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TECO®

Fast Candida Mannan Antigen Lateral Flow Assay

Instructions for use

English

CE

Catalogue No. TE1081
UDI-DI 7640146270146

TE1081_AA_E_11/2024

TECOmedical AG

www.tecomedical.com

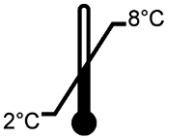
Symbol Description

Read electronic kit instructions

LOT

Lot number

Expiry date



Storage temperature

Not intended for self-testing
Or near-patient testing

Manufacturer

REF

TE 1081

UDI-DI

Unique Device Identifier

IVD

In Vitro Diagnostics

50 tests

CE

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

TECO*medical* AG
A Eurobio Scientific Company
Gewerbestrasse 10
4450 Sissach, Switzerland
Phone +41 61 985 81 00
info@tecomedical.com
www.tecomedical.com

Eurobio Scientific SA
7 avenue de Scandinavie
ZA de Courtaboeuf
91940 Les Ulis, France
Phone +33 1 69 79 64 80
reglementaire@eurobioscientific.com

Any serious incident that has occurred in relation to this product shall be reported to TECOmedical AG and the competent authority of the Member State in which the user and/or the patient is established

Fast Candida Mannan Antigen Lateral Flow Assay

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** Ready to use	**4 x 2.5 mL**
C1	**Positive Control Serum** Ready to use Range as indicated on data sheet	**1 x 2.0 mL**
C2	**Negative Control Serum** Ready to use Range as indicated on data sheet	**1 x 2.0 mL**
	**eIFU indicator** Login address for electronic kit instructions	
	QR code on kit box lot-specific, for standard curve import	

Storage

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

Intended Use

The *Fast* Candida Mannan Antigen Lateral Flow Assay is used for the detection of Candida Mannan antigen in human serum samples, offering a diagnostic reference for Invasive Candidiasis (IC).

Clinical Use

In recent years, with the increase of risk factors such as oncological chemotherapy, organ transplantation, glucocorticoids, and the widespread use of immunosuppressive broad-spectrum antimicrobial drugs, the incidence of Invasive Candidiasis (IC) has been on the rise significantly.
Among them, candidemia is the most common clinical type of Invasive Candidiasis and often has a poor prognosis. Early diagnosis and timely treatment can significantly improve the prognosis of Invasive Candidiasis. Invasive Candidiasis is most often seen in immunocompromised patients, with a prevalence of 2.1 to 21/100 000 and a mortality rate of 40% to 60%.
The main risk factors for Invasive Candidiasis include multisite colonization, severe sepsis, total parenteral nutrition (TPN), central venous catheter (CVC) indwelling, broad-spectrum antimicrobial drug exposure, glucocorticoid use, and major abdominal surgery [1].
Invasive Candidiasis involves various tissues and organs of the body with different clinical manifestations. Mannans are the main structural component of the Candida cell wall, accounting for 7% of the cell dry weight, and are released into the bloodstream during Candida infection. This product uses fluorescence immunochromatographic technique to detect Candida mannans in serum, providing an effective aid for the detection of susceptible people.

Limitations

- The *Fast* Candida Mannan Antigen Lateral Flow Assay is a prescription-use laboratory assay that provides aid to the diagnosis of Invasive Candidiasis.
- The results of this test are for reference only, and the test results alone should not be used as the sole basis for disease diagnosis. For diagnostic purposes, test results should be used in conjunction with clinical symptoms, medical history and other test results.
- The use of the antiviral drugs acyclovir and valacyclovir [2] may cause false-positive test results.
- In some patients with Candida infection, mannans can be broken down or neutralized by antibodies and cause false negatives.
- The test results for the same patient may be different at different stages of the disease, under different physiological conditions and under different medications.

References

[1] Chinese adult candidiasis diagnosis and management expert consensus group. Expert consensus on the diagnosis and treatment of adult candidiasis in China
Chinese Journal of Internal Medicine, 2020, 059 (001) : 5-17

[2] Nihtinen A, Anttila V J, Richardson M, et al
Factors influencing the performance level of Candida mannan antigen testing in allogeneic stem cell transplant recipients not receiving fluconazole prophylaxis.
Transplant Infectious Disease, 2011, 13(3) : 266-272.

