Universal Biosensors

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Xprecia™ Systems

PT CONTROLS English

PT CONTROLS
The Xprecia™ Systems PT Controls kit contains assayed controls for the assessment of precision and accuracy in the normal (Liquid Quality Control PT1) and therapeutic (Liquid Quality Control PT2) range for the prothrombin time (PT) to be used with Xprecia Prime™ PT/INR Test Strips and Xprecia Stride® PT/INR Test Strips. Universal Biosensors recommends that Quality Control (QC) tests be performed with every new lot, new shipment, or as required by local, state, and federal or national regulations.

INTENDED USE
Xprecia™ Systems PT Controls is a combination package containing lyophilized normal and abnormal plasma controls to be reconstituted with $CaCl_2$ diluent for use with Xprecia™ Coagulation Systems for PT/INR determinations by professional healthcare providers.

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 Prime™ and Xprecia Stride® Coagulation Analyzers.

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 your Xprecia Prime™ or Xprecia Stride® Coagulation Analyzer.

REAGENTS

DESCRIPTION		STORAGE °C	STORAGE °F	STABILITY AFTER RECONSTITUTION °C	STABILITY AFTER RECONSTITUTION °F
PT CONTROL 1	lyophilized preparation of human plasma buffers stabilizers	2–8°	35.6–46.4°	15–25°	59–77°
				25 minutes (closed vial)	
PT CONTROL 2	lyophilized preparation of human plasma buffers stabilizers	2–8°	35.6–46.4°	15–25°	59–77°
				25 minutes (closed vial)	
$CaCl_2$ DILUENT	$CaCl_2$ 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.

WARNINGS AND CAUTIONS
Safety data sheets (MSDS/SDS) available at www.universalbiosensors.com/products/xprecia/xprecia-prime-resources/.

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 Prime™ or Xprecia Stride® Coagulation Analyzer
- Xprecia Prime™ PT/INR Test Strips or Xprecia Stride® PT/INR Test 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.

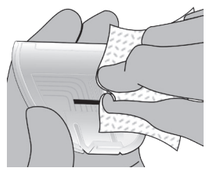
- Use reconstituted control solutions stored at 2–8°C (36–46°F) within 60 minutes (closed vial), and those stored at 15–25°C (59–77°F) within 25 minutes (closed vial).

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 of your Xprecia Prime™ or Xprecia Stride® Coagulation 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.
   - Xprecia Prime™ and Xprecia Stride® Coagulation Analyzers sound 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. Only use the recommended germicidal wipe as detailed in the Xprecia Prime™ or Xprecia Stride® Coagulation Analyzer User Guide.
   Requirement You must remove, clean, disinfect, and dry the cap and test strip port after every quality control 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) or in seconds. Only INR results have the assigned QC range. No result is displayed if the LQC is not in range. If no result appears, repeat the LQC test. If the error screen appears, refer to the Troubleshooting section of the Xprecia Prime™ or Xprecia Stride® Coagulation Analyzer User Guide.

SYMBOLS

	This symbol indicates to not reuse the product.	LOT	This symbol indicates the product batch code.
	This symbol indicates that you should consult instructions for use.	Rx only	This symbol indicates the product is for prescription use only.
	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 indicates the name and location of the product manufacturer.
	This symbol alerts you to a biohazard.	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	This symbol indicates an *in vitro* diagnostic device or an *in vitro* diagnostic medical device.	NON STERILE	This symbol indicates a medical device that has not been subjected to a sterilization process.
36°F 46°F	This symbol indicates that the product has a temperature limitation. You need to store the product between 36–46°F.		
EXP	This symbol indicates the product use by date.		

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For all product support related inquires please contact your authorized distributor (see www.universalbiosensors.com), email XpreciaHelp@universalbiosensors.com or call us on + 1 (202) 932-7918.

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