ProC® Control Plasma
ProC CONTROL

Revision bar indicates update to previous version.

CE 0197

Intended Use

ProC CONTROL is an assayed intralaboratory control to estimate precision and analytical deviation of the ProC® Ac R and ProC® Global tests in the pathological range.

Reagents

Reagent	Description	Storage	Stability
ProC® Control Plasma ProC CONTROL	Lyophilized reagent containing: • human plasma[a] • rabbit plasma[a] • 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 hours; ≤ –20 °C: reconstituted, 4 weeks Do not refreeze!

[a] see below

ProC CONTROL is obtained from pooled plasma from selected healthy donors and is adjusted to a defined sensitivity value by adding rabbit plasma[1]. Rabbit Factor V, like Factor V Leiden, is not rapidly degraded by Activated Protein C (APC), thereby reducing the coagulation time in APC-dependent tests[2].

ProC CONTROL contains no preservative.

Reconstituted ProC CONTROL can be frozen and thawed once. The plasma must be frozen as rapidly as possible in a tightly closed container. Thawing should be accomplished at 37 °C within 10 minutes. The 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.

Caution
This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

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 ProC CONTROL in the labelled amount of distilled or deionized water, shaking carefully to dissolve (without foam formation).

Let stand at least 15 minutes at 15 to 25 °C.

Mix carefully once more before using.

Procedure

Materials Provided

REF	Contents	
OQKE17	ProC® Control Plasma ProC CONTROL Table of lot-specific Assigned Values	6 × → 1.0 mL

Materials Required but not Provided

Item	Description
REF OPBC03	ProC® Ac R
REF OQLS13	ProC® Global
Coagulation analyzers[b], such as:	• AUTOMATED BLOOD COAGULATION ANALYZER CS-2500 (CS-2500 System) • AUTOMATED BLOOD COAGULATION ANALYZER CS-5100 (CS-5100 System)

[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.

ProC CONTROL is used for quality control of the results in the pathological range with the corresponding reagents in accordance with the assay protocol in the relevant Instructions for Use. The results obtained must lie within the range given in the lot-specific Table of Assigned Values. Do not report results if ProC CONTROL is out of range.

Limitations

If coagulation analyzers with other measurement principles are used, the results obtained may deviate from those given for the range.

Expected Values

The assigned values were calibrated against STANDARD PLASMA by the manufacturer using the respective reagents on the coagulation analyzers.

Expected Values are provided for each lot of ProC CONTROL in the enclosed Table of Assigned Values. If used for precision control, the laboratory should establish its own control value and control limits in a preliminary period.

Technical Assistance

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

References

1. Kraus M, Römisch J. Factor V-Leiden like behaviour of non-human plasma and its possible use for calibration of APC-dependent assays. Blood Coag Fibrinol 1996; **7**: 295-302.
2. Bertina RM, Koeleman BP, Koster T, et al. Mutation in blood coagulation factor V associated with resistance to activated protein C. Nature. 1994; 369: 64-7.

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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