eurobioteco

TECO®

Fast Fungus (1-3)-ß-D-Glucan Lateral Flow Assay

Instructions for use
English

CE

Catalogue No. TE1088
UDI-DI 6930317801462

TE1088_AA-E_02/2025

TECOmedical AG

www.tecomedical.com

Symbol Description

Read electronic kit instructions

LOT

Lot number

Expiry date

Storage temperature

Not intended for self-testing
Or near-patient testing

Manufacturer

REF

TE 1088

UDI-DI

Unique Device Identifier

IVD

In Vitro Diagnostics

50 tests

CE

EC REP

EU representative

Professional Use only
Not intended for self-testing or near-patient testing

Manufactured for TECOmedical by:
Dynamiker Biotechnology (Tianjin) Co., Ltd.
Building 2, Rongzhi Industry Park, 3667, Zhongbin Avenue, Zhongxin Eco-city,
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EC REP

Lotus NL B.V.
Koningin Julianaplein 10, 1st stock
2595AA The Hague, the Netherlands.
Email: peter@lotusnl.com

CONT **Reagents and Materials Supplied:**

SYMBOL	DESCRIPTION	FORMAT
1	**Test cassette** Ready to use Cassette is for single use only DO NOT REUSE	**50 bags** (1 test cassette/bag)
2	**Sample Treatment Solution A** Ready to use	**4 x 2.5 mL**
3	**Sample Treatment Solution B** Ready to use	**4 x 2.5 mL**
C1	**Positive Control** Range as indicated on data sheet	**1x 2.5 mL**
C2	**Negative Control** Range as indicated on data sheet	**1x 2.5 mL**
	**eIFU indicator** on kit box Login address for electronic kit instructions	
	QR code lot-specific, for standard curve import	

Storage

Store the kit at 2 - 8°C in a dark place. Do not freeze.

Intended Use

TECO® *Fast* Fungus (1-3)-ß-D-Glucan Lateral Flow Assay is used for the quantitative detection of (1-3)-ß-D-Glucan in human serum or plasma samples, offering an early diagnosis of invasive fungal infections.

Clinical Use

(1-3)-β-D-Glucan is a component of the cell walls of many pathogenic fungi (except zygomycetes and cryptococcus) and is a unique marker of fungi. When the blood and deep tissues of the human body are invaded by fungi, (1-3)-β-D-Glucan derived from the fungal cell wall is phagocytosed and digested by phagocytes and can be released from the fungal cell wall into blood and other body fluids. Therefore, (1-3)-β-D-Glucan can be used for the early diagnosis of invasive fungal infections [1].

In recent years, with the rising numbers of stem cell transplantation and solid organ transplant recipients, increasing use of excessively high dose immunosuppressant and aggressive chemotherapy, widespread use of interventional therapy and indwelling catheters, the incidence of invasive fungal diseases (IFD) have increased significantly. IFD becomes a major cause of death and severe complications for patients who receive bone marrow or organ transplant and patients who receive chemotherapy due to malignant hematopathy and tumor, AIDS patients, and those in critical conditions. Diagnosis of invasive mycoses usually involves non-specific diagnostic or radiological techniques.

(1-3)-β-D-Glucan is the main cell wall component of most fungi, such as Candida, Aspergillus and Fusarium, etc. and does not exist in bacteria, virus, or human cells. For this reason, detection of (1-3)-β-D-Glucan in human serum offers a diagnostic reference for invasive fungal diseases.

Limitations

- In some patients with fungal infections, (1-3)-β-D-Glucan will be decomposed or neutralized by antibodies, resulting in false negative result.

- Test results are for reference only. Single test result cannot be considered as the only basis of disease diagnosis. To achieve the diagnosis purpose, test results can be used as a reference combining clinical symptoms, medical history, and other testing results.

- The kit can only be used to test the content of (1-3)-β-D-Glucan and cannot be used to distinguish fungal species nor test zygomycetes and cryptococcus.

- The test results of the same patient may be different at different stages of the disease, in different pathological states or under different medication conditions.

References

[1] Li Zhanjia, Zhai Hongyan, Chen Shuiping**.**
The Latest Progress of G Test in the Diagnosis of Invasive Fungal Disease
J. of Laboratory Medicine, 2019, 34(09): 859-863

[2] Marty F M, Lowry C M, Lempitski S J, et al
Reactivity of (1, 3)-β-D-glucan assay with commonly used intravenous antimicrobials
J. of Antimicrobial agents and chemotherapy, 2006, 50(10): 3450-3453.

