Fibrinogen Calibrator Kit

FIBRINOGEN CALIBRATOR

Revision bar indicates update to previous version.

CE 0197

for the fibrinogen assay

Intended Use

CALIBRATOR 1 to CALIBRATOR 6 are used to prepare reference curves for the assay of fibrinogen by the method of Clauss[1] using Multifibren® U.

Reagents

Reagent	Description	Storage	Stability
Fibrinogen Calibrator Kit FIBRINOGEN CALIBRATOR			
CALIBRATOR 1	Lyophilized reagent containing: • human plasma[a] • Buffer • Stabilizer: • 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: • human plasma[a] • Buffer • Stabilizer: • 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: • human plasma[a] • Buffer • Stabilizer: • 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: • human plasma[a] • Buffer • Stabilizer: • 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: • human plasma[a] • Buffer • Stabilizer: • 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: • human plasma[a] • Buffer • Stabilizer: • 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 Menzie[2] 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.

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State through your local distribution representative in which the user and/or patient is established.

Safety data sheets (MSDS/SDS) available upon request.

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.

Summary of Safety and Performance (SSP) is available in the European database on medical devices (see Eudamed public website: https://ec.europa.eu/tools/eudamed). In case Eudamed is not available, SSP can be delivered by the manufacturer on request.

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 × → 1 mL
	Fibrinogen Calibrator, level 2 CALIBRATOR 2	1 × → 1 mL
	Fibrinogen Calibrator, level 3 CALIBRATOR 3	1 × → 1 mL
	Fibrinogen Calibrator, level 4 CALIBRATOR 4	1 × → 1 mL
	Fibrinogen Calibrator, level 5 CALIBRATOR 5	1 × → 1 mL
	Fibrinogen Calibrator, level 6 CALIBRATOR 6	1 × → 1 mL
	Table of lot-specific Analytical Value	

Materials Required but not Provided

Item	Description
REF OWZG	Multifibren® U
Coagulation analyzers[b], such as:	• Automated Blood Coagulation Analyzer CA-600 series (CA-600 series)

[b] Availability of analyzers may vary by country.

Please note that the applications on other analyzers can be validated by the instrument manufacturer in accordance with the requirements of the REGULATION (EU) 2017/746 under their responsibility as long as the intended purpose and performance are not modified.

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.

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
LOT	Batch Code	REF	Catalogue Number
	Caution		Manufacturer
EC REP	Authorized representative in the European Community	CH REP	Authorized representative in Switzerland
	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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