FUJIFILM
Value from Innovation

Wako

β-GLUCAN TEST

EARLY DETECTION OF INVASIVE FUNGAL INFECTION

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

+ Monotest assay
+ Ready to use reagents

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 outstanding importance for improving patient outcomes. However, traditional diagnostic tools such as pathologic histological and fungal cultures lack the sensitivity and capacity needed for early diagnoses.

In most pathogenic fungi, (1→3)-ß-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)-ß-D-glucan as well as with endotoxin. The ß-Glucan Test exclusively measures the (1→3)-ß-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.

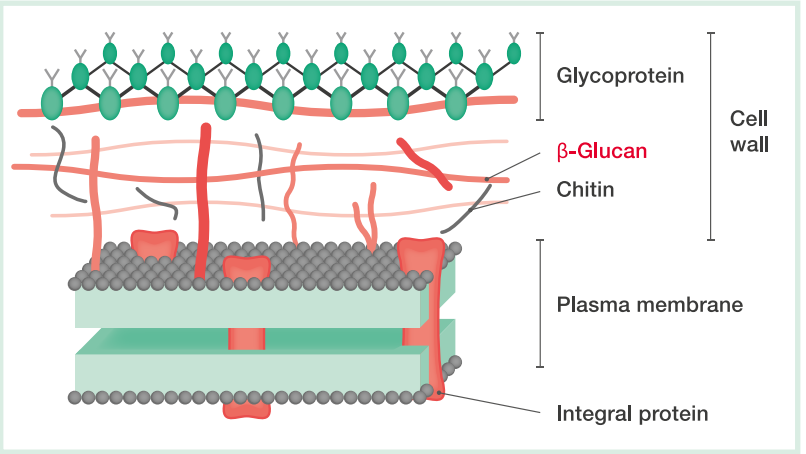


Fig. 1: Scheme of fungal cell wall

INTENDED USE

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

KEY FEATURES

+ Monotest reagent
+ Calibration by QR code scan
+ Quality control available
+ Simple procedure thanks to ready-to-use reagents and intuitive software
+ Quantitative ß-glucan measurement by the kinetic turbidimetric method

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 pretreatment sample is mixed with the LAL solution, (1→3)-ß-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).

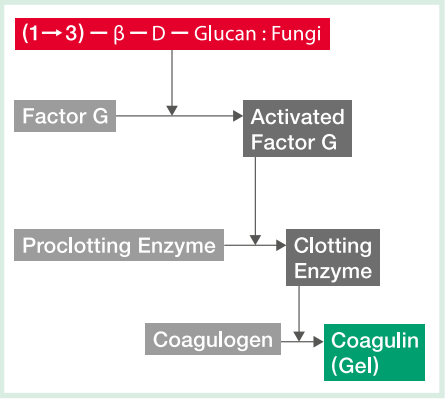


Fig. 2: Cascade reactions of LAL

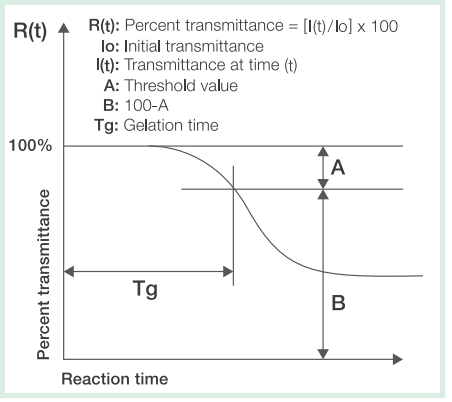


Fig. 3: Principle of kinetic turbidimetric method

The log (ß-glucan concentration) is in inverse proportion to log [log(Tg)]. When the Tg of an unknown sample is measured, the ß-glucan concentration of the sample can be obtained from a standard curve.

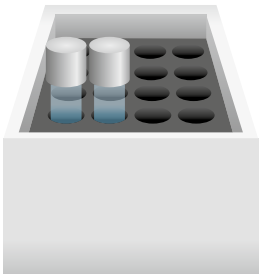
TESTING PROCEDURE

PIPET SAMPLE PRETREATMENT

Pipet sample
0.1 mL

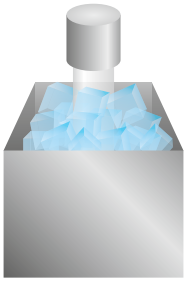
Pretreatment
reagent

Incubate at 70 °C



Thermostation

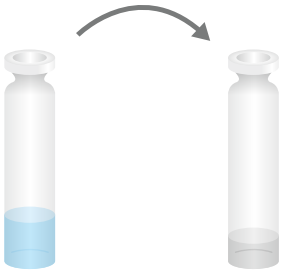
Cool on ice



Ice box

MEASUREMENT

Transfer sample
0.2 mL



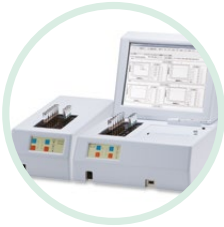
Pretreatment
sample

LAL
reagent

Mixing

Set the tube in the Toxinometer

INSTRUMENT FEATURES



KINETIC TURBIDIMETRIC ASSAY

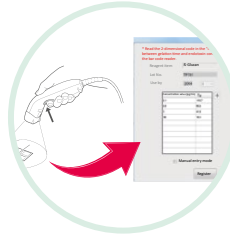
+ 16 sample positions, up to 64 with extension module
+ Measurement starts automatically after sample is inserted
+ Touchscreen display