Assay Principle

The *Fast* Candida Mannan Antigen Lateral Flow Assay uses double antibody sandwich fluorescence immunochromatography to detect Candida mannan in human serum.
The fluorescent microsphere-labeled sheep anti-Candida antibody 1 is pre-embedded on the fluorescent pad, and the sheep anti-Candida antibody 2 and the rabbit anti-sheep IgG antibody are encapsulated on the detection line (T) and the quality control line (C), respectively.

– Positive samples: the Candida mannan in the sample binds to the fluorescent microsphere-labeled sheep anti-Candida antibody 1 to form a complex, which moves forward along the paper strip under chromatography and appears as a fluorescent band when it passes through the detection line (T) with the pre-encapsulated sheep anti-Candida antibody 2, and when it passes through the quality control line (C) with the pre-encapsulated rabbit anti-sheep antibody.
- Negative samples do not contain Candida mannan, do not form immune complexes and do not show a band at the detection line (T), but only at the quality control line (C). The fluorescence band shown in the quality control line (C) is the criterion for determining whether the chromatographic process is normal or not, and also serves as an internal control standard for the reagents.
  The fluorescence signal is obtained by scanning the detection area using a fluorescence immunoassay analyzer, which shows the concentration value of Candida mannoprotein.

Materials Required and not Supplied

- Pipettes and tips, 100 µL – 1000 µL
- Polypropylene centrifuge tubes 1.5 mL with screw caps or safety lock caps
- Centrifuge (10 000 x g)
- Vortex mixer
- Water bath or Heat block (100-110°C required)
- Timer
- Fluorescence Immunoassay Analyzer 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 cassettes within 30 minutes after opening of the bag. 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.
   Follow General Precautions when handling the contents of this kit and any patient samples.
3. Disposal of containers and unused contents should be done in accordance with federal and local regulatory requirements.
4. Use the supplied components as an integral unit prior to the expiration date indicated on the package label.
5. 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.

Sample transportation

Sample transportation should comply with national biosafety requirements.

Stability

Maximum 72 hours at 2-8°C

Maximum 12 months at -20°C

Maximum 5 freeze/thaw cycles

Assay procedure

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

Allow all components to stand at room temperature (20–25°C) for approximately 30 minutes. Test cassettes should be used within 30 minutes after opening the bag. Sample treatment solution is stable for 4 weeks at 2-30°C after opening, Controls are stable for 2 weeks after opening.

Prepare the FIC-Q100N fluorescence immunoassay analyzer according to the Operational Guide.
Note: Scan the QR code on the box to import the correct standard curves.

1. Sample treatment

- Add 300 µL serum into screw-cap tubes.
- Add 100 µL Sample Treatment Solution into the tubes containing serum.
- Vortex for 10 seconds to mix well, spin down in a centrifuge for 5 seconds at 10,000 × g.
- Heat the tubes at 110°C (Heat Block) or at 100°C (Water Bath) for 3-4 minutes.
- Centrifuge the tubes at 10,000 × g for 10 min.
- Collect supernatant and use it for testing.
- After preparation, the supernatant may be collected/saved and stored at 2-8°C for up to 48 hours prior to testing. If analysis of the results indicates that retesting is required, another aliquot of the sample must be treated for testing.
- NOTE: controls do not need treatment

2. Lateral Flow Procedure

- Carefully refer to the instruction for use before performing the test.
- Before testing, ensure that all kit components and samples are at room temperature.
- Place test cassettes on a flat and clean bench; slowly dispense 100 µL of sample supernatant or **untreated** control solution into the sample pad.
- Make sure the batch specific QR code has been uploaded to the reader and is activated.
- Read and record the results with the fluorescence immunoassay analyzer after 20 minutes (no longer than 25 minutes, as abnormal results may occur).

QUALITY CONTROL

- The fluorescence immunoassay analyzer will calculate the signal of the Control Line (C) automatically. If it fails, it will show “Invalid”. 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

The following cut off limits were identified in the population studied to obtain the performance characteristics; however, each laboratory may wish to establish their own cut off values and negative and positive interpretation with their patient population:

- result ≥ 60 pg/mL is considered to be positive for the candida mannoprotein.
  Note: For all positive patients, it is recommended to repeat testing with a new aliquot of the same sample.
- result < 60 pg/mL is considered to be negative for the candida mannoprotein.
  Note: A negative result may indicate that the patient's result is below the detectable level of the assay. Negative results do not rule out the diagnosis of Invasive candidiasis. Repeat testing is recommended if the result is negative, but the disease is suspected.

