

# HBV Immunoassay Control

## Identification of the IVD reagent

HBV Immunoassay Control

## Intended use

For In Vitro Diagnostic Use.

For Quality Control of HBs antigen, HBe antigen, HBs antibody, HBe antibody and HBc antibody.

## Components

1. HBV Antigen Positive Level 1 (HBsAg, HBeAg) 3 mL x 2
2. HBV Antigen Positive Level 2 (HBsAg, HBeAg) 3 mL x 2
3. HBV Antibody Positive Level 1 (Anti-HBs, Anti-HBe) 3 mL x 2
4. HBV Antibody Positive Level 2 (Anti-HBs, Anti-HBc) 3 mL x 2

None of the components contain materials of human origin.

Antigen controls contain non-infective recombinant antigens, and antibody controls contain non-infective mouse monoclonal and rabbit polyclonal antibodies.

## Warnings and precautions

1. Because the antibody used for this control is mouse monoclonal and rabbit polyclonal antibodies, this control cannot be used in the measurement system with an anti-human IgG antibody.
2. Each control contains sodium azide. Since sodium azide reacts with lead tubing and copper tubing to generate metal azides which can explode, use plenty of water when disposing of it.

In case of contact with the eyes, mouth, or hands, carry out emergency treatment such as washing with plenty of water. If necessary, consult a physician.

## Examination procedure

Dispense the amount appropriate for the reagent you are using (about 40-50µL/drop).

Carry out procedures according to the package insert for each Assay kit.

## Storage and shelf life after first opening

Store at 2-8°C. The shelf life is 30 days after opening. Do not freeze.

## Manufacturer



**Sysmex Corporation**  
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## Authorized representative / Distributors

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09/2015

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## Target Value

Lot No.	HB-000
Expiry	YYYY-MM-DD

Target values of this lot are described below.

### HBV Antigen Positive Level 1

	Item	Target Value	Range
Lot HBG-1##	HBs antigen	0.00 IU/mL	0.00~0.00 IU/mL
	HBe antigen	00.0 COI	00.0~00.0 COI

### HBV Antigen Positive Level 2

	Item	Target Value	Range
Lot HBG-2++	HBs antigen	00.00 IU/mL	00.00~00.00 IU/mL
	HBe antigen	00.0 COI	00.0~00.0 COI

### HBV Antibody Positive Level 1

	Item	Target Value	Range
Lot HBB-1##	HBs antibody	00.0 mIU/mL	00.0~00.0 mIU/mL
	HBe antibody	00.0 Inh%	00.0~00.0 Inh%

### HBV Antibody Positive Level 2

	Item	Target Value	Range
Lot HBB-2++	HBs antibody	000.0 mIU/mL	000.0~000.0 mIU/mL
	HBc antibody	00.0 COI	00.0~00.0 COI

† The above target values were set by the results of HISCL-5000 at Sysmex Corporation.

† These target values and ranges may vary according to the device or reagent.

† Target values and ranges were set by the results of HISCL HBsAg Assay Kit (Lot No. \*\*\*\*\*), HBeAg Assay Kit (Lot No. \*\*\*\*\*), Anti-HBs Assay Kit (Lot No. \*\*\*\*\*), Anti-HBe Assay Kit (Lot No. \*\*\*\*\*), Anti-HBc Assay Kit (Lot No. \*\*\*\*\*), and in-house standard materials.



Catalogue number



In vitro diagnostic medical device



Manufacturer



Consult instructions for use



Temperature limitation



Use by



Batch code