SIEMENS Healthineers

Test Thrombin Reagent

TEST THROMBIN

Revision bar indicates update to previous version.

Intended Use

Reagent for the determination of the thrombin time in human plasma.

Summary and Explanation

The determination of the thrombin time with Test Thrombin Reagent is suitable for:

1. monitoring of fibrinolytic therapy[1,2],
2. screening for disorders of fibrin formation or in suspected cases of severe fibrinogen deficiency states[1,2],
3. differentiation between heparin-induced prolongation of the thrombin time and disorders of fibrinogen formation[1,2].

The thrombin time is found to be prolonged not only due to disorders in fibrin polymerization but also due to the presence of heparin. Differentiation can be achieved using Batroxobin Reagent (Siemens Healthineers, REF OUOV).

Principles of the Procedure

Thrombin converts Fibrinogen which is contained in the plasma sample into fibrin, where upon a clot forms. The time to clot formation is measured.

Reagents

Note: TEST THROMBIN can be used manually or on automated coagulation analyzers.
Siemens Healthineers provides Reference Guides (Application Sheets) for several coagulation analyzers. The Reference Guides (Application Sheets) contain analyzer/assay specific handling and performance information which may differ from that provided in these Instructions for Use. In this case, the information contained in the Reference Guides (Application Sheets) supersedes the information in these Instructions for Use. Please also consult the instruction manual of the instrument manufacturer!

Reagent	Description	Storage	Stability
Test Thrombin Reagent TEST THROMBIN			
REAGENT	Lyophilized reagent containing: • Thrombin, bovine (reconstituted: 1.5 IU/mL) • BSA	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	37 °C: reconstituted, 8 hours; 15–25 °C: reconstituted, 10 hours; 2–8 °C: reconstituted, 7 days; ≤ –20 °C: reconstituted, 4 weeks
REAGENT DILUENT	Ready to use liquid containing: • HEPES (25 mmol/L) • reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one / 2-methyl-2H-isothiazol-3-one (3:1) pH 7.4	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	2–25 °C: once opened, 12 weeks

Reconstituted TEST THROMBIN REAGENT can be frozen once in the original vial.

On-board stability
Information regarding on-board stability is specified in the Reference Guides (Application Sheets) for the different coagulation analyzers.

Warnings and Precautions

For *in-vitro* diagnostic use only.

For laboratory professional use.

Safety data sheets (MSDS/SDS) available on siemens-healthineers.com/sds.

CAUTION!
Federal (USA) law restricts this device to sale by or on the order of licensed healthcare professionals.

TEST THROMBIN REAGENT DILUENT
Hazardous ingredient: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one / 2-methyl-2H-isothiazol-3-one (3:1).
May produce an allergic reaction.

Caution
TEST THROMBIN REAGENT
This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all government requirements.

Preparing Reagents

To reconstitute a vial of TEST THROMBIN REAGENT dissolve in the labelled quantity of TEST THROMBIN REAGENT DILUENT.

Manual test methods: Prior to the assay warm the reagent solution to 37 °C in the original vial or in a plastic tube.

Siemens Healthineers recommended automated coagulation analyzers prewarm the reagent solution automatically.

Mix carefully once more before using.

Specimen Collection and Handling

Collecting the Specimen

To obtain the plasma, carefully mix 1 part sodium citrate solution 0.11 mol/L (3.2 %) with 9 parts venous blood, avoiding the formation of foam. Centrifuge immediately at no less than 1 500 g/L for at least 15 minutes, remove the supernatant plasma and keep at 15 to 25 °C until required in the test. Please refer to CLSI document H21-A5 for further details[3].

Storing the Specimen

Stability of the samples at 15 to 25 °C: 4 hours.

Measure heparin-containing samples within 2 hours.

