACL Elite, ACL Elite Pro (1등급, 서울 수신 01-2037호) : 검체 량은 3ul이며, 시약 량은 Chromogenic substrate는 30ul, Factor Xa reagent 는 125ul이다.

참고

- ACL TOP Family :
  ACL TOP, ACL TOP 700 Base, ACL TOP 700 CTS, ACL TOP 700 LAS, ACL TOP 500 CTS, ACL TOP 300 CTS
- ACL Family :
  ACL 200, ACL 7000, ACL Elite, ACL Elite Pro, ACL 8000, ACL 9000, ACL 10000
- ACL Classic :
  ACL 200, ACL 7000

참고

	Factor Xa reagent	Chromogenic Substrate
ACL TOP Family (PN 0020030100)	4 vials x 4.5 mL	4 vials x 4.5 mL
ACL TOP Family, ACL Classic (PN 0020300400)	2 vials x 2 mL	2 vials x 2 mL
ACL Elite/Elite Pro/8/9/10000 (PN 0020002500)	4 vials x 4 mL	2 vials x 2 mL

5. 결과 판정

환자 결과는 다음의 단위로 보고된다.

- % 활성도

추가적인 정보는 장비 사용자 매뉴얼을 참고하도록 한다.

기대치

건강한 사람에게서의 Antithrombin 활성도는 대략 83-128%의 범위를 가진다. Antithrombin은 신생아/영유아에서 낮으며 성인이 되면 증가 한다; 결과에 영향을 줄 수 있는 많은 요인이 있기 때문에, 각 검사실에서는 반드시 자체적으로 정상범위를 검증하도록 한다.

6. 정도관리

- 완전한 정도관리 프로그램을 위해서는 정상과 비정상 정도관리 물질을
  사용하기를 권장한다.
- 다음의 정도관리 물질을 사용할 수 있다.
  HemosIL Normal Control Assayed, HemosIL Low Abnormal Control Assayed, HemosIL High Abnormal Control Assayed, HemosIL Special Test Control Level 1, HemosIL Special Test Control Level 2
- 각 검사실은 자체적인 평균값과 표준편차를 설정하고 검사실 검사를 관리할 수 있는 정도관리 프로그 램을 도입하도록 한다.
- 정도관리 물질은 적어도 8시간에 한 번 검사하도록 한다.
- 추가적인 정보는 기기의 작동매뉴얼을 참조한다.
- 정도 관리 물질이 허용 범위를 벗어나는 경우, Westgard et al.을 참조한다.

사용시 주의사항]

1. 체외진단용으로만 사용해야 한다.
2. 삼키거나 피부와 눈에 닿지 않게 한다.
3. 보호복을 착용하고 검사하도록 한다.
4. 사람에서 유래된 물질을 취급할 때에는 주의해야 한다. 모든 검체는 감염성 위험이 있는 것으로 간주한다. HBV, HCV, HIV 1+2 혹은 다른 감염성 물질이 없다고 완전히 확신할 수 있는 시험법은 없다.
5. 검체 및 시험구성품으로부터 나온 고형 및 액상폐기물의 취급, 사용, 보관 및 폐기는 관련 규정에 따라야 한다.
6. 아지드화나트륨은 납 또는 구리와 반응하여 배관에서 폭발성이 높은 아지드화 금속을 형성할 수 있다. 남아있는 시약을 버릴 때에는 물로 충분히 씻어낸다.
   (주의 : 잠재적 생물학적 위해물질)
7. 다른 로트의 시약을 섞거나 혼합하여 사용하지 않는다.
8. 모든 유효기간은 엄격히 지켜야 한다.

저장방법

(1) HemosIL Liquid Antithrombin 0020300400

명 칭	개봉 여부	보관조건	사용기한	비고
Chromogenic substrate	미개봉	2-8°C 보관	제조일로부터 36개월	완제품
	개봉	2-8°C 보관	개봉일로부터 5주	
		ACL Classic 장착 시	장착 후 8시간	
		ACL TOP Family 장착 시	장착 후 48시간	
Factor Xa reagent	미개봉	2-8°C 보관	제조일로부터 36개월	완제품
	개봉	2-8°C 보관	개봉일로부터 5주	
		ACL Classic 장착 시	장착 후 8시간	
		ACL TOP Family 장착 시	장착 후 48시간	

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Liquid Antithrombin - 0020300400

ENGLISH - Insert revision 12/2018

Intended use

Automated chromogenic assay 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 and thrombosis. Antithrombin deficiency is associated with a high risk of thromboembolic disorders.[1,2,3]
Liquid Antithrombin 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, DIC,[6] nephrotic syndromes, liver diseases[7] and in therapy with heparin or antithrombin concentrates.[8,9]
The Liquid Antithrombin 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** kit consists of:

S **Chromogenic substrate** (Cat. No. 0020300420): 2 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.

