# Control Plasma P

CONTROL P

Revision bar indicates update to previous version.

CE 0197

## Intended Use

CONTROL P is an assayed control used for the assessment of precision and analytical deviation of the following analytes in the pathological range:

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (APTT)
3. Fibrinogen (Clauss method)
4. Coagulation factors II, V, VII, VIII, IX, X, XI, XII, XIII and vWF
5. Inhibitors: Antithrombin III, protein C, protein S, $\alpha_2$-antiplasmin, C1-Inhibitor
6. Plasminogen
7. Thrombin time[a]

The values were determined using Siemens Healthineers reagents on mechanical and photo-optical coagulation analyzers.

[a] Availability of application and assigned value may vary by country

## Reagents

**Note:** CONTROL P 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!

| Reagent | Description | Storage | Stability |
|---|---|---|---|
| Control Plasma P<br>CONTROL P | Lyophilized reagent containing:<br>• human plasma[b]<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[c];<br>≤ –20 °C: reconstituted, 4 weeks[c] |

[b] from pooled plasma collected from selected healthy blood donor

[c] closed original vial

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

CONTROL P contains no preservatives.

Reconstituted CONTROL P can be frozen and thawed once. The reconstituted control plasma must be frozen as rapidly as possible in a tightly closed container. Thawing should be accomplished at 37 °C within 10 minutes. The reconstituted control plasma should not be exposed to 15 to 25 °C for longer than 2 hours after thawing.

## 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**
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 CONTROL P 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

## Materials Provided

| REF | Contents | | |
|---|---|---|---|
| OUPZ17 | Control Plasma P<br>CONTROL P<br>Table of lot- and method-specific Assigned Values and Ranges | 10 × → | 1 mL |

## Materials Required but not Provided

| Item | Description |
|---|---|
| Coagulation analyzers[d], 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) |

[d] 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.

Use with the corresponding reagents in accordance with the directions in the reagents' Instructions for Use. CONTROL P should be run at least once every 8 hours for any assays run for patient testing during that interval or according to local guidelines/ requirements. Controls should be run after each new calibration curve and after each change of reagent vial. Recalibration may be necessary if control values are outside the target range. Do not report test results if controls are out of range.

## Expected Values

Expected values are provided in the enclosed lot- and method-specific table of assigned values. These values are provided as a guideline only; it is recommended that each laboratory establish its own target range.

## Limitations of the Procedure

If coagulation analyzers with other measurement principles are used, the coagulation times obtained may differ from the values provided.

## 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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