# Standard Human Plasma

**STANDARD PLASMA**

Revision bar indicates update to previous version.

CE 0197

## 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, $\alpha_2$-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. Sysmex 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!

### Standardization

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).

The reference material and the uncertainty of the Standard compared to the reference material are included in the Certificates of Traceability (CoT). The CoTs are available upon request.

| Reagent | Description | Storage | Stability |
|---|---|---|---|
| Standard Human Plasma<br>STANDARD PLASMA | Lyophilized reagent containing:<br>• human plasma[a]<br>• Stabilizer:<br>  • HEPES (reconstituted: 12 g/L) | 2–8 °C<br>May be used up to the expiry date indicated on the label if stored unopened. | 15–25 °C: reconstituted, 4 hours[b];<br>≤ −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 through your local distribution representative in which the user and/or patient is established.

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

**Caution! Potential Biological Risk**
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

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<br>STANDARD PLASMA | 10 × → | 1 mL |
| | Table of lot- and method-specific Assigned Values and Ranges | | |

### Materials Required but not Provided

| Item | Description |
|---|---|
| Coagulation analyzers[c], such as: | • Automated Blood Coagulation Analyzer CA-600 series (CA-600 series)<br>• AUTOMATED BLOOD COAGULATION ANALYZER CS-2500 (CS-2500 System)<br>• AUTOMATED BLOOD COAGULATION ANALYZER CS-5100 (CS-5100 System)<br>• Automated Blood Coagulation Analyzer CN-3000/CN-6000 (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.

## 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.

The manufacturer 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 the manufacturer 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 Application Sheets or these Instructions for Use.

## Technical Assistance

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

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