CoaguChek XS Pro Medical Mobile Unit: Appendix A - CoaguChek XS PT Test Strip

PRINCIPLE OF THE TEST

- Electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin.

CONTENTS OF THE PACK

- CoaguChek XS PT test strips (for use with CoaguChek XS/XS Plus/ XS Pro meters).
- 1 code chip
- 1 package insert

MEASURING RANGE, THERAPEUTIC RANGE, AND REPRODCUBILITY

- CoaguChek XS /XS Plus/ XS Pro monitor can display results in the following units:
  INR (International Normalized Ratio). (%Quick and seconds not in use – seconds are reported during external proficiency testing
- Measuring range is: 0.8-8.0 INR
- Imprecision of results in the normal and abnormal therapeutic range by manufacturer is:
  Capillary blood INR CV < 4.5 %
  Venous blood INR CV < 3.5%

SAMPLE MATERIAL

- Use only fresh capillary blood from a fingertip, heel or venous whole blood from a non-additive syringe. No anticoagulants (heparin, EDTA, citrate, oxalate) added.
- Apply the first drop of blood from a capillary finger or heel puncture.
- If using a capillary tube, collect using only the dedicated CoaguChek capillary tube
- (REF 1 1621173).
- If venous, dispense the first four drops of blood from the non-additive syringe.
- Apply within the first fifteen seconds of the sample puncture or venous collection.

STABILITY AND STORAGE

- Store at room temperature or refrigerated. (+2^{o}C to +30^{o}C)
- Open vials can be used up until the expiry date printed on the package and container.
- Use the test strip within 10 minutes of removing from the test strip container.

Note: Close container immediately after removing a test strip to ensure continued integrity of the remaining test strips due to exposure to light and humidity

ADDITIONAL MATERIALS REQUIRED

- CoaguChek XS Plus (CoaguChek XS) monitor.
- Blood collection supplies.

TEST STRIP CODE CHIP

- Each code chip belongs to a particular lot number of test strips.
- Code chip will have an “S” with the corresponding code number.
- Confirm that the code chip matches the number on the label of the test strip container.
- Replace the code chip from the old pack (if still in the monitor) with the one supplied in the new pack.
- The code chip number is confirmed in the instrument with each patient or control test performed.

Note: Use of the wrong code chip can produce incorrect results.

PATIENT TEST OR QUALITY CONTROL TEST

- Each test strip has an integrated quality control function.
- Refer to manual for institutional procedure of the Liquid Quality Control.
- Refer to troubleshooting guide for any possibly causes of error and interference.

A display of Error 6 or Error 7 results in rare cases in patients with prolonged clotting times. Repeat with a second test strip; confirm with the Reference Hematology laboratory analyzer. Consult the physician immediately.

TEST STRIP COMPOSITION AND ACCURACY

- Contains reagent (human recombinant thromboplastin 1.5 U) stabilizers, preservatives and additives.
- Each lot of test strips is calibrated to a reference lot that is traceable to the WHO International Reference Preparations.
- Laboratory reference method Innovin (Dade-Behring) was chosen for clinical study comparison.
- Majority of slopes were found between 0.93 and 1.04 for venous results, and between 0.92 and 1.03 for capillary results.

TEST LIMITATIONS

- Blood drop is a minimum of 8 uL in volume.
- Low sample volume will cause an error message.
- Hematocrit range is between 0.25 and 0.55.
- Spiked samples of the following showed no significant effect on test results:
  Bilirubin up to 513 umol/L
  Hemolysis up to 0.62 mmol/L
  Triglycerides up to 5.7 mmol/L
  Heparin concentrations up to 0.8 U/L
- Low molecular weight heparins (LMWH) up to 2 IU/mL: anti-factor Xa activity.

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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