CoaguChek Outpatient Clinic: 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°C 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

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