

Fibrinogen Calibrator Kit

FIBRINOGEN CALIBRATOR

Revision bar indicates update to previous version.

for the fibrinogen assay

Intended Use

FIBRINOGEN CALIBRATOR 1 to 6 are used to prepare reference curves for the assay of fibrinogen by the method of Clauss¹ using Siemens Healthineers Multifibren® U.

Reagents

Reagent	Description	Storage	Stability
Fibrinogen Calibrator Kit FIBRINOGEN CALIBRATOR			
CALIBRATOR 1	Lyophilized reagent containing: <ul style="list-style-type: none"> human plasma^a Buffer Stabilizer: <ul style="list-style-type: none"> HEPES 	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 4 h; –20 °C: reconstituted, 4 weeks
CALIBRATOR 2	Lyophilized reagent containing: <ul style="list-style-type: none"> human plasma^a Buffer Stabilizer: <ul style="list-style-type: none"> HEPES 	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 4 h; –20 °C: reconstituted, 4 weeks
CALIBRATOR 3	Lyophilized reagent containing: <ul style="list-style-type: none"> human plasma^a Buffer Stabilizer: <ul style="list-style-type: none"> HEPES 	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 4 h; –20 °C: reconstituted, 4 weeks
CALIBRATOR 4	Lyophilized reagent containing: <ul style="list-style-type: none"> human plasma^a Buffer Stabilizer: <ul style="list-style-type: none"> HEPES 	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 4 h; –20 °C: reconstituted, 4 weeks

Reagent	Description	Storage	Stability
CALIBRATOR 5	Lyophilized reagent containing: <ul style="list-style-type: none"> • human plasma^a • Buffer • Stabilizer: <ul style="list-style-type: none"> • HEPES 	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 4 h; –20 °C: reconstituted, 4 weeks
CALIBRATOR 6	Lyophilized reagent containing: <ul style="list-style-type: none"> • human plasma^a • Buffer • Stabilizer: <ul style="list-style-type: none"> • HEPES 	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 4 h; –20 °C: reconstituted, 4 weeks

^a from pooled plasma collected from selected healthy blood donor

FIBRINOGEN CALIBRATOR consist of pooled plasma from selected, healthy donors, that has been diluted with buffer solution or supplemented with purified fibrinogen and are stabilized with Hepes Buffer Solution and lyophilized.

Once reconstituted, **FIBRINOGEN CALIBRATOR** can be frozen and thawed once. They must be frozen as rapidly as possible in a well-closed container. Thawing is to be accomplished at 37 °C within a maximum of 10 minutes.

FIBRINOGEN CALIBRATOR should then not be exposed to 15 to 25 °C for longer than 2 hours after thawing.

FIBRINOGEN CALIBRATOR are supplied in siliconized vials in order to prevent contact activation of the coagulation system.

FIBRINOGEN CALIBRATOR are adjusted to the following values:

fibrinogen concentration (approximately)

	(g/L)
CALIBRATOR 1	0.6
CALIBRATOR 2	1.1
CALIBRATOR 3	2.5
CALIBRATOR 4	3.7
CALIBRATOR 5	6.0
CALIBRATOR 6	9.0

FIBRINOGEN CALIBRATOR are calibrated by determining the quantity of coagulable fibrinogen by the method of Ratnoff and Menzie² as well as by the Kjeldahl method. The exact values are given on the enclosed lotdependent table of analytical values.

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.

**CAUTION! POTENTIAL BIOHAZARD**

CALIBRATOR 1, **CALIBRATOR 2**, **CALIBRATOR 3**, **CALIBRATOR 4**, **CALIBRATOR 5**, **CALIBRATOR 6**

Each donor or donor unit was tested and found to be negative for human immunodeficiency virus (HIV) 1 and 2, hepatitis B virus (HBV) and hepatitis C virus (HCV) using either tests that are CE marked or FDA approved for this purpose. Because no known test can offer complete assurance of the absence of infectious agents, all human derived products should be handled with appropriate caution.

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

Reconstitute the Fibrinogen Calibrators with 1.0 mL of distilled water, shaking carefully to dissolve (without foam formation). Allow to stand for at least 15 minutes at 15 to 25 °C.

Shake carefully before use.

Procedure**Materials Provided**

REF	Contents
OQVK11	Fibrinogen Calibrator Kit FIBRINOGEN CALIBRATOR
	Fibrinogen Calibrator, level 1 CALIBRATOR 1 1 x → 1 mL
	Fibrinogen Calibrator, level 2 CALIBRATOR 2 1 x → 1 mL
	Fibrinogen Calibrator, level 3 CALIBRATOR 3 1 x → 1 mL
	Fibrinogen Calibrator, level 4 CALIBRATOR 4 1 x → 1 mL
	Fibrinogen Calibrator, level 5 CALIBRATOR 5 1 x → 1 mL
	Fibrinogen Calibrator, level 6 CALIBRATOR 6 1 x → 1 mL
	Table of lot-specific Analytical Value

Materials Required but not Provided

Item	Description
REF OWZG	Multifibren® U
Coagulation analyzers, such as:	<ul style="list-style-type: none"> • BCS® XP System • BFT // Analyzer • SYSMEX CA-600 series • SYSMEX CA-1500 System

Performing Calibration

The reference curve is prepared from duplicate or triplicate determinations of the **FIBRINOGEN** **CALIBRATOR** coagulation times as instructed in the respective Instructions for Use. The mean values are plotted on doublelogarithmic graph paper against the labelled fibrinogen concentration (see lot-specific analytical table) and are then connected with a template to provide the reference curve.

Internal Quality Control

The accuracy of the calibration curve should be assessed by running appropriate controls, which are listed in each related reagent Instructions for Use.

If the controls exhibit systematic deviations from the declared confidence interval of the lot-dependent Table of Assigned Values, a new reference curve must be established.

Limitations

The reference curve is valid for the relevant lot of the reagent used and must be renewed after a change of lot as well as after any change in the experimental conditions.

Technical Assistance
























For customer support, contact your local technical support provider or distributor.
 siemens-healthineers.com

References

1. Clauss A. Gerinnungsphysiologische Schnellmethode zur Bestimmung des Fibrinogens. Acta Haematol. 1957; 17: 237-46.
2. Ratnoff OD, Menzie C. A new method for the determination of fibrinogen in small samples of plasma. J Lab Clin Med. 1951; 37: 316 - 20.

Definition of Symbols

The following symbols may appear on the product labeling:

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

Legal Information

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