This assay is intended to be used as an aid in the diagnosis of Invasive candidiasis. Positive results obtained with this assay should be considered in conjunction with other diagnostic procedures such as clinical symptoms, histological examination, and other findings.

Test Performance

Diagnostic Sensitivity and Specificity

The *Fast* Candida Mannan Antigen Lateral Flow Assay uses a clinical research method that compares the assessment reagents with the clinical diagnosis results on the same serum samples and compares the consistency of the results. The clinical agreement study evaluated a total of 155 serum samples (59 biopsy and pathology confirmed serum samples and 96 negative serum samples).

The compliance rate of the assessment reagent and clinical diagnosis is evaluated, the result shows that: the diagnostic sensitivity is 88.1% and the diagnostic specificity is 96.9%. The total compliance rate is 93.5%.

Examination reagent results	Compare reagent results		Total
	Positive	Negative	
Positive	52	3	55
Negative	7	93	100
Total	59	96	155

Sensitivity

To evaluate the lowest limit of detection (LOD), first the limit of blank (LOB) was determined:
5 blank references (negative serum samples) were tested with each of 3 batches of kits for 3 days each, with 2 replicates per day for each of the 3 instruments (5 references x 3 instruments x 3 days x 2 replicates/day = 90 results/batch of reagents). The LOB was calculated to be 20.0 pg/mL and two samples with concentrations at the limit of detection were tested with 3 batches of kits, for 3 days, and 4 replicates were done per sample per day (2 samples × 3 days × 4 replicates/day × 3 batches = 72 results). The LOD value of the three batches of kits was 21.5 pg/mL, therefore the detection limit was set at 21.5 pg/mL.

Precision

(Intra and Inter assay)

5 clinical samples (1 low-value negative sample, 1 high-value negative sample, 1 critical-positive sample, 1 medium-positive sample, 1 strong-positive sample) were tested on 3 different instruments, 2 operators for each instrument (6 operators in total), 3 different batches for 5 days and 5 replicates per sample per day (3 instruments x 3 kit batches x 5 days x 5 replicates/day = 225 results per sample) in order to obtain within lot and between lot precision.

The CVs of repeatability, indoor precision, and inter-batch precision for positive and strongly positive samples in the three instruments were all less than 15% which meets requirements (repeatability CV ≤ 15%, inter-batch CV ≤ 20%).

The positive detection rate of critical positive is ≥ 95%, the negative detection rate for both low value negative samples and high value negative samples was 100%.

Interference

Controlled test of potential interfering substances showed that there was no interference in the under-mentioned concentrations.

Substance	Concentration
Hemoglobin	<7 mg/mL
Bilirubin	<300 mg/L
Cholesterol	<10 mg/mL
Triglyceride	<7.5 mmol/L
Voriconazole	40 μg/mL
Amphotericin b	1 mg/mL
Caspofungin	0.27 mg/mL

Cross reaction

No false-positive Candida test results were observed on specimens from the following disease states or specific conditions, respectively:

Cross reactant	Number of serum samples	Number of positive values
Cryptococcal positive antigen	10	0
Aspergillus positive antigen	10	0
Rheumatoid factor	10	0
Antinuclear antibody	10	0
Anti-double stranded DNA	10	0

Hook effect

The Candida Mannan antigen was diluted to the following concentrations of 10 000, 5 000, 1 000, 500, 250, 100, 50 and 20 pg/mL then tested in triplicates in three batches of reagents to check whether there is a hook effect. Fluorescence intensities are shown in relative fluorescent units (RFU).

