FUJIFILM
Value from Innovation

Wako

β-D-GLUCAN TEST

EARLY DETECTION OF INVASIVE FUNGAL INFECTION

FOR DETERMINING (1→3)-β-D-GLUCAN BY A KINETIC TURBIDIMETRIC ASSAY

+ Single test assay
+ Ready to use reagents
+ User-friendly system



reddot winner 2022

LIMUSAVE MT-7500

DESIGN AWARD 2022

INTRODUCTION

Invasive fungal diseases are a significant worldwide health problem, and their prevalence is increasing. These opportunistic infections affect immunocompromised patients, those undergoing intensive care treatment and people with chronic disorders, in particular lung diseases. Invasive fungal diseases are important causes of morbidity and mortality and difficult to diagnose. The early recognition and diagnosis of mycoses is of critical importance for improving patient outcomes. However, traditional diagnostic tools such as pathologic histological and fungal cultures lack the sensitivity and capacity needed for early diagnosis.

In most pathogenic fungi, (1→3)-β-D-glucan is an integral component of the cell wall (Fig. 1). Small quantities are released into the blood during infection. The Limulus reagent (LAL: Limulus Amebocyte Lysate), made from the extract of blood cells of horseshoe crabs, has drawn attention as an *in vitro* diagnostic reagent for mycosis. It reacts with (1→3)-β-D-glucan as well as with endotoxin. The β-Glucan Test exclusively measures the (1→3)-β-D-glucan concentration through a kinetic turbidimetric assay in a sample pretreated with a solution which inactivates endotoxin by the use of a non-ionic detergent and polymyxin B.

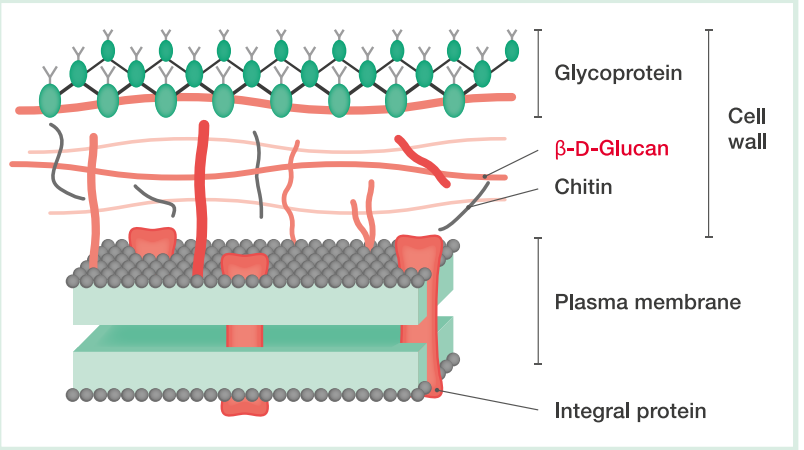


Fig. 1: Scheme of fungal cell wall

INTENDED USE

***IN VITRO* DIAGNOSTIC USE FOR THE QUANTITATIVE DETERMINATION OF (1→3)-β-D-GLUCAN IN SERUM OR PLASMA**

CLINICAL DIAGNOSTIC PERFORMANCE

Various researchers in Europe published their study results on the FUJIFILM Wako β-Glucan Test. Alone or in combination with other tests, it showed very good diagnostic performance, and can thus be used in clinical routine practice.

	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Invasive aspergillosis	80.0 % (32 / 40)	97.3 % (182 / 187)	86.5 % (32 / 37)	95.8 % (182 / 190)
Candidiasis	98.7 % (77 / 78)	97.3 % (182 / 187)	93.9 % (77 / 82)	99.5 % (182 / 183)
***Pneumocystis* pneumonia**	94.1 % (16 / 17)	97.3 % (182 / 187)	76.2 % (16 / 21)	99.5 % (182 / 183)

Table 1: Diagnostic performance of the β-Glucan Test in major fungal infections (based on cut-off value of 7 pg/mL)[1]

[1] De Carolis et al. Comparative performance evaluation of Wako β-glucan test and Fungitell assay for the diagnosis of invasive fungal diseases. PLoS One 2020 Jul 29;15(7).