Assay Principle

The TECO® *Fast* Fungus (1-3)-ß-D-Glucan Lateral Flow Assay product uses double-antibody sandwich fluorescence immunochromatography to detect (1-3)-β-D-Glucan in human serum or plasma samples.

Fluorescent microsphere-labeled Fungus (1-3)-β-D-Glucan antibody and fluorescent microsphere-labeled chicken IgY antibodies are pre-embedded on release pads, and Fungus (1-3)-β-D-Glucan antibody and anti-chicken IgY antibodies are respectively coated at the Test Line (T) and the Quality Control Line (C).

- Positive samples : the Fungus (1-3)-β-D-Glucan in the sample binds to the Fungus (1-3)-β-D-Glucan antibody labeled with fluorescent microspheres to form a complex, which moves forward along the paper strip under the action of chromatography and combines with the pre-coated Fungus (1-3)-β-D-Glucan antibody, developing a fluorescent band, while passing the Test Line (T), and fluorescently labeled chicken IgY antibody combines with anti-chicken IgY antibody at the Quality Control Line (C), developing a fluorescent band.
- Negative samples :do not contain Fungus (1-3)-β-D-Glucan and will not have immune complexes formed, thus no bands will appear at the Test Line (T), but the bands only appear at the Quality Control Line (C). The Quality Control Line (C) will show the fluorescent band, which is the criterion for determining whether the chromatographic process is normal, and also serves as an internal control standard for the reagent.
- The testing area is scanned by a fluorescence immunoassay analyzer to obtain a fluorescent signal, which indicates the concentration of Fungus (1-3)-β-D-Glucan.

Materials Required and not Supplied

- Pipettes 100 µL
- Polypropylene centrifuge tubes 1.5 mL
- Vortex mixer
- Timer
- Fluorescence Immunoassay Analyzer: Model FIC-Q100N

Warnings and precautions

This kit is intended for in vitro use by professional persons only.

Follow the instructions carefully.

Observe expiry dates stated on the labels. Use reagents within 30 minutes after opening of the kit. Refer to ”Materials Safety Data Sheet” for more detailed safety information.
Material of animal origin used in the preparation of this kit has been obtained from animals certified as healthy, but these materials should be handled as potentially infectious.
TECOmedical AG is not liable for loss or harm caused by non-observance of the kit instructions.

1. For in vitro diagnostic use.
2. Treat all specimen samples as potentially biohazardous material.
3. Follow General Precautions when handling the contents of this kit and any patient samples.
4. Disposal of containers and unused contents should be done in accordance with federal and local regulatory requirements.
5. Use the supplied components as an integral unit prior to the expiration date indicated on the package label.
6. Store assay components as indicated.

Preparation and stability of samples

Collect samples according to standard laboratory procedures. Avoid cross - contamination among samples. Sample labeling should be clear and correct without mistake. Avoid using samples with severe hemolysis, microbial contamination, and hyperlipidemia.

Sample Type

The assay is validated for serum and plasma.

Sample transportation

Sample transportation should comply with national biosafety requirements.

Stability

Maximum 48 hours at 2-8°C

Maximum 12 months at -20°C

Maximum 5 freeze/thaw cycles

Assay procedure

All samples are assayed in singlicate. Test should be performed as quickly as possible. Long-time exposure of test to air and moisture will cause invalid results.

Allow all components to stand at room temperature (20–25°C). Test cassette should be used within 0.5 hour after opening the bag. **After opening, sample treatment solutions A and B are stable 4 weeks at 2-8°C after opening, Control C1 and C2 are stable for 12 weeks at 2-8°C after opening.**

1. Sample/Control treatment

- Add 90 µL sample/control into a centrifuge tubes.
- Add 90 µL Sample Treatment Solution A into the tubes containing sample/control.
- Vortex for 10 seconds to mix well.
- Immediately add 90 µL Sample Treatment Solution B into the tubes.
- Vortex again for 10 seconds to mix well

2. Lateral Flow Procedure

- Standard curve import: Use the instrument scanner to scan the QR code of the standard curve on the kit to import the standard curve.
- The import of a standard curve is required in case of use for the first time or changes of product batch.
- Carefully refer to the instruction for use before performing the test.
- Before testing, ensure that tests and samples are at room temperature.
- Place test cassettes on a flat and clean bench; slowly dispense 90 µL of sample into the sample pad.
- Read and record the concentration value with the fluorescence immunoassay analyzer after 15 minutes (No longer than 17 minutes, as abnormal results may occur).

3. Quality Control

- The fluorescence immunoassay analyzer will calculate the signal of Control Line (C) automatically. If it fails, it will show ”Invalid result”. The test needs to be repeated.
- Recommendations are at least one control measurement per kit, or at least one control run per month.