Candida mannoprotein concentration (pg/mL)	Batch Nr 200201 Average RFU	Batch Nr 200202 Average RFU	Batch Nr 200203 Average RFU
10 000	151992	151816	151286
5 000	123197	122447	124669
1 000	52779	49183	48809
500	31240	31577	32957
250	18601	19100	19048
100	8327	8381	8630
50	4736	4583	4469
20	2073	1970	1894

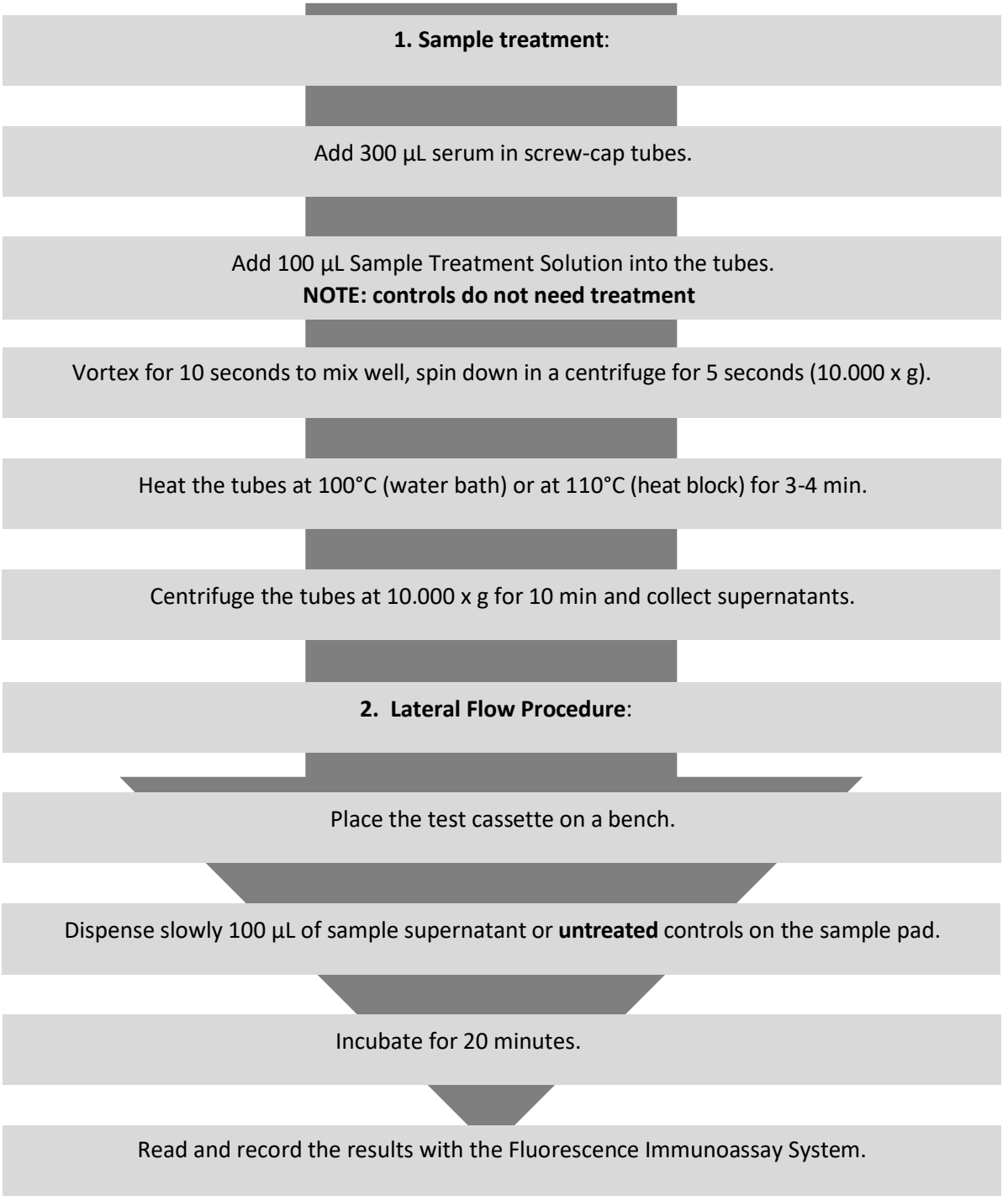
It can be seen from the above experimental results that there is no hook effect up to the concentration of Candida Mannan of 10 000 pg/mL.

Notes

Fast Candida Mannan Antigen Lateral Flow Assay

Assay Procedure – Quick Guide

Bring samples and components to room temperature (20-25°C) for 30 min. Mix the samples well.
Prepare the FIC-Q100N according to the Operational Guide.



Please read Kit instruction before using the Quick Guide