SIEMENS

Xprecia™ System

PT CONTROLS

English

PT CONTROLS

The Xprecia™ System PT Controls kit contains assayed Liquid Quality Controls (LQC) for the assessment of precision and accuracy in the normal (PT Control 1) and therapeutic (PT Control 2) range for International Normalized Ratio (INR) to be used with Xprecia™ System PT/INR Strips. You must peform a Quality Control (QC) test at the start of each shift and with every new lot, new shipment, or as required by local, state, and federal or national regulations.

INTENDED USE

Xprecia™ System PT Controls is a combination package containing lyophilized normal and therapeutic plasma controls for use with Xprecia™ Coagulation System for PT/INR determinations by professional healthcare providers. This product is for *in vitro* diagnostic use.

SUMMARY AND EXPLANATION

The PT Control 1 and PT Control 2 are run and evaluated the same way as patient samples. The method-dependent assigned values and ranges for each lot of PT Control 1 and PT Control 2 appear on each vial as a barcode to be read by the Xprecia System. When the barcode on the control vial is scanned, the assigned range for each lot-specific level of LQC can be read on the analyzer screen display as an INR value. The assigned ranges are set as ± 0.2 INR from the mean assigned value for PT Control 1 and ± 0.6 INR from the mean assigned value for PT Control 2. The assigned ranges are based on 2SD of the system's total variability.

For details regarding the principle of the procedure, any additional materials required, PT Control 1 and PT Control 2 for internal quality control, calculation of the analytical results, and performance characteristics of the tests, please consult the test strip instructions for use and the user guide for the Xprecia analyzer.

REAGENTS

DESCRIPTION	STORAGE °C	STORAGE °F	STABILITY AFTER RECONSTITUTION °C	STABILITY AFTER RECONSTITUTION °F
PT CONTROL 1 (1): lyophilized; preparation of human plasma; buffers and stablizers (approx 12.0 g/L)	2–8°	35.6–46.4°	15–25°	59–77°
			25 minutes (closed vial)	
PT CONTROL 2 (2): lyophilized; preparation of human plasma; buffers and stablizers (approx 12.0 g/L)	2–8°	35.6–46.4°	15–25°	59–77°
			25 minutes (closed vial)	
$CaCl_2$ DILUENT (D): $CaCl_2$ solution [0.010 mol/L]; Preservative: EC No. 47-500-7 5-chloro-2-methyl-4-isothiazolin-3-one; Preservative: EC No. 220-239-6 2-methyl-4-isothiazolin-3-one 3:1 [<0.00015%]	2–8°	35.6–46.4°	Use immediately after opening	

STORAGE STABILITY

The reagent may be used up to the expiration date indicated on the label if stored unopened. Always store the control vials as packaged and use within the expiration date printed on the control vial.

- Unopened storage: Store at 2–8°C (36–46°F), use before the 24 month lot expiration date printed on the vial label.
- Opened storage: Use reconstituted control solutions stored at 2–8°C (36–46°F) within 60 minutes (closed vial), and those stored at 15–25°C (59–77°F) within 25 minutes (closed vial).

WARNINGS AND CAUTIONS

Safety data sheets (MSDS/SDS) available at www.siemens.com/poc.

CAUTION! POTENTIAL BIOHAZARD The device contains human source material. 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 test found to be in conformance with the *In Vitro* Diagnostic Directive in the EU or FDA approved tests. 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.

CONTENTS

Materials provided

- 4 x PT Control 1
- 4 x PT Control 2
- 8 x 1.0 mL $CaCl_2$ Diluent
- 8 x Transfer pipettes
- 1 x Instructions for Use

Materials required but not provided

- Xprecia analyzer
- Xprecia System PT/INR Strips

IMPORTANT

- Always perform QC tests in accordance with local, state, and federal or national guidelines.
- Don't use the control solution after the expiration date on the bottle.
- Use reconstituted control solutions stored at 2–8°C (36–46°F) within 60 minutes (closed vial), and those stored at 15–25°C (59–77°F) within 25 minutes (closed vial).

RECONSTITUTING REAGENTS

INSTRUCTIONS

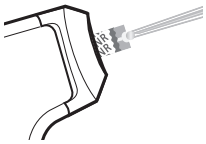
1. Use 1 transfer pipette to combine the entire volume of 1 vial of diluent ($CaCl_2$) into 1 control vial.
2. Mix carefully, by swirling the bottle using a circular motion, to completely dissolve all of the control plasma inside. Don't shake in order to avoid foam formation.

3. Close the bottle and allow to stand for at least 5 minutes at 15–25°C (59–77°F). Gently swirl the bottle again prior to use.
   Tip Retain the transfer pipette for use during the application of the control solution to a test strip.

