MeMed



MeMed BV®
EXTERNAL CONTROL

Please read this document carefully before using MeMed BV® EXTERNAL CONTROL

IFU12013 MeMed BV® External Control IFU | Revision: 1.0

MeMed BV® EXTERNAL CONTROL

CAUTION!
This device is restricted to sale by or on the order of a physician or licensed practitioner.

Intended Purpose

The MeMed BV® External Control is an ancillary control material. The reagents are intended for quality control testing in clinical laboratory immunoassay of MeMed BV® test via MeMed Key® analyzer.

Reagents

The set includes two 1.5 ml control vials (EC1 and EC2) each containing purified TRAIL, IP-10, and CRP antigens in a protein buffer. The controls represent viral and bacterial MeMed BV® test scores.

The External Control contains 0.024% CMIT/MIT.

Warning:

P273: Avoid release to the environment.
P280: Wear protective gloves/protective clothing/eye protection/face protection
P302+P352: IF ON SKIN: Wash with soap and water
H317: May cause an allergic skin reaction
P333+P313: IF skin irritation or a rash occurs: Get medical advice/attention
P363: Wash contaminated clothing before reuse
H412: Harmful to aquatic life with long lasting effects
For detailed safety information, refer to MeMed BV® Calibrator and External Control Safety Data Sheet (SDS11001). The document can be accessed at www.me-med.com/IFU.

Test Principle

The method for quantitative determination of TRAIL, IP-10 and CRP proteins is a sandwich chemiluminescence immunoassay. All reagents and disposables are contained within the cartridge and the events that occur within the analyzer are transparent to the user.
For each analyte, the analyzer combines specific antibody-coated magnetic particles, assay buffer, enzyme-linked specific antibodies and the patient specimen to create analyte-specific immune complexes (either via one-step or two-step incubation periods). Subsequently, the analyzer applies a magnetic field to separate the immune complexes from unbound materials and to allow washing of non-specific binding events. Then the analyzer adds chemiluminescence substrate to the reaction, which emits light in a manner correlated to the amount of target analyte present in the specimen. The photo detection device in the analyzer detects the photons that are emitted during the reaction.

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Materials Provided

MeMed BV® External Control FG12001

Accompanying Products

The following equipment and materials are used before and during the external control process:

- MeMed BV® test cartridge
- MeMed Key® analyzer – refer to the analyzer IFU (IFU13002) for step-by-step instructions

Reagent Storage and Preparation

Store the external controls in a temperature-controlled area at 2-8°C (do not freeze). Remove from refrigerator and open just before use. The product is stable until the expiration date when stored tightly capped at 2-8°C.

External Control Procedure

Caution:
Do not interchange vial caps. Doing so may cause cross contamination.

Refer to MeMed Key® analyzer IFU for external control workflow instructions.
The external control process should take approximately 30 minutes.
For every stage, dispense 5 drops directly to the sample well of the MeMed BV® test cartridge.
After every stage, recap the vials and return them to storage at 2-8°C.

Caution:
In case of failed external control, repeat the process with a new cartridge(s). If the problem persists, contact MeMed for further support.

Caution:
Any serious incident that has occurred in relation to the MeMed Key® analyzer and its ancillaries shall be reported to the manufacturer and local competent authorities.

Labels and Symbols

Symbol	Description	Symbol	Description
	Warning/Caution		Manufacturer
	Bio-hazard warning		Manufacture date
	Keep dry		Authorized representative in EU
	Refer to IFU		Expiration date
	Humidity limits		This side up
	Temperature limits		Stacking limit
	Fragile, handle with care		In-vitro diagnostic device
	Keep away from direct sunlight		Customer service email address
	Part number		Customer service telephone number
	Batch number		External Control
	Sufficient for **n** EC runs		

MeMed BV® EXTERNAL CONTROL

REF	FG12001
CE	Conformité Européenne (CE Mark)
IVD	In vitro diagnostic medical device
	MeMed Diagnostics Ltd. Nahum Heth 7, Tirat Carmel, 3508506 ISRAEL
	www.me-med.com/support
	IL/EMEA: support@me-med.com USA: help@me-med.com
	+972 (4) 8500302, 1-888-3960030 (US Toll-free) | +49 3031196750 (EU)
EC REP	Qarad EC-REP BV, Pas 257, 2440 Geel, Belgium
Rx ONLY	Prescription use only

Revision History

Revision	Date	Description
1.0	2023-06-27	New document

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