Control Plasma N

CONTROL N

Revision bar indicates update to previous version.

CE 0197

Intended Use

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

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (APTT)
3. Thrombin time (TT)
4. Batroxobin time
5. Fibrinogen
6. Coagulation factors II, V, VII, VIII, IX, X, XI, XII, XIII and vWF
7. Inhibitors: Antithrombin III, protein C, protein S, α_2-antiplasmin, C1-Inhibitor
8. Plasminogen
9. ProC line analytes
10. Lupus anticoagulants

The assigned values were determined at the manufacturer using Siemens Healthineers reagents on mechanical and photo-optical coagulation systems.

Reagents

Note: CONTROL N 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 N CONTROL N	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.

CONTROL N contains no preservatives.

Reconstituted CONTROL N 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 N 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		
ORKE41	Control Plasma N CONTROL N 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:	• Automated Blood Coagulation Analyzer CA-600 series (CA-600 series) • AUTOMATED BLOOD COAGULATION ANALYZER CS-2500 (CS-2500 System) • AUTOMATED BLOOD COAGULATION ANALYZER CS-5100 (CS-5100 System) • 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.

Use with the corresponding reagents in accordance with the direction in the reagents' Instructions for Use.

CONTROL N 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 other measurement principles are employed, the coagulation times obtained may differ from the given assigned values, depending on which instrument is used. The assigned values (mean coagulation times) given for the PT, APTT, thrombin time in seconds and the lupus anticoagulant assay are highly dependent on method, instrument and technique and therefore serve only as a guide.

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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