



REF BX-457-600

HISCL™ M2BPGi™ Control**Identification of the IVD reagent**

HISCL™ M2BPGi™ Control

Intended use

For In Vitro Diagnostic Use

For quality control of HISCL M2BPGi Assay Kit

Components

1. HISCL M2BPGi Control Level 1 2mL × 3
2. HISCL M2BPGi Control Level 2 2mL × 3

Warnings and precautions

1. HISCL M2BPGi Control Level 1 and Level 2 contain a noninfective recombinant antigen, and the control components do not contain human-derived materials.
2. Each control contains sodium azide. Sodium azide reacts with lead tubing and copper tubing to generate metal azides, which can explode; therefore, use a large quantity of water when disposing of the control.
3. In case the control comes into contact with the eyes, mouth, or hands, use emergency procedures such as washing these parts with a large quantity of water. If required, consult a physician.

Examination procedure

Dispense about 200µL (5 drops) of each control.

Carry out procedures according to the package insert for the HISCL M2BPGi Assay Kit.

Storage and shelf life after first opening

Store at 2-8°C. The shelf life is 90 days after opening. Do not freeze.

Manufacturer**Sysmex Corporation**

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Date of issue revision

12/2017

Reference Value

Reference values of this lot are described below.

Lot No.	QNMB-0XX	
Expiry	YYYY-MM-DD	
	Reference value	Reference range
Level 1 (Lot No. QNMB-1##)	0.00 C.O.I.	0.00 ~ 0.00 C.O.I.
Level 2 (Lot No. QNMB-2++)	0.00 C.O.I.	0.00 ~ 0.00 C.O.I.

† The abovementioned reference values have been set on the basis of results obtained with HISCL-5000 at Sysmex Corporation.

† There is a possibility of variation in the reference value and range depending on the device or reagent used.

† The reference value and range for M2BPGi have been set on the basis of results of the HISCL M2BPGi Assay Kit (Lot No. *****), Inhouse standard materials.

† The range of the reference value was set ±30% of the reference value for calculation.

Symbol

Refer to the HISCL Instructions for Use for the details of the symbols written on the outer box.

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