TEST PRINCIPLE

Endotoxin in a sample is inactivated by heating the sample at 70 °C for 10 minutes with the pretreatment solution, which contains non-ionic detergent and polymyxin B. This pretreatment also deactivates inhibitory protein substances in the sample. When the pretreated sample is mixed with the LAL solution, (1→3)-β-D-glucan in the sample activates Factor G, which initiates the cascade reactions shown in Fig. 2. The turbidity change caused by the gelation reaction is detected as transmittance change. The time taken for the transmittance to reach the threshold value is measured. This interval is defined as gelation time (Tg, Fig. 3). The log [(1→3)-β-D-glucan concentration] is in inverse proportion to log [log(Tg)]. When the Tg of an unknown sample is measured, the (1→3)-β-D-glucan concentration of the sample can be obtained from a standard curve.

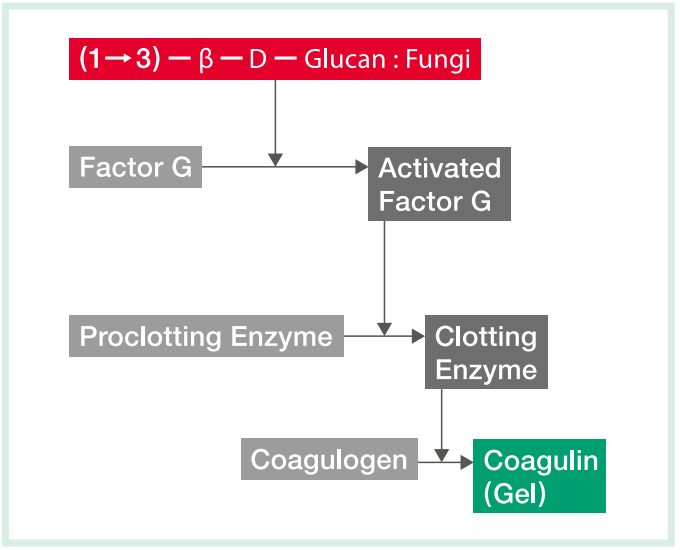


Fig. 2: Cascade reactions of LAL

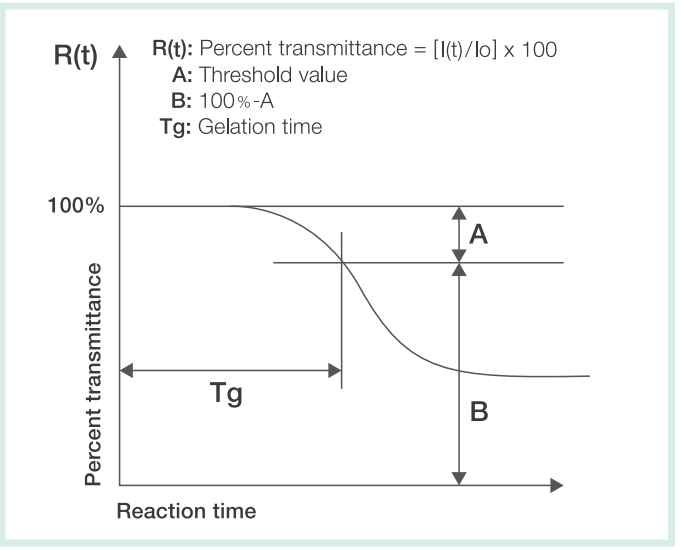


Fig. 3: Principle of kinetic turbidimetric method

TEST PROCEDURE

MEASUREMENT OPERATION

SAMPLE PRETREATMENT

MEASUREMENT

Pipette sample 0.1 mL

Incubate at 70 °C 10 minutes

Cool min. 3 minutes

Transfer sample 0.2 mL

Place tube in instrument



Pretreatment Solution

THERMOSTATION TS-70/20

Cooling Station

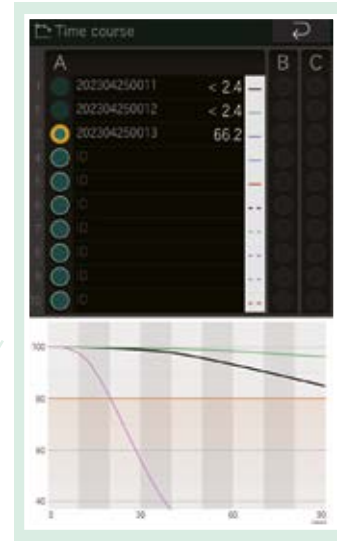
Pretreated sample

LAL Reagent

LIMUSAVE MT-7500

INSTRUMENT FEATURES

+ 10 sample positions, up to 30 with Extension Modules
+ Random access test measurement
+ Calibration by barcode scan
+ Patient ID by barcode scan
+ Small size
+ Simple operating screen
+ Data printout and LIS integration option







TEST FEATURES

+ Single test reagent
+ LAL based test principle
+ Quantitative (1→3)-β-D-glucan measurement by kinetic turbidimetric method
+ Quality control available
+ Measurement range: 6 to 600 pg / mL
+ Clinical cut-off value: 7 pg / mL
+ Measurement time: Max. 90 minutes
+ Precision: Max. CV of 6.6 % in within-run experiments







INSTRUMENTS

Code	Product
167-47686	LIMUSAVE MT-7500[1]
167-47727	LIMUSAVE MT-7500 Extension Module[1]
167-47703	LIMUSAVE MT-7500 THERMOSTATION TS-70/20[1]
998-22211	Cooling Station[2]

REAGENTS AND CONSUMABLES[2]

