ClotPro EN

QC 2

For viscoelastic quality control

REF 113102 CE IVD

15 8°C 2°C

6 198438 339756

enicor GmbH
Reichenbachstr. 27 - 80469 Munich - Germany
Phone: +49 89 997 428 181 - www.clot.pro - info@clot.pro

PN 113102-IE (AA) 2021-07

For in vitro diagnostic use.

Intended Purpose

QC 2 is a quality control material for monitoring the accuracy and precision of tests carried out on the ClotPro® analyzer [1]. Using QC 2, a semi-automated and semi-quantitative quality control measurement is executed, using the ClotPro analyzer, Cups and Pins, and the respective Active Tip.

Intended User

For use by trained healthcare professionals. Near patient and laboratory professional use.

Package format

5 x 1 glass vial QC 2 lyophilized, 1.36 ml

After reconstitution each vial is sufficient for 3 assays.

Constituents

QC 2 control plasma (lyophilized) is made from human plasma collected using sodium citrate as an anticoagulant (0.129 mol/l). The plasma was adjusted for receiving values on the ClotPro system approximating the abnormal range in whole blood. Stabilizers and buffers were added prior to lyophilizing.

Additional materials required

- ClotPro analyzer
- ClotPro Cups & Pins
- ClotPro QCdil
- ClotPro IN-test, EX-test, TPA-test, HI-test, AP-test, FIB-test or RVV-test
- Pipette

Preparation

The contents of a vial of QC 2 must be reconstituted with 1.36 ml QCdil solution from the manufacturer (QCdil, 5.0 ml). QCdil is provided using pre-filled tubes containing 5 ml Aqua dest. with a low concentration of $CaCl_2$.

Allow the reconstituted and re-sealed vial (with stopper and screw cap closed) to stand at room temperature for 15 minutes. Swirl gently to mix – do not shake! The solution should be yellow-colored.

Prior to analysis the vial shall be warmed for at least 3 min and up to 5 min in the respective pre-heating position on the ClotPro analyzer. The control can also be reconstituted on the pre-heating position on the analyzer.

Principle

Analysis of QC 2 using EX-test, IN-test, TPA-test, HI-test, AP-test, FIB-test, or RVV-test 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 values.

Storage and stability

Store at +2 to +8°C.The unopened QC 2 reagent vial is stable until the expiration date printed on the vial label. Reconstituted vials QC 2 are stable for 2 hours at room temperature. Avoid contamination and always close the vial again (stopper and screw cap) in case of storage between analyses.

Warnings and precautions

For use by trained healthcare professionals.

Each donor unit used in the manufacturing of QC 2 has been tested for antibodies against HIV type 1 and 2, Hepatitis C-Virus antibodies as well as Hepatitis B surface-antigen. These plasma were found to be negative on the tested parameters.

QC 2 control plasma are **potentially infectious** and should be handled with care, following general precautions recommended for potentially bio-hazardous material [2].

General precautions (e.g. wear gloves, minimise exposure of the skin 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.

Residual Risks

Sources of reagent error:

- Improper use of reagents can lead to wrong test results.

Sources of procedural error:

- A defective electronic pipette or its improper use can lead to incorrect pipetting volumes.
- Wrong sample temperature can lead to impaired test results.
- Excessive time elapsed between pipetting steps can lead to wrong test results.

Procedure

Use the QC 2 reagent as specimen in the respective assays.

Follow the instructions as provided in the product insert of the respective test [4].

Recommended control procedure

Conducting a quality control serves as internal control of the ClotPro analyzer and reagent.

It is common practice to run QC once per week alternating between QC 1 and QC 2 on all channels in operation for extrinsically and intrinsically activated viscoelastometry (EX-test and IN-test).

Additionally, QC is recommended after each new installation of the system (e.g. after transport or maintenance) and if implausible measurement results occur.

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

Target values

Each batch of QC 2 is provided with a target value sheet with a table of reference ranges for the respective extrinsic and intrinsic assays and its main parameters.

When using QC 2 and the ClotPro system reagents, the results for the specified tests should be within these ranges. If other reagents are used, reagent specific target values must be established individually by the user.

Results of the control

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 ClotPro software settings (service menu). Please contact your local customer support.

If both measurements are outside the target range please contact your local customer support.

Limitations of the procedure

Variables such as temperature, storage, instrument properties and individual use techniques may affect the final result. Therefore, strictly follow the manufacturer's guidance on the use of the ClotPro analyzer and reagents [3; 4].

Packaging Symbols

Symbol	Description
	Near patient testing
	Remove Cups & Pins from packaging together
	Do not touch the Pins
+	Use Cups & Pins together with Active tips™

Revision History

Version	Modification
AA	Initial version acc. to regulation (EU) 2017/746 (IVDR)

Literature

1 Calatzis A., Wittwer M., Leyser H., Hipp Q., Spannagl M. ClotPro – a new generation viscoelastic whole blood coagulation analyser. Hämostaseologie 2018; 4a, A32, P013

2 Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Washington, 5th Edition

3 ClotPro user manual

4 Product Inserts EX-test, IN-test, TPA-test, HI-test, AP-test, ECA-test, FIB-test, or RVV-test

Technical Assistance

You can contact us for technical assistance – please see contact details below.

Incident Reporting

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Manufacturer

enicor GmbH - Reichenbachstr. 27 - 80469 Munich - Germany - Phone: +49 89 997 428 181 - www.clot.pro - info@clot.pro