



### Intended use

LAL Control is designed to be used as quality control material for the quantitative determination of (1→3)- $\beta$ -D-glucan in serum or plasma. Use the reagents with the  $\beta$ -Glucan Test.

### Reagents and ingredients

- |   |                       |
|---|-----------------------|
| 1) R1: LAL Control (lyophilized)<br>(Lentinan, human serum) | for 0.5 mL x 10 vials |
| 2) R2: Control Dissolution Buffer                           | 2 mL x 10 bottles     |
| 3) Accessory:<br>Assigned values card, cap opener           |                       |

### Determination of assigned values

Assigned value: See assigned values card

Determination: The (1→3)- $\beta$ -D-glucan concentration is determined by measuring a control with the  $\beta$ -Glucan Test reagent and the Wako 1st  $\beta$ -Glucan standard. The Wako 1st  $\beta$ -Glucan standard was prepared using Lentinan.

### Reagents preparation

- 1) Use cap opener to open R1: LAL Control by twisting it slowly to an angle of 30–40 degrees in order to remove the aluminum seal and rubber cap. Cover the tube with Aluminum Cap.
- 2) Remove the seal of the R2: Control Dissolution Buffer. Add 0.5 mL of the R2: Control Dissolution Buffer to the R1: LAL Control.
- 3) Leave it for 3 to 5 minutes and then mix it by vortex mixer for 1 minute.
- 4) Leave it for 15 minutes or more.
- 5) Pretreat and measure it within 1 hour as positive control.
- 6) Use the R2: Control Dissolution Buffer as negative control without R1: Pretreatment Solution.
- 7) Use positive control with R1: Pretreatment Solution and R2: LAL Reagent like a sample.

### Warning and precautions

- For *in vitro* diagnostic use.
- The usage and application of these controls is reserved for professional use only. Please refer to respective national and local regulations and legislation.
- Not to be used internally in humans and animals.
- The R1: LAL Control contains materials of human origin. The materials have been tested and found negative for HBsAg, anti-HIV-1/HIV-2 antibodies, and anti-HCV antibody. Since the risk of infection cannot be excluded with certainty, the products must be handled as potentially biohazardous like patients' sera.

#### <Precautions for procedure>

- Do not use the reagents in any procedures and purposes other than those described herein.
- Store the reagents under the specified conditions. Do not use reagents after the expiration date stated on each reagent container label.
- After opening the reagent, it is recommended to use it immediately, do not store it.
- Equipment must not be contaminated with (1→3)- $\beta$ -D-glucan.
- Avoid contamination by (1→3)- $\beta$ -D-glucan during assay operation.
- Do not use the containers or other materials in the kit for any purpose other than those described herein.
- Do not reuse the tip when the control is added to R1: Pretreatment Solution.

#### <Precautions for protection from hazards>

- If the reagents come in contact with the mouth, eyes, or skin, wash off immediately with a large amount of water. Consult a physician if necessary.
- In the case of using a glass pipette, do not pipette by mouth, but use a safety pipette.
- Be careful not to cut yourself with the aluminum seal when removing it from the vial.

#### <Precautions for disposal>

- When discarding the reagents, dispose of them according to local or national regulations.
- All the devices including reagents and reagent bottles that come in contact with specimens should be considered potentially infectious.

### Storage condition

Product	Storage condition
LAL Control	Store between 2–10 °C

### Ordering information

Code	Product	Package
993-04201	$\beta$ -Glucan Test R1: Pretreatment Solution	50 x 0.9 mL
997-04101	$\beta$ -Glucan Test R2: LAL Reagent	50 x for 0.2 mL
995-04401	LAL Control R1: LAL Control (lyophilized) R2: Control Dissolution Buffer	10 x for 0.5 mL 10 x 2 mL
999-04301	$\beta$ -Glucan Sample Diluent	10 x 0.9 mL
995-04901	Aluminum Cap	10 x 10 unit
995-05001	BC Tip EXT	100 tips
991-05101	BC Tip 1000-R	100 tips
993-04701	Toxinometer MT-6500	1 unit
999-04801	MT-6500 Extension Module	1 unit
993-03601	Thermostation TS 70/16	1 unit

Product	Package
LIMUSAVE MT-7500*	1 unit
LIMUSAVE MT-7500 Extension Module*	1 unit
LIMUSAVE MT-7500 THERMOSTATION TS-70/20*	1 unit

\*Manufacturer: FUJIFILM Corporation

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**FUJIFILM Wako Pure Chemical Corporation**

1-2, Doshomachi 3-Chome, Chuo-ku, Osaka 540-8605, Japan  
Tel.: +81-6-6203-3749 · Fax: +81-6-6203-1917  
URL: [fujifilm.com/ffwk](http://fujifilm.com/ffwk)



**FUJIFILM Wako Chemicals Europe GmbH**

Fuggerstr. 12, 41468 Neuss, Germany  
Tel.: +49 2131 311 272 · Fax: +49 2131 311 110  
URL: [wako-chemicals.de](http://wako-chemicals.de)

