Instructions for use – Cups & Pins RUO
For research use only

REF 4010GL – Cups & Pins RUO

Intended purpose

The Cups & Pins RUO are research use only single use specimen receptacles, intended for viscoelastometry analysis of citrated blood samples.

Principle of the method

Viscoelastometry [1-2] allows for the detection of whole blood formation in whole blood, and thus detects coagulation initiation (by the clotting time, CT), blood clot firmness (by the maximum clot firmness, MCF, or related parameters, such as the A20, amplitude 20 minutes after CT) and clot stability or fibrinolysis (by the maximum lysis, ML).

In viscoelastometry the kinetics of the whole blood clot formation are measured as follows: The blood sample (typically 340 µl) is placed between a cylindrical cup and a cylindrical pin. The viscoelastometry instrument creates a periodic rotation between the cup and the pin by approx. 5°. As long as the blood is fluid this relative movement is maximal. When the blood clots, the blood clot adheres to the surfaces of the cup and the pin and interferes with the relative movement between these surfaces. The reduction of the relative rotation of cup and pin is a measure for the mechanical strength of the blood clot. It is continuously detected by the viscoelastometry instrument and transformed into the clot amplitude, which is expressed in mm for historic reasons. The cup & pin is used in combination with the respective viscoelastometry reagents.

To ensure a good attachment of the blood clot onto the surfaces of cup and pin, the blood-contacting surfaces are coated with a plastic polymer coating. For quality control purposes this coating includes a light silver color.

Materials provided

120 Cup & Pins provided in 6 packages of 20 Cups & Pins each, composed of the plastic Cup and plastic Pin coated with a plastic polymer.

Additional materials and devices required

- Viscoelastometry analyzer
- Electronic pipette
- Viscoelastometry reagents
- Blood collection tube (3.2% sodium citrate) for coagulation testing

Product preparation

The product is ready to use.

Storage and stability

Store at room temperature in the provided primary packaging. The Cups & Pins are stable until the expiration date stated on the label.

Warnings and precautions

For professional use by trained personnel.

Do not use receptacles from defective packaging.

Intended for single use - do not reuse.

Human blood samples should be handled with care, following general precautions recommended for bio-hazardous materials [3].

General precautions (e.g., wear gloves and minimize skin exposure to specimen and reagents) should be followed when handling all materials. Dispose of waste according to local regulations. A material safety data sheet is available upon request.

Sample collection

Collect a venous blood sample according to the recommended procedures [4-5] using a blood collection tube with 3.2% sodium citrate. Samples should be analyzed within 3 hours from blood collection. Store the blood at room temperature. Always ensure blood collection tubes are filled to the indicated fill volume to avoid excessive citrate levels.

Test procedure

1. Check the expiry date of the device. Expiry date format is yyyy-mm-dd. Do not use the expired product.
2. Create the test in the software of the viscoelastometry analyzer according to the analyzer manual.
3. Open the primary packaging of the Cups & Pins. If necessary, tear the seal (label) open.
4. Remove one Cup & Pin (together). Do not touch the outer surface of the pin!

Do not touch the outer surface of the Pin!

5. Place the Cup and Pin into the analyzer according to the analyzer manual. Make sure the cup and the pin are completely inserted into the corresponding parts of the analyzer. An

incomplete insertion of Cup and / or Pin into their designated places in the analyzer can lead to wrong test results.

6. Add the sample and the reagents to the Cup as described in the instructions for use of the respective assay.
7. Start the test as described in the analyzer manual.
8. The test will stop, or you can stop the test as described in the analyzer manual.
9. Remove the Cup and the Pin and dispose according to local regulations.

Manufacturer

APIRO Diagnostics Kft.
Liget utca 3/2, HU-2040 Budaörs, Hungary
+36 30 203 3334 / info@apiro.eu / http://www.apiro.eu

Symbols

Symbol	Meaning
	Manufacturer
	Batch code
	Country of manufacture
	Consult instructions for use or electronic instructions for use
	Biological risks
	Do not touch pins

Symbol	Meaning
	Use-by date
	Catalogue number
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Contains sufficient for <n> tests

References

[1] Volod O, Bunch CM, Zackariya N, Moore EE, Moore HB, Kwaan HC, Neal MD, Al-Fadhl MD, Patel SS, Wiarda G, Al-Fadhl HD, McCoy ML, Thomas AV, Thomas SG, Gillespie L, Khan RZ, Zamlut M, Kamphues P, Fries D, Walsh MM. Viscoelastic Hemostatic Assays: A Primer on Legacy and New Generation Devices. J Clin Med. 2022 Feb 7;11(3):860.

[2] Heubner L, Mirus M, Vicent O, Güldner A, Tiebel O, Beyer-Westendorf J, Fries D, Spieth PM. Point of care coagulation management in anesthesiology and critical care. Minerva Anestesiol. 2022 Jul-Aug;88(7-8):615-628.

[3] Biosafety in microbiological and biomedical laboratories; U.S. Department of Health and Human Services, Washington, 5th Edition.

[4] CLSI/NCCLS H03-A6; Procedures for the collection of diagnostic blood specimens by venipuncture.

[5] CLSI H21-A5 Collection, transport, and processing of blood specimens for testing plasma-based coagulation assays and molecular hemostasis assays.

Version history of these instructions for use

Date	Version	Change description
2024-09-25	1	Initial version