

REF 054-2311-1

HISCL™ HBsAg Calibrator

Identification of the IVD reagent

HISCL™ HBsAg Calibrator

Intended use

For In Vitro Diagnostic Use

For calibration of HISCL HBsAg Assay Kit.

Components

1. HISCL HBsAg C0 (HBsAg 0 IU/mL)
2. HISCL HBsAg C1 (HBsAg 0.25 IU/mL)
3. HISCL HBsAg C2 (HBsAg 2.5 IU/mL)
4. HISCL HBsAg C3 (HBsAg 25 IU/mL)
5. HISCL HBsAg C4 (HBsAg 250 IU/mL)
6. HISCL HBsAg C5 (HBsAg 2,500 IU/mL)

HISCL HBsAg C1-C5 contain recombinant HBsAg, and none of the components contain human-derived materials.

Warnings and precautions

Each calibrator 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 about 200 µL (5 drops) of each calibrator.

Carry out procedures according to the package insert for the HISCL HBsAg 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

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

Traceability of values assigned to calibrators and trueness-control materials

HISCL HBsAg Calibrator has been adjusted by WHO Standard 00/588.

Date of issue or revision

08/2015

Printed in Japan



Catalogue number



In vitro diagnostic medical device



Manufacturer



Consult instructions for use



Temperature limitation



Use by



Batch code