sysmex

REF AJ-255-081

HISCL™ Immuno Multi Control

Identification of the IVD reagent

HISCL™ Immuno Multi Control

Intended use

For in vitro diagnostic use only
This control can only be used for quality control for HISCL.
The applicable parameters to be used are as follows: TSH, FT3, FT4, PSA, AFP, CEA, CA125, CA19-9, Ferritin, Insulin and CA15-3.

Components

HISCL Immuno Multi Control Level 1	For 3 mL × 3
HISCL Immuno Multi Control Level 2	For 3 mL × 3

Warnings and precautions

1. In case of contact with the eyes, mouth, or hands, carry out emergency treatment such as washing with plenty of water.
2. HISCL Immuno Multi Control Level 1 and Level 2 contain human-derived materials. Handle as potentially infectious and discard it in a similar manner of a specimen.
3. The bottles are breakable. There is a risk of them being cracked or broken during use. Handle them with care.
4. Preservative is not included in this product. Handle with care after reconstitution.
5. Reconstitute the control with distilled water at room temperature, do not use cold distilled water as it may lead to high test results.
6. In case of spillage of samples, liquid wastes or any other biohazard materials, wipe and disinfect the area with 2% glutaraldehyde solution or 0.1% or more sodium hypochlorite.

Examination procedure

1. Add 3 mL of distilled water to HISCL Immuno Multi Control Level 1 and Level 2, recap, and stand for 15 min. Invert the vial 10-20 times carefully (ensuring that there is no form formation).
2. Do not spill the contents when opening the rubber stopper because it could lead to incorrect results. Therefore, handle each control carefully.
3. Dispense about (200 + sample volume) µL of each control. Check the package insert of each reagent for the required sample volume.
4. Carry out procedure according to the instructions on the package insert for each Assay Kit.
5. After reconstitution, the control is stable in accordance with the storage condition listed in table below.
6. Freezing and thawing should not be more than 5 times.

Storage and shelf life after first opening

State	Estimated usable period
Storage at 2-8°C (Do not freeze) before reconstitution	Expiration date
After reconstitution at -20°C or lower	90 days
After reconstitution at 2-8°C	7 days
After reconstitution at 8-30°C	8 hours (except Insulin)

※If used for insulin measurement, HISCL Immuno Multi Control should be stored at 2-8°C or at -20°C or lower immediately after reconstitution and measurement.

Manufacturer

Sysmex Corporation
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Authorized representatives

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REF	Catalogue number
IVD	In vitro diagnostic medical device
	Manufacturer
	Consult instructions for use
	Temperature limitation
	Use by
LOT	Batch code
	Biological Risks
RCNS X mL	Reconstitute with

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Target Value

Lot No.	QQIM-0xx					
Expiry	YYYY-MM-DD					
	Item	Target Value		Range		
Level1 (Lot No.QQIM-1##)	TSH	○.○○○	µIU/mL	○.○○○	～ ○.○○○	µIU/mL
	FT3	○.○○	pg/mL	○.○○	～ ○.○○	pg/mL
	FT4	○.○○	ng/dL	○.○○	～ ○.○○	ng/dL
	PSA	○.○○○	ng/mL	○.○○○	～ ○.○○○	ng/mL
	AFP	○.○	ng/mL	○.○	～ ○.○	ng/mL
	CEA	○.○	ng/mL	○.○	～ ○.○	ng/mL
	CA125	○○.○	U/mL	○○.○	～ ○○.○	U/mL
	CA19-9	○○.○	U/mL	○○.○	～ ○○.○	U/mL
	Ferritin	○○.○	ng/mL	○○.○	～ ○○.○	ng/mL
	Insulin	○.○	µIU/mL	○.○	～ ○.○	µIU/mL
	CA15-3	○○.○	U/mL	○○.○	～ ○○.○	U/mL
Level2 (Lot No.QQIM-2##)	TSH	○.○○○	µIU/mL	○.○○○	～ ○.○○○	µIU/mL
	FT3	○.○○	pg/mL	○.○○	～ ○.○○	pg/mL
	FT4	○.○○	ng/dL	○.○○	～ ○.○○	ng/dL
	PSA	○○.○○○	ng/mL	○○.○○○	～ ○○.○○○	ng/mL
	AFP	○○○.○	ng/mL	○○○.○	～ ○○○.○	ng/mL
	CEA	○○.○	ng/mL	○○.○	～ ○○.○	ng/mL
	CA125	○○.○	U/mL	○○.○	～ ○○.○	U/mL
	CA19-9	○○.○	U/mL	○○.○	～ ○○.○	U/mL
	Ferritin	○○○.○	ng/mL	○○○.○	～ ○○○.○	ng/mL
	Insulin	○○.○	µIU/mL	○○.○	～ ○○.○	µIU/mL
	CA15-3	○○.○	U/mL	○○.○	～ ○○.○	U/mL

† 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.
† Control ranges were computed with ±20% of target values.

Assay Kit	Lot No.	Assay Kit	Lot No.	Assay Kit	Lot No.
HISCL TSH Assay kit	******	HISCL AFP Assay kit	******	HISCL Ferritin Assay kit	******
HISCL FT3 Assay kit	******	HISCL CEA Assay kit	******	HISCL Insulin Assay kit	******
HISCL FT4 Assay kit	******	HISCL CA125 Ⅱ Assay kit	******	HISCL CA15-3 Assay kit	******
HISCL PSA Assay kit	******	HISCL CA19-9 Ⅱ Assay kit	******		

† Target values and ranges were set by the results of Assay Kit above, and in-house standard materials.