Interpretation of results

1. The risk of fungal infection is low if the concentration of (1-3)-β-D-Glucan is <80 pg/mL. If the result is negative but a fungal infection is still suspected, retesting is recommended.
2. The risk of fungal infection is high if the concentration of (1-3)-β-D-Glucan is ≥100 pg/mL. Positive results should be used in conjunction with clinical symptoms, medical history, and other findings.
3. If the concentration of (1-3)-β-D-Glucan is ≥ 80 pg/mL and ≤ 100 pg/mL, continuous testing and observation are recommended.
4. Each laboratory shall consider the applicability of the cut-off and, if necessary, determine its own values.
5. It has been reported in the literature that the administration of some antimicrobial drugs prior to testing may interfere with the test results [2].

Test Performance

Clinical performance

A comparison study was performed between the TECO® *Fast* Fungus (1-3)-β-D-Glucan Lateral Flow Assay and an established reference method on 75 positive serum samples and 60 negative serum samples.

		TECO® *Fast* Fungus (1-3)-β-D-Glucan Lateral Flow Assay		
		Positive	Negative	Total
Reference method	Positive	74	1	75
	Negative	2	58	60
	Total	76	59	135

The Negative coincidence rate, positive coincidence rate and total coincidence rate of the TECO® *Fast* Fungus (1-3)-β-D-Glucan Lateral Flow Assay were 96.67 %, 98.67 %, and 97.78 %, respectively.

Analytical sensitivity

To determine the assay’s Limit of detection negative serum samples spiked with 5 different concentrations of (1-3)-β-D-Glucan were measured 30 times each using 3 different kit batches.
A Limit of Detection (LoD) of 35.00 pg/mL was determined.

Precision
(Intra and Inter assay)

On 4 clinical samples; Critical positive (100 pg/mL), strong positive (500 pg/mL), medium positive (200 pg/mL) and negative (50 pg/mL), within and between-lot precision tests were performed for 5 days, 5 replicates per sample, using 3 different kit lot, this results in a total of N = 75 values per sample.

- The intra-assay and inter-assay precision of each sample were all less than or equal to 15%.
- The positive detection rate of critical positive samples is ≥95%, and the positive detection rate of high-value positive samples and low-value positive samples is 100%
- The negative detection rate of negative samples was 100%, which met the requirement

Interferences and cross reaction

Controlled test of potential interfering substances and cross reactants in serum and plasma samples showed that there was no interference in the under-mentioned concentrations

Substance	Concentration
Hemoglobin	<7 mg/mL
Bilirubin	<300 mg/L
Triglyceride	<7.5 mmol/L
Heparin	75 IU/mL
EDTA	0.75%
Sodium raffinate	1.5%
Endotoxin	1 EU/mL

HOOK effect

(1-3)-β-D-Glucan was added to negative serum samples to concentrations of 10, 50, 100, 500, 1000, 5000 and 10000 pg/mL then tested in three batches of reagents to check whether there is a hook effect.

(1-3)-β-D-Glucan concentration (pg/mL)	Batch Nr 200901 (RFU)	Batch Nr 200902 (RFU)	Batch Nr 200903 (RFU)
10	5940	6824	5738
50	6065	7351	6575
100	6767	8383	7033
500	46576	49452	40358
1000	93075	133285	98406
5000	115403	133877	103564
10000	115754	138567	108738

No HOOK effect was observed when 10000 pg/mL of Fungus (1-3)-β-D-Glucan was added to serum.

Linearity

A high value reference L1 (concentration 1200 pg/mL) close to the upper limit of the linear interval and a low value linear reference L2 (concentration 37.5 pg/mL) close to the lower limit of the linear interval were mixed into 7 concentration samples at the ratio of 6:0, 5:1, 4:2, 3:3, 2:4, 1:5 and 0:6, respectively. Linearity was measured in 3 kit batches.

