Liquid Control Set

Liquid Control Set

REF		CONTENT	SYSTEM
06675999190	06675999500	**S1**: 2 x 4 mL **S2**: 1 x 2 mL	Multiplate

English

System information

For use on the Multiplate analyzer.[1]

Intended use

For use as a quality control for impedance aggregometry based on the analysis of an artificial liquid control material.

Summary

Whole blood impedance aggregometry is based on the measurement of a change in electrical impedance caused by the aggregation of blood platelets on a pair of electrodes. The specific evaluation and assessment of the instrument to detect a change in the electrical current may be tested using artificial control material.[1]

Test principle

The Liquid Control Set (LQC) consists of two fluids, Solution 1 and Solution 2, with different ionic strengths. The mixing of both fluids results in a change of electrical conductivity, which is recorded as a change in impedance in the Multiplate analyzer. The set contains material for level 1 and level 2 controls for all 5 channels of the Multiplate analyzer.

Reagents - working solutions

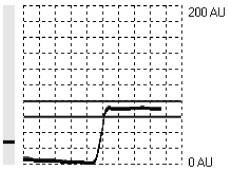
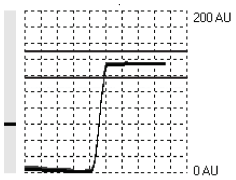
S1: 2 tubes, each containing 4.0 mL of Solution 1.

S2: 1 tube, containing 2.0 mL of Solution 2.

Target ranges

Expected values for two Liquid Control levels are marked by two horizontal lines in the graphic window.

Expected values (Aggregation in aggregation units-AU) of liquid quality control range from:

Level 1 (59.1-78.7 AU)	Level 2 (117.9-149.6 AU)
	

If results of the Liquid Control Set analysis are not within the expected range, repeat the analysis. If results repeatedly fail, lock the failing channel(s) in the Multiplate software and contact the manufacturer for service.

Precautions warnings

For in vitro diagnostic use for laboratory professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Handling

The product is ready for use.

The 3 tubes must be preheated for 20 minutes prior to use in the preheating positions of the Multiplate analyzer.

Storage and stability

Store at 2-8 °C.

The unopened controls are stable up to the stated expiration date.

Stability of the opened control vial:	
at 15-25°C	24 hours

Materials provided

- See “Reagents – working solutions” section for reagents.

Materials required (but not provided)

- REF 06675590001, Test Cells, 6 x 10 pieces
- Multiplate analyzer. See operator’s manual and Quick Start Guide of the analyzer for additionally required materials.
- General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Place S1 and S2 in the designated positions. Run measurements for both level 1 and level 2 controls as follows:

Test procedure for liquid quality controls	
Level 1	**Level 2**
Load all 5 channels with Test Cells	
Connect the sensor cables to the Test Cells.	
Add 600 µL of **Solution 1** into each Test Cell.	
Select **F2: Start timer** for 3 minutes incubation phase.	
Select **F3: Start test** for all 5 free channels to start the measurement simultaneously.	
Select **F2: Start timer** again (immediately after starting the measurement). The first 3 minutes of measurement will be recorded as baseline.	
After the 3 minutes add **100 µL of Solution 2 onto** the surface of Solution 1 in all Test Cells. Do not immerse the pipette tip into Solution 1 to avoid air bubbles.	After the 3 minutes add **200 µL of Solution 2 onto** the surface of Solution 1 in all Test Cells. Do not immerse the pipette tip into Solution 1 to avoid air bubbles.
After additional 3 minutes the measurement stops automatically.	
Enter a patient ID (e.g. Lot Test Cells and Lot LQC kit) and select **Liquid Control level 1/level 2** as a test during the running measurement.	
Print out and compare aggregation results with expected values.	

Temperature conditions and incubation times must be precisely observed. When using the electronic pipette follow the software instructions displayed by the Multiplate analyzer.

The use of non-preheated solutions or shorter incubation times may skew results. It is important that Solution 2 is added **onto** the surface of Solution 1.

Limitations - interference

The Liquid Control Set is an artificial control for Multiplate analysis. The accurate function of the electronic parts and sensors of the Multiplate system is assessed.

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Physiological quality control of platelet function tests is hampered by the fact that platelets cannot be stabilized for longer time periods without significant loss of their functional activities.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

References

1 Köppen K., Wittwer M., Calatzis A., et al.: External quality control of impedance aggregometry analysis: a feasibility study; poster abstract P-14-13; GTH congress, Society of Thrombosis and Haemostasis annual meeting, Wiesbaden 2008.

For further information, please refer to the appropriate operator's manual and quick start guide for the Multiplate analyzer, the respective applications sheets, the product information, and Method Sheets of all necessary components.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

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.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume for reconstitution
GTIN	Global Trade Item Number

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Additions, deletions or changes are indicated by a change bar in the margin.

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CE

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