

DIAGNOSTIC KIT FOR DETERMINATION OF ANTITHROMBIN III CONCENTRATION



OS – ANTITHROMBIN III

INTRODUCTION

Antithrombin III (AT III) is an α 2-glycoprotein of MW 58000 and is made in the liver. AT III is one of the most important regulators of the coagulation system. AT III inactivates thrombin and factors Xa, IXa, XIa and XIIa. This anticoagulant activity is enhanced by the presence of heparin, which forms a ternary complex with AT III and these procoagulant factors. Reduced concentration of AT III in blood means a great and well established risk for thrombotic complications. Clinical low value are associated with congenital or acquired deficiencies caused by a decreased biosynthesis (liver disease, medical treatment) or an increased loss (gastrointestinal disease, nephrotic syndrome) or an increased consumption (sepsis, major trauma due to surgery and burns wounds).

METHOD PRINCIPLE

The antithrombin III presents in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum measured at $\lambda=340$ nm is proportional to antithrombin III concentration in the sample.

REAGENTS

Package

- 1-Reagent 1 x 33.5 ml
- 2-Reagent 1 x 9 ml

Buffer (1-Reagent) stored at 2-25°C and antiserum (2-Reagent) stored at 2-8°C are stable until expiry date printed on the package. Store closed and avoid contamination.

Concentrations in the test

Tricine buffer (pH 8.0); PEG; sodium chloride; anti human antithrombin III antiserum; HEPES buffer (pH 7.4); sodium azide (< 1 g/l); stabilizers.

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Products from human source have been tested for the HIV antibody, HbsAg and HCV and found to be non-reactive. However this material should be handled as though capable of transmitting infectious disease.
- Products contain sodium azide (< 1 g/l) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Citrated plasma.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analysers Olympus AU400/AU640.

1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION

Reagent ID: 507

Specific Test Parameters											
General		LIH	ISE	Range							
Test name:		[ATTIII]		Type:		[Plasma]		Operation:		[Yes]	
Sample: Volume	[4]	μL	Dilution	[0]	μL	Pre-Dilution Rate:	[1]				
Reagents: R1 Volume	[150]	μL	Dilution	[0]	μL	Min OD	Max OD				
R2 Volume	[30]	μL	Dilution	[0]	μL	L	[-2.0000]	H		[2.5000]	
Wavelength: Pri. [340]						Sec. [700]		Reagent OD Limit:			
Method: [END]						First L		[-2.0000]	First H		[2.5000]
Reaction Slope: [+]						Last L		[-2.0000]	Last H		[2.5000]
Measuring Point 1: First [0]						Last [27]		Dynamic Range:			
Measuring Point 2: First [0]						Last [10]		Correlation Factor:			
Linearity: [] %						A		[1.000]	B		[0.000]
No-Lag-Time: []						On-board Stability Period: []					

Specific Test Parameters										
General		LIH	ISE	Range						
Test name:		[ATTIII]		Type:		[Plasma]				
Value/Flag:		[#]	Level L:		[#]	Level H:		[#]		
Normal Ranges:										
	Sex	Age L	Age H	L	H					
		Year	Month	Year	Month					
1.	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]
2.	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]
3.	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]
4.	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]
5.	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]
6.	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]	[#]
7. None Selected						[#]	[#]	[#]	[#]	[#]
8. Out of Range						[#]	[#]	[#]	[#]	[#]
Panic Value:						[#]	[#]	Unit:	[mg/l]	Decimal Places: [1]

Calibration Specific											
General		ISE									
Test name:		[ATTIII]		Type:		[Plasma]					
Calibration Type:		[6AB]	Formula:		[Spline]	Counts:	[1]	Process:		[CONC]	
	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H						
Point 1:	[#]	[#]	[**]	[-2.0000]	[2.5000]						
Point 2:	[#]	[#]	[*]	[-2.0000]	[2.5000]						
Point 3:	[#]	[#]	[*]	[-2.0000]	[2.5000]						
Point 4:	[#]	[#]	[*]	[-2.0000]	[2.5000]						
Point 5:	[#]	[#]	[*]	[-2.0000]	[2.5000]						
Point 6:	[#]	[#]	[*]	[-2.0000]	[2.5000]						
Point 7:	[#]	[#]	[#]	[#]	[#]						
1-Point Cal.Point:		[]	[]	with CONC=0		Slope Check:		[None]	Advanced Calibration:		[#]
MB Type Factor:						Calibration Stability Period:					

- # User defined
- * Calibrator value
- ** Saline should be used as calibrator 1

REFERENCE VALUES

plasma	0.25 – 0.45 g/l
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It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL III (Cat. No 4-291) with each batch of samples.

For the calibration of automatic analysers systems the CORMAY IMMUNO-MULTICAL (Cat. No 4-287) is recommended.

The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analysers BS-400 and Cobas Mira. Results may vary if a different instrument or manual procedure is used.

- **Sensitivity:** 0.125 g/l.
- **Linearity:** 0.7 g/l.
- **Interferences**

Hemoglobin up to 0.32 g/dl, bilirubin up to 29.5 mg/dl, triglycerides up to 1000 mg/dl, heparin up to 0.5 g/l, sodium fluoride up to 4 g/l, EDTA up to 5 g/l, sodium citrate up to 5 g/l do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	19.4	0.2	1.1
level 2	31.7	0.5	1.7

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	19.5	0.4	2.2
level 2	31.4	0.8	2.5

- **Method comparison**

A comparison between antithrombin III values determined at BS-400 (y) and at Hitachi 912 (x) using 21 samples gave following results:

$y = 0.641x + 0.096$ mg/dl;

$R = 0.9830$ (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Tietz Textbook of Clinical Chemistry, W.B. Saunders, Philadelphia, (1994)
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4. Menache, D. et al, Transfusion, 32, 580-588 (1992).Bergstrom, K. & Lefvert,
5. A.K. Scand.J.clin.Lab.Invest. 40 (1980) 637.
6. Roitt, I., Essential Immunology, Blackwell, Oxford, (1991).

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