Procedure

Materials Provided

REF	Contents		
OWHM13	Test Thrombin Reagent TEST THROMBIN		
	Test Thrombin Reagent TEST THROMBIN REAGENT	10 × →	5 mL
	Buffer Solution TEST THROMBIN REAGENT DILUENT	1 ×	50 mL

Materials Required but not Provided

Item	Description
REF ORKE45	CONTROL N, Control Plasma N
Coagulation analyzers, such as:	• SYSMEX CA-600 series • SYSMEX CA-1500 System • SYSMEX CS-2500 System • SYSMEX CS-5100 System

Manual Testing

Pipette into a test tube pre-warmed to 37 °C:	
Citrated plasma	100 µL
	Incubate at 37 °C for 60 seconds.
TEST THROMBIN (pre-warmed to 37 °C)	200 µL
	On adding the reagent start the stopwatch or timer on the coagulometer and determine the coagulation time.

Internal Quality Control

Normal range: CONTROL N

A quality control has to be measured at start of the test run, upon reagent vial changes and at least every 8 hours during each day of testing. The control should be processed just like the samples. Each laboratory should determine its own quality control range, either by means of the target values and ranges provided by the manufacturer of the controls or by means of its own range established in the laboratory. If the measured control value lies outside the range previously established, then the

reagent and the coagulation analyzer should be examined. Do not release patient results until the cause of deviation has been identified and corrected.

Results

The result is given in seconds.

Limitations

Siemens Healthineers has validated use of these reagents on various analyzers to optimize product performance and meet product specifications. User defined modifications are not supported by Siemens Healthineers as they may affect performance of the system and assay results. It is the responsibility of the user to validate modifications to these instructions or use of the reagents on analyzers other than those included in Siemens Healthineers Reference Guides (Application Sheets) or these Instructions for Use.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Carry-over of traces of thrombin can interfere with subsequent coagulation analyses.

If possible, use only single-use plastic material.

Expected Values

14 to 21 seconds.

Systematic deviations from this range may be due to the instrument used. If necessary, the laboratory will have to establish its own reference interval.

Performance Characteristics

Precision

For normal plasmas the coefficient of variation within series is 1.9 % (n = 20) and from day to day 2.5 % (n = 10).

Method Comparison

A comparison test of TEST THROMBIN REAGENT with another commercial thrombin time reagent using normal and heparin containing plasmas yielded a correlation coefficient of 0.803.

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens-healthineers.com

Current Version of Application Sheets

TEST THROMBIN can be used in combination with various automated coagulation analyzers. Siemens Healthineers provides Reference Guides/Application Sheets for the coagulation analyzers listed in section "Materials Required but not Provided", page 3 under the dedicated link below:

siemens-healthineers.com/rg

As Siemens Healthineers continuously monitors the product performance and safety, the users are required to ensure that they work with the correct revision of the instructions for the product lots in use. Please periodically review the availability of new electronic labeling revisions to ensure safe use of the product.

The IFU version number is visible on each product box label. Siemens Healthineers ensures that all products lots bearing the same IFU version number are compatible with the electronic labeling provided via siemens-healthineers.com/eIFU.

References

1. Sirridge, M.S. Laboratory evaluation of hemostasis. 2nd Ed. Philadelphia: Lea & Febiger; 1974: 148.
2. Biggs, R. Human blood coagulation, haemostasis and thrombosis. 2nd Ed. Oxford: Blackwell Scientific Publications; 1976: 722.
3. CLSI. Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays. Approved Guideline – Fifth Edition. CLSI document **H21-A5** [ISBN 1-56238-657-3]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2008.

Definition of Symbols

The following symbols may appear on the product labeling:

	Do not reuse		Use By
LOT	Batch Code	REF	Catalogue Number
	Caution		Manufacturer
EC REP	Authorized representative in the European Community		Contains sufficient for <n> tests
	Biological Risks	IVD	*In Vitro* Diagnostic Medical Device
	Temperature Limitation		Consult instruction for Use
	Non-sterile	CE	CE marking of conformity
CE 0197	CE marking of conformity with notified body ID number. Notified body ID number can vary.	CONTENTS	Contents
	Reconstitution volume	LEVEL	Level
	Keep away from sunlight and heat	WARNING	Warning
DANGER	Danger	RxOnly	Prescription device (US only)
UDI	Device Identification (UDI) barcode	REACH xx/xx/xx	REACH Authorization Number

Legal Information

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Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestraße 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens-healthineers.com

Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany
siemens-healthineers.com