

CoaguChek XS Pro Medical Mobile Unit: Appendix B - CoaguChek XS PT Quality Control

INTENDED USE:

For system checks and quality control of prothrombin time testing with the CoaguChek XS, XS Plus, XS Pro instruments and CoaguChek XS PT test strips.

- The CoaguChek XS instruments have a number of inbuilt system checks.
- The CoaguChek XS PT test strip has an inbuilt quality control function.
- The liquid quality control solution complements these inbuilt system checks.

RUNNING LIQUID QUALITY CONTROL:

- Perform \ a liquid control with each new shipment or new lot number of test strips received.
- Perform once per week, after a battery change
- Refer to Weekly Liquid Quality Control Procedure.

STORAGE

- Stored at 2° to 8°C up to the expiry date printed on the pack.
- Bone Marrow Fridge Room 2K7 (C&W).

Note: Controls are warmed to room temperature 18°C to 32°C before use – minimum of 10 minutes.

STABILITY

- Control solution is used after 1 minute and within 30 minutes of reconstitution.

MATERIALS PROVIDED

CoaguChek XS PT Control Box consists of \:

- 4 bottles of dried (lyophilized) control plasma Level 1
- 4 diluent-filled droppers
- 1 code chip - marked with “C” and the code number.
- 1 package insert.

CONTROL COMPOSITION

- Each bottle of control contains 307 mg of anticoagulated domesticated rabbit plasma (before lyophilization) and 3 mg of additives.
- Each diluent-filled dropper contains 0.84 mg of calcium chloride, 0.1ug of preservatives and water.

QUALITY CONTROL CODE CHIP – FOR USE WITH THE COAGUCHEK XS PLUS / XS PRO

- Contains lot-specific control ranges for the Control Level 1.
- Control Code Chip will have a “C” with the corresponding code number.
- The control values are read when the quality control code chip is inserted into the CoaguChek XS Plus instrument/meter when prompted.
- The control values are saved in memory at initial use of the quality control code chip.
- Re-insertion of the quality control code chip is not necessary with further use.

TEST REPRODUCIBILITY:

- Imprecision is 2.8% CV for an INR of 1.8.

PRECAUTIONS AND WARNINGS:

- For in vitro diagnostic use only.

REFERENCES

CoaguChek XS PT Test Strip directional insert, Roche Diagnostics
201 Boul, Armand-Frappier, Laval, Quebec H7V 4A2 Canada 2010-05

REVISION & APPROVAL LOG

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0		New document		Elvira Kozak	Dr. Cathy Halstead
1.1	Minor	Document title and number change. Upload to QMS document control	28 Dec 2016		Dr. Benjamin Jung

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