E **Factor Xa reagent** (Cat. No. 0020300410): 2 x 2 mL vials of a solution containing bovine Factor Xa (20 nkat/vial), heparin, buffer, bovine serum albumin and preservatives.

PRECAUTIONS AND WARNINGS:
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.
Factor Xa reagent:

Danger
Hazard class: Resp. Sens. 1, H334
Hazard statements: H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements: P261: Avoid breathing vapors/spray. P284: [In case of inadequate ventilation] wear respiratory protection. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor. P501: Dispose of contents/container in accordance with local/regional/national/international regulation.
Supplemental hazard information: Contains Factor Xa. Up to 3.4% of the mixture consists of component of unknown acute toxicity (oral, dermal, inhalation) for the human health and unknown hazard to the aquatic environment.
Chromogenic Substrate:
Hazard class: none
Hazard statements: none
Precautionary statements: none
Supplemental hazard information: none
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, 8 hours at 15°C on the ACL Classic (100-7000) or 48 hours at 15°C on the ACL TOP® Family and ACL TOP Family 50 Series†. Do not freeze.
Factor Xa reagent - Opened reagent is stable 5 weeks at 2-8°C in the original vial, 8 hours at 15°C on the ACL Classic (100-7000) or 48 hours at 15°C on the ACL TOP Family and ACL TOP Family 50 Series†. 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 3.2% trisodium citrate. Refer to CLSI Document H21-A5 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	0020003700	0020003700
Normal Control	0020003120/0020003110	0020003110
Special Test Control Level 1	0020011000	0020011000
Special Test Control Level 2	0020012000	0020012000
Low Abnormal Control	0020003220/0020003210	0020003210
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, 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 situtations.[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 Classic (100-7000) 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.
Antithrombin results on the ACL TOP Family and ACL TOP Family 50 Series† 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 10 mg/mL, Heparin Cofactor II up to 4 U/mL, hemoglobin up to 500 mg/dL, bilirubin up to 40 mg/dL and triglycerides up to 2300 mg/dL.

Expected values

Antithrombin activity levels in healthy individuals are approximately in the range of 83 -128%. Antithrombin levels are low in neonates/infants and increase to adult levels by approximately 1 year of age; levels are then slightly higher than in adults up to age 16 year.[15]
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 Classic (100-7000)	Mean (% activity)	CV % (Within run)	CV % (Total)
Normal Control	102.6	2.54	3.51
Special Test Control Level 1	53.6	3.27	5.47
Special Test Control Level 2	22.1	7.54	11.52
ACL TOP Family	**Mean (% activity)**	**CV % (Within run)**	**CV % (Total)**
Normal Control	104.4	2.2	3.1
Special Test Control Level 1	62.1	3.5	3.8
Special Test Control Level 2	31.4	7.4	8.6
ACL TOP Family 50 Series†	**Mean (% activity)**	**CV % (Within run)**	**CV % (Total)**
Normal Control	98.7	1.6	2.2
Special Test Control Level 1	56.7	2.0	4.9
Special Test Control Level 2	26.7	6.6	7.4

Correlation:

System	n	slope	intercept	r	Comparative method
ACL Classic (100-7000)	118	0.99	-2.35	0.995	HemosIL Antithrombin
ACL TOP Family	118	1.06	0.443	0.986	HemosIL Antithrombin
ACL TOP Family 50 Series†	122	0.97	-3.38	0.978	HemosIL Antithrombin on ACL TOP 500 CTS

In an additional clinical study comparing Liquid Antithrombin to Antithrombin (Cat. No. 0020008900), samples from 64 patients (26 normals, 11 undergoing heparin therapy, 5 undergoing OAT, 4 undergoing antithrombin substitution therapy, 5 with congenital AT deficiency, 5 with liver disease, 4 with DIC and 4 others with high AT) were evaluated. The correlation (r) was 0.997 on the ACL Futura/ACL Advance.
The precision and correlation results were obtained using specific lots of reagents and controls.

Detection limit:

System	
ACL TOP Family / ACL TOP Family 50 Series†	7.2 %

Linearity:

System	
ACL Classic (100-7000)	10 -150 (% activity)
ACL TOP Family and ACL TOP Family 50 Series†	

† ACL TOP Family 50 Series = ACL TOP 350 CTS; ACL TOP 550 CTS; ACL TOP 750; ACL TOP 750 CTS; ACL TOP 750 LAS

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Symbols used

IVD *In vitro* diagnostic medical device	LOT Batch code	Use by	Temperature limitation	Consult instructions for use	CONTROL Control	Biological risks	Manufacturer	EC REP Authorised representative

Instrumentation Laboratory
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