BARCODE READER

+ Registering reagent and patient information

PRETREATMENT AND LAL REAGENT REQUIRED

+ Easy reagent handling



CALIBRATION WITH BARCODE

+ Reading the calibration data card

+ LIS integration capability
+ Minimal maintenance necessary
+ Dimensions

Toxinometer MT-6500:
350 x 420 x 356 mm (W x D x H), 14 kg

Thermostation TS-70/16:
110 x 260 x 145 mm (W x D x H), 2.5 kg

MT-6500 Extension Module:
190 x 420 x 130 mm (W x D x H), 6.5 kg

TEST FEATURES

CHARACTERISTICS

+ LAL (Limulus Amebocyte Lysate) based test principle
+ Specimen: Serum and plasma
+ Measurement time: Maximum 90 minutes

PERFORMANCE DATA

+ Measurement range: 6 to 600 pg/ml
+ Lentinan used as standard
+ Cut-off value: 11 pg/ml
+ Precision: Maximum CV of 6.6 % was observed in within-run experiments
+ Interference: No significant interference observed through bilirubin, hemolysis and antifungal drugs

INSTRUMENTS

CODE	PRODUCT	PACKAGE
993-04701	Toxinometer MT-6500	1 unit
999-04801	MT-6500 Extension Module	1 unit
993-03601	Thermostation TS-70/16	1 unit

REAGENTS AND CONSUMABLES

CODE	PRODUCT	PACKAGE
997-04101	ß-Glucan Test	50 x for 0.2 mL
993-04201	ß-Glucan Pretreatment	50 x 0.9 mL
999-04301	ß-Glucan Sample Diluent	10 x 0.9 mL
995-04901	Aluminum Cap	10 x 10 units
995-05001	BC Tip EXT	100 units
991-05101	BC Tip 1000-R	100 units
995-04401	LAL Control	10 x for 0.5 mL

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

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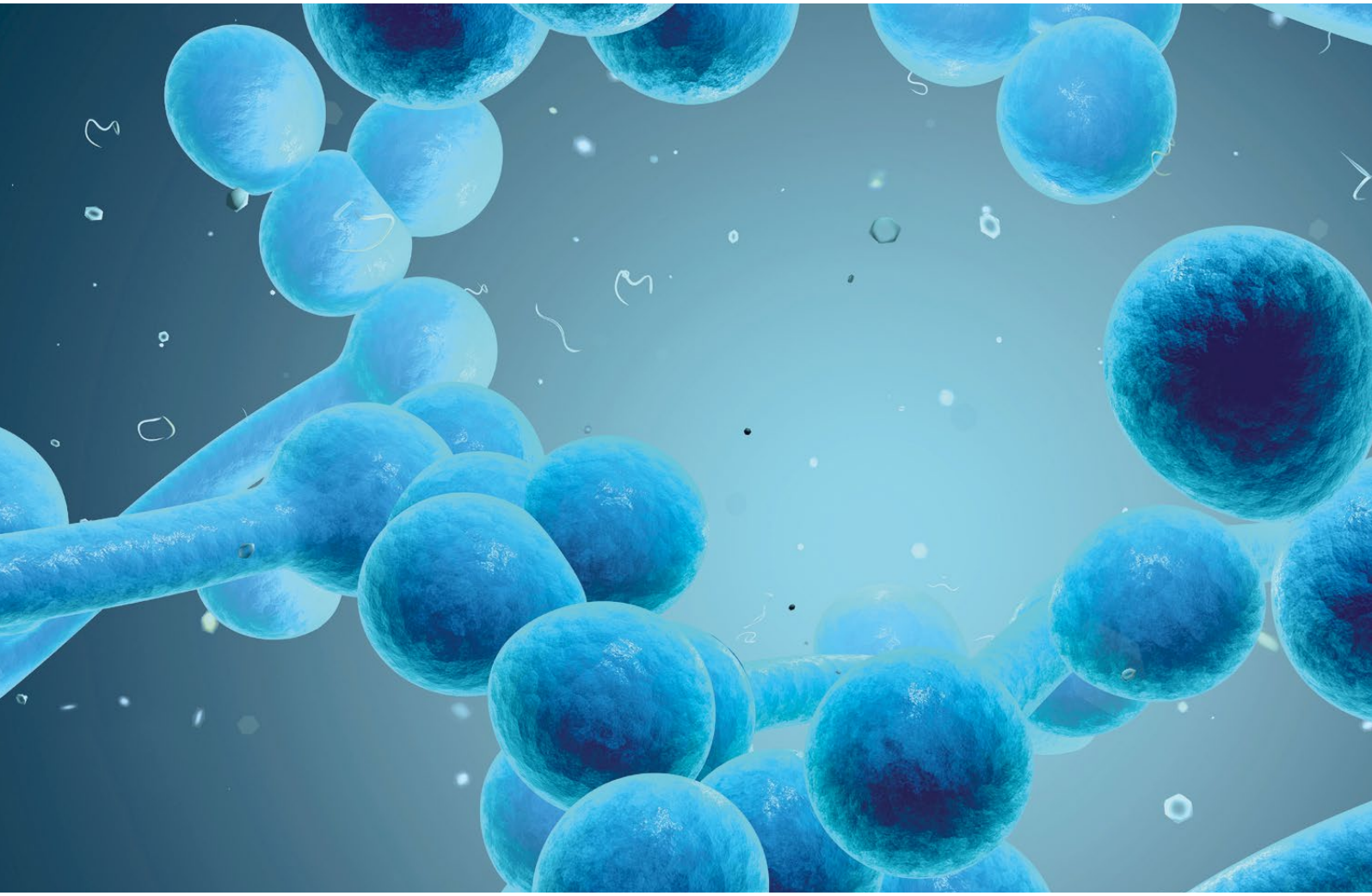

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