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
995-04901	Aluminum Cap	10 x 10 pieces
995-05001	BC Tip EXT	100 tips
991-05101	BC Tip 1000-R	100 tips
999-04301	β-Glucan Sample Diluent	10 x 0.9 mL
995-04401	LAL Control R1: LAL Control (lyophilized) R2: Control dissolution buffer	 10 x for 0.5 mL 10 x 2 mL

[1] Manufacturer: FUJIFILM Corporation
[2] Manufacturer: FUJIFILM Wako Pure Chemical Corporation

SPECIFICATIONS

LIMUSAVE MT-7500

Measurement method		Kinetic turbidimetric assay
Number of tests that can be carried out simultaneously		Maximum 10 tests (for main module only) Maximum 30 tests (when 2 Extension Modules are connected)
Environment (when in operation)		Temperature: 15 to 32 °C (temperature fluctuation: within ± 2 °C/hour) Humidity: 30 to 80 % RH (no vapor condensation)
Light source		LED, center wavelength: 660 ± 10 nm
Temperature control		37 °C ± 0.5 °C, warming up time: 15 minutes (at a room temperature of 25 °C)
Display		Color LCD (7-inch touch panel), status indicator LED
Alarm function (main module)		Notification by alarm and display
Printer		Thermal type (paper size: 58 mm x 25 m)
External connections	**USB**	1 port (for USB flash drive)
	LAN	1 port (for LIS)
	RS232C	1 port (for LIS)
Weight		Main module: 8.1 kg, Extension Module: 2.2 kg
External dimensions		Main module: (W) 250 × (D) 400 × (H) 180 mm, Extension Module: (W) 100 × (D) 270 × (H) 125 mm
Number of Extension Modules that can be connected		Maximum 2 Extension Modules
Others		2D barcode reader

LIMUSAVE MT-7500 THERMOSTATION TS-70/20

Temperature control	70 °C ± 0.5 °C
Number of wells	20
Environment	Temperature: 15 to 32 °C Humidity: 30 to 80 % RH (no vapor condensation)
Weight	2.6 kg
External dimensions	(W) 110 × (D) 320 × (H) 125 mm

COOLING STATION

Name	Test tube cooling container
Weight	Approx. 1,600 g
Dimensions	(W) 200 × (D) 160 × (H) 190 mm, metallic container: (W) 130 × (D) 104 × (H) 88
Number of contained test tube	20 pcs
Test tube diameter	12 mm
Cooling temperature	0 to 5 °C
Cold insulation time	Approx. 12 hours (measured at room temperature of 23 °C)

For further information on our products or
to place an order, please contact us.

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