

# **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

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 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

# Authorized representative / Distributors

Asia-Pacific: Sysmex Asia Pacific Pte Ltd.

9 Tampines Grande #06-18, Singapore 528735

# Date of issue or revision

09/2015

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#### **Target Value**

Lot No.	HB-0OO
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	0.00	0.00~0.00
	antigen	IU/mL	IU/mL
	HBe	00.0	00.0~00.0
	antigen	COI	COI

HBV Antigen Positive Level 2

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

HBV Antibody Positive Level 1

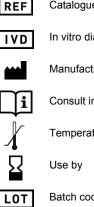
	Item	Target Value	Range
Lot HBB-1##	HBs	00.0	00.0~00.0
	antibody	mIU/mL	mIU/mL
	HBe	00.0	00.0~00.0
	antibody	Inh%	Inh%

HBV Antibody Positive Level 2

	Item	Target Value	Range
Lot HBB-2++	HBs	0.000	000.0~000.0
	antibody	mIU/mL	mIU/mL
	HBc	00.0	00.0~00.0
	antibody	COI	COI

<sup>+</sup> The above target values were set by the results of HISCL-5000 at Sysmex Corporation.

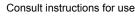
- <sup>+</sup> These target values and ranges may vary according to the device or reagent.
- Target values and ranges were set by the results of HISCL HBsAg Assay Kit (Lot No. \*\*\*\*\*\*), HBeAg Assay Kit (Lot No. \*\*\*\*\*\*), Anti-HBs Assay Kit (Lot No. \*\*\*\*\*\*), + Anti-HBe Assay Kit (Lot No. \*\*\*\*\*), Anti-HBc Assay Kit (Lot No. \*\*\*\*\*\*), and in-house standard materials.

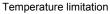


Catalogue number

In vitro diagnostic medical device

Manufacturer





Batch code