SIEMENS Healthineers

Standard Human Plasma

STANDARD PLASMA

CE 0197

Revision bar indicates update to previous version.

Intended Use

STANDARD PLASMA is used for the calibration of the following tests:

1. Prothrombin time (PT)
2. Fibrinogen (Clauss method)
3. Coagulation factors: FII, FV, FVII, FVIII, FIX, FX, FXI, FXII, FXIII and vWF
4. Inhibitors: Antithrombin III, protein C, protein S, α_2-antiplasmin, C1-Inhibitor
5. Plasminogen

Furthermore, STANDARD PLASMA shall be used as sample dilution medium for selected assays, if indicated in the application sheets for these assays.

In addition, the stated sensitivity values for ProC® reagents are provided for calculating the normalized ratio for ProC® Global and ProC® Global/FV.

Reagents

Note: STANDARD PLASMA 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!
The percentage values given in the enclosed Table of Analytical Values relate to a pool of fresh citrated human plasma, which by definition, exhibits 100 % of the norm for all the factors. Coagulation factors and inhibitors for which a WHO Standard is available are referenced to this standard and the values are given in International Units (IU).

Reagent	Description	Storage	Stability
Standard Human Plasma STANDARD PLASMA	Lyophilized reagent containing: • human plasma[a] • Stabilizer: • HEPES (reconstituted: 12 g/L)	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	15–25 °C: reconstituted, 4 hours[b]; ≤ –20 °C: reconstituted, 4 weeks[b]

[a] from pooled plasma collected from selected healthy blood donor
[b] closed original vial

To avoid contact activation of the coagulation system the preparation is supplied in siliconized vials.

STANDARD PLASMA contains no preservatives.

Reconstituted STANDARD PLASMA should not be stored at 2 to 8 °C but can be frozen and thawed once. The reconstituted plasma must be frozen as rapidly as possible in a tightly closed container. Thawing should be accomplished at 37 °C within 10 minutes. Thawed plasma should be used within 2 hours when held at 15 to 25 °C.

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 in which the user and/or patient is established.

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

CAUTION! POTENTIAL BIOHAZARD
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 Siemens Healthineers on request.

Preparing Reagents

1. Reconstitute STANDARD PLASMA by adding 1.0 mL distilled or deionized water.
2. Shake carefully to dissolve (without foam formation).
3. Allow to stand at 15 to 25 °C for at least 15 minutes.
4. Before use, again shake carefully.

Procedure

For establishing standard curves and/or determining a laboratory factor STANDARD PLASMA is used with the corresponding reagents in accordance with the assay protocol in the relevant Instructions for Use.

Materials Provided

REF	Contents		
ORKL17	Standard Human Plasma STANDARD PLASMA Table of lot- and method-specific Assigned Values and Ranges	10 × →	1 mL

Materials Required but not Provided

Item	Description
Coagulation analyzers[c], such as:	• Atellica® COAG 360 System • BCS® XP System • BFT *II* Analyzer • SYSMEX CA-500/CA-600 series • SYSMEX CA-1500 System • SYSMEX CS-2000i/CS-2100i System • SYSMEX CS-2500 System • SYSMEX CS-5100 System • SYSMEX CN-3000/CN-6000 System

[c] 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.

Internal Quality Control

The accuracy of the standard 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 assigned ranges of the lot- and method-specific Table of Analytical Values, a new standard curve must be established.

The values can be entered via data storage device on the Atellica® COAG 360 System and BCS® XP System.

Limitations

The standard curve is valid for the respective lot of the reagent used and must be renewed if the lot is changed as well as after any change in experimental conditions.

Siemens Healthineers has validated use of these reagents on various analyzers to optimize product performance and meet product specifications. 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. 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 Application Sheets or these Instructions for Use.

Technical Assistance

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

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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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