Instructions for use – QC2

REF 2021EU – QC2 UDI 59998629922021EU_1U3

Intended purpose

CE 2265 IVD **The QC2 is a quality control material based on normal plasma with the addition of an anticoagulant for in-vitro diagnostic professional use, intended for internal quality control of reagents for viscoelastometry analysis.**

CAUTION: A use of the device outside of its intended purpose, may lead to the test results being incorrectly interpreted by the user.

Indications for use

Indicated to be used when the verification of the ongoing performance of viscoelastometry analyzer or reagents is aimed for.

Contra-indications for use

As the device is a control material for viscoelastometry analysis, no limitations on its use are introduced.

Intended users

- trained healthcare professionals,
- trained laboratory professionals

Environment of use

Indoors in a typical setting of a laboratory, equipped and designed to ensure standard electrical connections, adequate lighting as well as standard environment settings regarding temperature, humidity and pressure to ensure the functionality of typical electrical devices like electrical medical devices and personal computers.

Intended patient population

As the device is a control material for viscoelastometry analysis, no limitations on its use are introduced.

Principle of the method

Analysis of the QC2 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 control plasma (lyophilized) is made from citrated plasma donations of healthy donors with the addition of an anticoagulant, to render the coagulation activation process abnormal. Stabilizers and buffers were added prior to lyophilizing. Therefore, a prolonged coagulation activation is present in the control material plasma.

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 protection sleeve (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

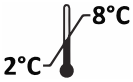
The contents of a product vial must be reconstituted with 1.05 mL high purity water. Carefully rotate the vial until the product is completely reconstituted (avoid foaming).

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.

CAUTION: Incorrect reconstitution and mixing of the product before use may affect reagent stability and lead to wrong test results.

CAUTION: 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.

CAUTION: Incorrect storage conditions may affect reagent stability and lead to wrong test results.

Warnings and precautions

For professional use by trained personnel.

CAUTION: Do not use control materials from defective vials.

CAUTION: Any serious incident that has occurred as a result of use of the device has to be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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

CAUTION: Each single donor plasma and each LOT of the QC2 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.

CAUTION: General precautions (e.g., wear gloves and minimize skin exposure to specimens and reagents) should be followed when handling all materials.

NOTE: Dispose of waste according to local regulations.

NOTE: A material safety data sheet is available upon request.

Residual risks, undesirable side-effects, and information for the patient

Warnings and notes are provided throughout the whole instructions for use.

Risk management activities for the device concluded that there are no residual risks for the device.

No undesirable side-effects were identified during the post-market activities for the device.

No information for the patient is required to be provided for the device.

Control procedure

1. Check the expiry date of the device. Expiry date format is yyyy-mm-dd. Do not use expired product.

   CAUTION: Do not use the expired product. The use of the expired product may lead to wrong test results.

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 and QC2 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.

Precision

In a precision study the QC2 material was tested in 3 runs, on three analyzers, using the EX, IN, FIB, AP, RVV, ECA and HI assays (n=18 for each assay). The resulting coefficient of variation (CV) for the EX-CT, EX-A20, IN-CT, IN-A20, FIB-A20, AP-A20, RVV-CT and HI-CT and ECA-CT (as the representative parameters for the respective assays) was as follows:

	CV
EX-CT (sec)	7.0%
EX-A20 (mm)	5.3%
IN-CT (sec)	1.9%
IN-A20 (mm)	4.2%
FIB-A20 (mm)	4.2%
AP-A20 (mm)	4.8%
RVV -CT (sec)	9.7%
HI-CT (sec)	2.5%
ECA-CT (sec)	8.6%

CT: clotting time, A20: amplitude 20 min after CT.

Limitations and interferences

As the device is a control material for viscoelastometry analysis, no limitations and interferences on its use are introduced.

The manufacturer's guidance on the use of the control materials, viscoelastometry analyzer and reagents must be followed to ensure the correct performance of the procedure.

Summary of safety and performance

Summary of safety and performance is provided in electronic format and is available for download on www.apiro.eu/eIFU.

Manufacturer

APIRO Diagnostics Kft.
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Authorized representative

Accumed Sagl
Viale Serfontana 10, CH-6834 Morbio Inferiore, Switzerland

Symbols

Symbol	Meaning
	Manufacturer
	Batch code
	Country of manufacture
	Temperature limit
	Consult instructions for use or electronic instructions for use
	Contains human blood or plasma derivatives
	Not intended for near-patient testing
	Unique device identifier
	Swiss authorized representative

Symbol	Meaning
	Use-by date
	Catalogue number
	Do not use if package is damaged and consult instructions for use
	Contains sufficient for <n> tests
	Biological risks
	Caution / Warning
	CE marking of conformity
	In vitro diagnostic medical device

References

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

Version history of these instructions for use

Date	Version	Change description
2026-04-13	1	Initial version