WQC

ANYSIS™ Wet Quality Control Test Cartridges (WQC1, WQC2)

INSTRUCTIONS FOR USE

English

TECHNICAL SUPPORT
(ROK) 02-537-5111 (International) +82-2-537-5111
techsupport@any-sis.com

INTENDED USE

The ANYSIS™ Wet Quality Control (WQC) is intended to be used with the ANYSIS analyzer as to set a basic standard of quantitative quality control. Additional information about running this control is located in the Package insert of the ANYSIS Test Kit.

REAGENTS

- ANYSIS WQC 1 diluent tubes containing 1.1 mL of optically absorbent suspension with polystyrene microspheres (W/V 0.15%), PBS, red pigment and preservative.
- ANYSIS WQC 2 diluent tubes containing 1.1mL of optically absorbent suspension with polystyrene microspheres (W/V 1.4%), PBS, red pigment and preservative.

SUMMARY AND EXPLANATION

The ANYSIS™ Instrument measures platelet aggregation-induced occlusion and provides a migration distance (MD) as a result. The ANYSIS™ Instrument consists of the test instrument and disposable test cartridges. Wet Quality Control measures positive and negative results for the platelet function testing.

GENERAL PRECAUTIONS

For *in vitro* diagnostic use.

The ANYSIS™ Instrument and its components should only be used as directed by the ANYSIS™ User Manual.

Before using the WQC material, the WQC material must be mixed well. If left as is, microbeads suspended in the WQC material will settle and accumulate at the bottom of the vessel. Therefore, it is necessary to uniformly mix the microbeads by stirring the WQC material using a vortexing equipment. If it is not mixed well, you may not get the results you want. This process applies to both WQC 1 and WQC 2 materials.

Used WQC materials in the ANYSIS Test should be discarded in accordance with institutional guidelines for biohazardous waste disposal.

STORAGE AND STABILITY

The WQC materials can be stored at room temperature (15°C to 30°C). Control materials are suitable for use until the expiration date stamped on the label. WQC materials can be re-used if sealed well after use. Do not freeze.

LIMITATIONS

WQC materials should be used prior to the expiration date on the label. If the WQC material does not produce a result within the range stated on the test device pouch, we recommend to stir the WQC materials with vortexing instrument and repeat the procedure with a new test kit. If results are still out of range, we recommend contacting technical support.

EXPECTED VALUES

WQC 1: The migration distance would be between 230 and 268.

WQC 2: The migration distance would be between 121 and 169

EXPLANATION OF SYMBOLS

ISO 15223-1:2016
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

5.1.1 	**Manufacturer**	5.1.3 	**Date of manufacture**
5.1.4 	**Use by date**	5.1.5 	**Batch code**
5.1.6 	**Catalogue number**	5.1.7 	**Serial number**
5.3.7 	**Temperature limits**	5.4.1 	**Biological risks**
5.4.2 	**Do not re-use**	5.4.3 	**Consult instructions for use**
5.4.4 	**Caution**	5.5.1 	**In-vitro diagnostic medical device**
5.5.5 	**Contains sufficient for < n > tests**		**CE certification**
	**European representative**		**Waste electrical and electronic equipment**

EC REP

RHEO Meditech

RheoMeditech, Inc.
2F, 32 Anam-ro, Dongdaemun-gu,
Seoul, Republic of Korea (02578)
Tel: +82-2-537-5111 Fax: +82-2-537-5103
www.any-sis.com

Javi Tech e.K.
Sachsenhausener Str. 16, 65824
Schwalbach a. Ts., Germany

CE

REF: 30040 2021-05 (Rev.1)