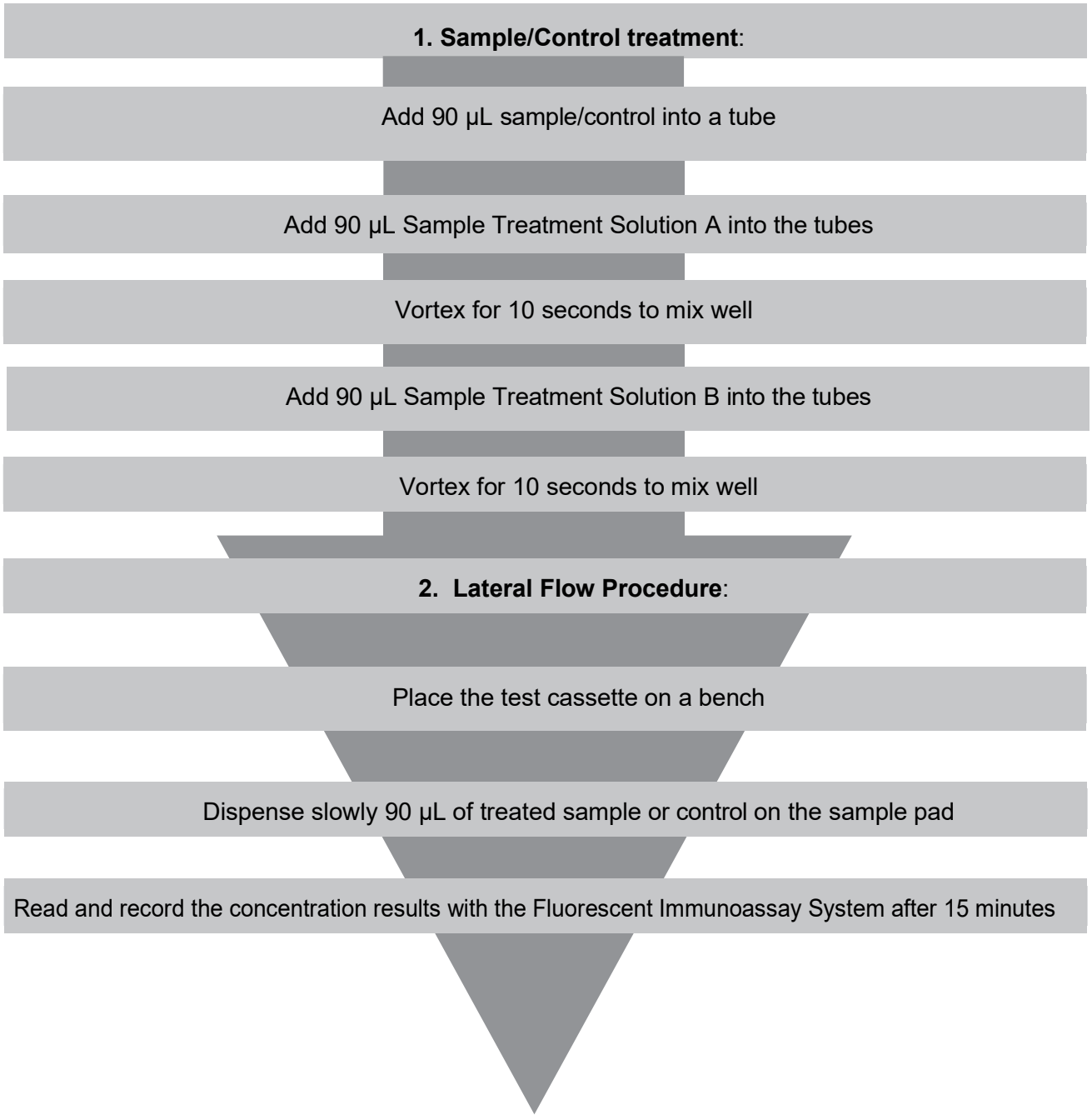
Kit lot	Dilution	Expected value pg/mL	Observed value pg/mL	Recovery (%)
200901	6:0	1200.00	1203.70	100.31
	5:1	1006.25	998.96	99.27
	4:2	812.50	816.13	100.45
	3:3	618.75	623.11	100.70
	2:4	425.00	422.79	99.48
	1:5	231.25	233.86	101.13
	0:6	37.50	36.39	97.04
Linear correlation (r) = 0.9999				
200902	6:0	1200.00	1206.30	100.53
	5:1	1006.25	994.27	98.88
	4:2	812.50	815.08	100.32
	3:3	618.75	622.65	100.63
	2:4	425.00	424.59	99.90
	1:5	231.25	234.69	101.49
	0:6	37.50	36.05	96.13
Linear correlation (r) = 0.9998				
200903	6:0	1200.00	1205.71	100.48
	5:1	1006.25	1005.86	99.96
	4:2	812.50	822.03	101.17
	3:3	618.75	616.03	99.56
	2:4	425.00	426.07	100.25
	1:5	231.25	229.50	99.24
	0:6	37.50	39.24	104.64
Linear correlation (r) = 0.9998				

Notes:

TECO® *Fast* Fungus (1-3)-ß-D-Glucan Lateral Flow Assay

Assay Procedure – Quick Guide

Bring samples and components to room temperature (20-25°C) for 30 min. Mix the samples well.



Please read Kit instruction before using the Quick Guide