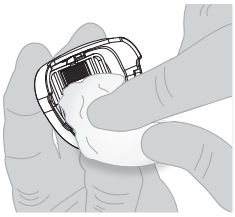
PERFORMING A QC TEST

INSTRUCTIONS

1. Prepare the analyzer to perform a QC test as detailed in the User Guide for the Xprecia analyzer.
2. Once the analyzer is ready for the QC test, apply the reconstituted control solution.
   - Horizontally position the transfer pipette so that the tip is almost touching the front edge of the test strip.
   - Gently squeeze the pipette base containing the control solution to apply some (a minimum of 6 µL) to the test strip target area. Capillary action draws the control solution into the test strip target area.
   - Stride sounds an audible tone when the test strip target area contains enough control solution.
   - Be careful to not overfill the test strip target area.



3. After the test finishes, read the result on screen.
4. Press the Test Strip Eject button to discard the test strip according to your facility's biohazard control policies. When ejecting a used test strip, always point the analyzer down facing your biohazard container before you press the Test Strip Eject button.
5. Follow the instructions in the user guide to clean and disinfect the entire exterior surface of the analyzer, and the test strip port protective cap, with a Siemens recommended germicidal wipe.
   Requirement You must clean and disinfect the device after every test. Don't use any non-recommended germicidal wipes to clean the analyzer, as they will damage the exterior.
6. Remove your gloves, thoroughly wash and dry your hands, and put on a new pair of gloves before performing a patient test.



RESULTS

Results are reported in the International Normalized Ratio (INR). The assigned QC range is displayed by the analyzer only as an INR value. For out of range or unexpected results, perform another QC test to confirm the results. An out-of-range result is indicated by the display of the "Control test result is out of range" error message. Siemens recommends you check if the controls have been stored according to manufacturer's instructions, are within their expiration date, and used within the manufacturer's recommended reconstitution time.
To determine if the test was performed properly, repeat the control with a new test strip. If the control is still out of range try another reconstituted vial. If the results are still unacceptable, contact your customer support representative.

PERFORMANCE CHARACTERISTICS

Reproducibility was determined by analyzing three (3) lots of Xprecia™ System PT Controls (PT Control 1 and PT Control 2) for 20 operational days, with 2 runs a day and 2 replicates per run for each control across 4 intended use sites and using three (3) lots of Xprecia™ System PT/INR test strips. The study was executed by a total of twelve (12) operators – three (3) at each site - covering four (4) intended use sites that randomly performed the runs.

Stride Reproducibility By Site													
				Within Run		Between Day		Between Run		Between Operator		Total	
Control Level	Site	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
PT Control 1	1	80	1.27	0.03	2.5	0.02	1.2	0.04	2.8	0.00	0.0	0.05	3.9
PT Control 1	2	80	1.29	0.03	2.3	0.00	0.3	0.02	1.5	0.00	0.0	0.04	2.8
PT Control 1	3	80	1.20	0.02	1.8	0.00	0.0	0.00	0.0	0.00	0.3	0.02	1.9
PT Control 1	4	80	1.24	0.04	3.3	0.03	2.3	0.03	2.1	0.03	2.2	0.06	5.0
PT Control 2	1	80	3.18	0.06	1.8	0.00	0.0	0.14	4.4	0.02	0.6	0.15	4.7
PT Control 2	2	80	3.22	0.07	2.2	0.03	1.1	0.06	1.9	0.00	0.0	0.10	3.1
PT Control 2	3	80	3.18	0.05	1.6	0.03	1.0	0.06	1.8	0.03	0.8	0.09	2.7
PT Control 2	4	80	3.11	0.11	3.6	0.14	4.3	0.11	3.7	0.15	4.8	0.26	8.3

Stride Reproducibility Combined Sites														
All Sites Combined			Within Run		Between Day		Between Run		Between Operator		Between Site/ Analyzer		Total	
Control Level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
PT Control 1	320	1.25	0.03	2.5	0.01	0.9	0.03	2.1	0.01	0.4	0.04	2.9	0.06	4.6
PT Control 2	320	3.17	0.08	2.4	0.07	2.1	0.10	3.2	0.06	2.0	0.03	1.0	0.16	5.0

SYMBOLS

This symbol indicates to not reuse the product.

This symbol indicates that you should consult instructions for use.

This symbol is used for both Warnings and Cautions.
A Warning indicates the risk of personal injury or loss of life if operating procedures and practices are not correctly followed.
A Caution indicates the possibility of loss of data or damage to or destruction of equipment if operating procedures and practices are not strictly observed.

This symbol alerts you to a biohazard.

IVD This symbol indicates an *in vitro* diagnostic device or an *in vitro* diagnostic medical device.

2°C 8°C This symbol indicates that the product has a temperature limitation. You need to store the product between 2–8°C.

This symbol indicates the product use by date.

EXP

LOT This symbol indicates the product batch code.

LOT

CE This symbol indicates that the product complies with the applicable directives of the European Union.

This symbol indicates the name and location of the product manufacturer.

EC REP This symbol indicates the manufacturer's authorized representative within the European community.

REF This symbol indicates the orderable material number of a part or product. This symbol indicates the revision letter of a part or product.

IVD 2°C 8°C

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