



REF AT-474-543

## Viratrol

### Identification of the IVD reagent

Viratrol

### Intended use

For in Vitro Diagnostic Use

For quality control of HBs antigen, HCV antibody, TP antibody, HIV antibody and HTLV-1 antibody.

### Components

Viratrol Level 1 For 3 mL×3

Viratrol Level 2 For 3 mL×3

### Warnings and precautions

1. This product is positive for HBs antigen, HCV, TP, HIV-1, HIV-2, and HTLV-1 antibodies, but it has not been examined for other infectious materials. This product is processed by heat treatment and S/D treatment\*<sup>1</sup> with the aim of inactivating viruses; however, it is recommended that this should be handled with the same as patients' samples.

#### 2. Disposal procedure

(a) This product and all used laboratory instruments should be sterilized in accordance with any of the following procedures.

- Immerse in 1% formalin solution for 1 h or longer, or in 0.05% formalin solution at 37°C for 72 h or longer.
- Immerse in 2% glutaraldehyde solution for 1 h or longer.
- Immerse in 0.1% sodium hypochlorite (1,000 ppm) for 1 h or longer.
- Autoclave at 121°C for at least 1 h.

(b) 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.

\*1: The New York Blood Center holds the patent for S/D (Solvent/Detergent) treatment, which is a processing method for inactivating viruses using organic solvent tri(n-butyl)phosphate and detergents. This method is considered to inactivate enveloped viruses (HIV, HCV, HBV, and HTLV-1), but it is not appropriate for inactivation of non-enveloped viruses (such as HAV and parvovirus B19).

### Examination procedure

Add 3 mL of distilled water per vial to dissolve each control (Level 1, 2). The reconstituted controls are stable for 4 weeks when stored at 2-8°C.

### Storage and shelf life after first opening

Storage: Store at 2-8°C.

Shelf life: 24 months (The expiry date is indicated on the package.)

Do not freeze.

## Target Value

Lot No.	VRAP-OXX		
Expiry	YYYY-MM-DD		
	Item	Target Value	Range
Level 1 (Lot No. VRAP-1XX)	HBs antigen	### IU/mL	### ~ ### IU/mL
	HCV antibody	### C.O.I.* <sup>2</sup>	### ~ ### C.O.I.* <sup>2</sup>
		### C.O.I.* <sup>3</sup>	### ~ ### C.O.I.* <sup>3</sup>
	TP antibody	## C.O.I.	## ~ ## C.O.I.
	HIV antibody	## C.O.I.	## ~ ## C.O.I.
Level 2 (Lot No. VRAP-2XX)	HBs antigen	### IU/mL	### ~ ### IU/mL
	HCV antibody	### C.O.I.* <sup>2</sup>	### ~ ### C.O.I.* <sup>2</sup>
		### C.O.I.* <sup>3</sup>	### ~ ### C.O.I.* <sup>3</sup>
	TP antibody	### C.O.I.	### ~ ### C.O.I.
	HIV antibody	### C.O.I.	### ~ ### C.O.I.
	HTLV-1 antibody	## C.O.I.	## ~ ## C.O.I.

† 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. \*\*\*\*\*),

\*<sup>2</sup> Anti-HCV Assay Kit (Lot No. \*\*\*\*\*), \*<sup>3</sup> Anti-HCV II Assay Kit (Lot No. \*\*\*\*\*),

Anti-TP Assay Kit (Lot No. \*\*\*\*\*), HIV Ag+Ab Assay Kit (Lot No. \*\*\*\*\*),

Anti-HTLV- I Assay Kit (Lot No. \*\*\*\*\*)

and in-house standard materials.

† Control ranges were computed with the following ranges.

HBs antigen: target value  $\pm$  20%

HCV antibody, TP antibody, HIV antibody, HTLV-1 antibody: target value  $\pm$  40%

## Manufacturer



**Sysmex Corporation**

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## Date of issue or revision

10/2023

Printed in Japan



Catalogue number



In vitro diagnostic medical device



Manufacturer



Consult instructions for use



Temperature limitation



Use by



Batch code



Biological Risks