

Intended use

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

Reagents and ingredients

- 1) R1: LAL Control (lyophilized) for 0.5 mL x 10 vials
(Lentinan, human serum)
- 2) R2: Control dissolution buffer 2 mL x 10 bottles
- 3) Accessory:
Assigned values card, cap opener

Determination of assigned values

Assigned value: See assigned values card

Determination: The β-glucan concentration is determined by measuring a control with the β-Glucan Test reagent and the FUJIFILM Wako 1st β-Glucan standard. The FUJIFILM Wako 1st β-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

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)-β-D-glucan.
- Avoid contamination by (1→3)-β-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	β-Glucan Test R1: Pretreatment Solution	50 x 0.9 mL
997-04101	β-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	β-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