Instructions for use – QC2 RUO
For research use only

REF 2020GL – QC2 RUO

Intended purpose

The QC2 RUO is a research use only plasma control that can be applied on viscoelastometry systems, produced using blood plasma from healthy individuals with the addition of an anticoagulant in order to render results that are in accordance with a inhibited plasmatic coagulation.

Principle of the method

Analysis of the QC2 RUO using viscoelastometry assays and an analyzer allows for an internal control of the correct performance of the analyzer and the reagent. The resulting values are compared to the target ranges provided in the target value sheet.

The QC2 RUO control plasma (lyophilized) is made from citrated plasma donations of healthy donors with the addition of an anticoagulant. Stabilizers and buffers were added prior to lyophilizing. Therefore, an abnormal clotting factor activity is present in the plasma control material.

Materials provided

- 6 glass vials with lyophilized control material made from citrated plasma donations of healthy donors with the addition of an anticoagulant, grouped in 3 vials each by a mesh hose (for protection during transportation)
- 3 empty pipette tips and
- 3 empty 5 mL tubes with caps to assist with the reconstitution.

Additional materials and devices required

- Viscoelastometry analyzer and receptacles (Cups & Pins)
- High purity water
- Pipette
- Viscoelastometry reagents

Reagent preparation

The contents of a product vial must be reconstituted with 1.05 mL high purity water. Carefully rotate the vial until the product is completely reconstituted (avoid foaming).

Allow the reconstituted and re-sealed vial (with stopper and screw cap closed) to stand on the heated plate (37°C) of the viscoelastometry analyzer for 15 min. Invert to mix before use (avoid foaming). The solution should be yellow-colored.

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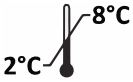
After reconstitution, one control material vial can be used to perform up to 3 tests, within one hour from reconstitution. Discard left over material according to local regulations. Do not freeze the reconstituted material.

Storage and stability



Store at +2 to +8 °C. The unopened control material vials are stable until the expiration date stated on the vial label. Reconstituted control material vials are stable for 1 hour at room temperature. Avoid contamination and always close the vial again (stopper and screw cap) during storage between analyses.

Warnings and precautions

For professional use by trained personnel.

Do not use control materials from defective vials.

Control materials should be handled with care, following general precautions recommended for bio-hazardous materials [1].

Each single donor plasma and each LOT of the QC2 RUO has been tested and found negative for HbSAg, HIV 1/2 Ab and HCV Ab. However, universal precautions (treating all human source materials as potentially infectious) should be exercised.

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.

Control procedure

1. Check the expiry date of the device. Expiry date format is yyyy-mm-dd. Do not use expired product.
2. Use the control material as specimen with the respective assays.
3. Follow the instructions as provided in the instructions for use of the respective assay.

Conducting a quality control serves as internal control of the viscoelastometry analyzer and reagent. It is common practice to run QC once per week alternating between QC1 RUO and QC2 RUO on all channels in operation for extrinsically and intrinsically activated viscoelastometry. Additionally, QC is recommended after each new installation of the analyzer (e.g. after transport or maintenance) and if implausible measurement results occur.

Alternatively, QC testing can be run according to local regulations.

Target ranges

Each batch of the control material is provided with a target range sheet that contains a table of reference ranges for the respective assays and their main parameters.

Target ranges for the control materials are provided in electronic format and are available for download on www.apiro.eu/eIFU.

When using the control material with Apiro manufactured reagents, viscoelastometry analyzer and receptacles, the results for the specified tests should be within the ranges provided in the respective target range sheet for the respective batch. If other reagents are used, reagent specific target values must be established individually by the user.

Result interpretation

If a result is outside the target range, the QC measurement should be repeated on the same channel, plus on another channel using the same reagent (if not already done). If results of both channels are within the target range, it is likely that a procedural error occurred during the initial control measurement on the channel in question. If a result outside the target range is reconfirmed on the channel in question by repeated QC and the result on another channel is within the target range, a channel-specific problem is likely. Do not use this channel for any further measurements anymore. You may lock this channel in the viscoelastometry software settings. Please contact your local customer support.

If both measurements are outside of target ranges, please contact your local customer support.

Manufacturer

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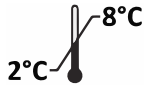
Symbols

Symbol	Meaning
	Manufacturer
	Batch code
	Country of manufacture

Symbol	Meaning
	Use-by date
	Catalogue number
	Do not use if package is damaged and consult instructions for use

Symbol	Meaning
	Temperature limit
	Consult instructions for use or electronic instructions for use
	Contains human blood or plasma derivatives

Symbol	Meaning
	Contains sufficient for <n> tests
	Biological risks

References

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

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

[3] 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
2025-08-06	1	Initial version