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TECO®

Fast Candida IgG Antibody – Lateral Flow Assay

Instructions for use
English

CE

Catalogue No. TE1083
UDI-DI 7640146270160

TE1083_AA_E_01/2025

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 1083

UDI-DI

Unique Device Identifier

IVD

In Vitro Diagnostics

50

50 tests

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

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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

TECO® *Fast* Candida IgG Ab 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 Dilution 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 For standard curve import, lot-specific	

Storage

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

Intended Use

The *Fast* Candida IgG Ab Lateral Flow Assay (LFA) is used for the detection of Candida IgG antibody (Ab) in human serum samples. It can be used for clinical auxiliary diagnosis of Invasive Candidiasis.

Clinical Use

In recent years, the infection rate of Candidiasis has been increasing significantly. Candida infections rank fourth among bloodborne infections and third among catheter-related infections. Even after antifungal treatment, the mortality rate is still as high as 40%. The main risk factors for invasive candidiasis include candida colonization, treatment with broad-spectrum antimicrobials, use of central venous catheters, total parenteral nutrition, gastrointestinal or cardiac surgery, extended hospital stay, ICU admission, burns, premature delivery, Neutropenia, systemic glucocorticoids, HIV infection and diabetes. Invasive candidiasis affects various tissues and organs of the human body, with different clinical manifestations. Currently, Candida infection lacks specific early diagnosis methods. The Candida IgG antibody is a specific antibody produced after the body is infected with Candida. This product uses fluorescence immunochromatography to detect specific antibodies in serum, providing an effective reference method for the detection of susceptible people.

Limitations

- The *Fast* Candida IgG Ab LFA is a prescription-use laboratory assay that provides aid to the diagnosis of Invasive Candidiasis. Positive results obtained with this assay should be considered in conjunction with other diagnostic procedures such as microbiological culture, histological examination of biopsy samples and radiographic evidence.
- **Note**: IgG antibody may not be detected in some immunocompromised patients
- 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] Pfaller MA, Diekema DJ.
Epidemiology of invasive candidiasis：a persistent public health problem
Clin Microbiol Rev, 2007, 20（1）: 133-163.

[2] Garey KW, Rege M, Pai MP, et al.
Time to initiation of fluconazole therapy impacts mortality in patients with candidemia：a multi-institutional study
Clin Infect Dis, 2006, 43（1）: 25-31.

[3] Chinese Medical Association "Candidiasis Diagnosis and Treatment Strategy Summit" Expert Group.
The diagnosis and treatment of Candidiasis: the expert consensus
Chin J Infect Chemother, 2011, 11(2) : 81-95

[4] Cornely O A, Bassetti M, Calandra T, et al **ESCMID** This guideline was presented in part at ECCMID 2011. European Society for Clinical Microbiology and Infectious Diseases guideline for the diagnosis and management of Candida diseases 2012：non-neutropenic adult patients**
Clinical Microbiology and Infection, 2012 (18) : 19-37.

Assay Principle

The *Fast* Candida IgG Ab LFA uses capture fluorescence immunochromatography to detect Candida IgG antibodies in human serum samples. The Candida Mannan antigen labeled with fluorescent microspheres and the chicken IgY antibody labeled with fluorescent microspheres are coated on a fluorescent pad, and the Test Line (T) and Quality Control Line (C) are coated with anti-human IgG antibody and anti-chicken IgY antibody, respectively.

- If the sample is positive, the Candida IgG antibody will combine with the fluorescent microsphere-labeled Candida Mannan antigen to form a complex and migrate further along on the nitrocellulose membrane. Anti-human IgG antibodies coated on the Test line (T) interact with the above complexes and display a fluorescent band, fluorescently labeled chicken IgY antibodies display fluorescence bands on the Quality Control Line (C) in combination with anti-chicken IgY antibody.
- If the test sample is negative, no immune complex will be formed, no band will appear at the Test line (T), and only a band will appear at the Quality Control Line (C). The control line (C) should always display a fluorescent band during the test: it is a way to check if the test works correctly and also an internal control standard. Read the detection area with a fluorescence immunoassay analyzer to get a fluorescence signal, interpreting the concentration value of Candida IgG antibody.

Materials Required and not Supplied

- Pipettes 5 µL – 200 µL
- Polypropylene centrifuge tubes, 1.5 mL
- Vortex mixer
- 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 test cassettes 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. 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 5 days at 2-8°C

Maximum 15 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 before testing. The test cassette is recommended to be used within 30 minutes after opening the bag. Sample Dilution Solution is stable 4 weeks at 2-8°C 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. Carefully refer to the instruction for use before performing the test.
2. Before testing, ensure that all kit components and samples are at room temperature.
3. Dilute the sample in two steps 1:200 with the Sample Dilution Solution:
   a. First step: 5 µl sample + 20 µl Sample Dilution Solution
   b. Second step: 5 µl of the first step dilution + 195 µl Sample Dilution Solution

   Controls should not be diluted.
4. Place test cassettes on a flat and clean bench; slowly dispense 100 µL of sample supernatant or untreated control solution into the sample pad.
5. Make sure the batch specific QR code has been uploaded to the reader and is activated.
6. Read and record the concentration value with the fluorescence immunoassay analyzer after 15 minutes (No longer than 20 minutes, as abnormal results may occur).

QUALITY CONTROL

- The fluorescence immunoassay analyzer will calculate the signal of 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 offs values and negative and positive interpretation with their patient population:

- Concentration value ≥ 135 AU/mL is considered to be positive for Candida IgG antibody.
  Note: For all positive patients, it is recommended that a new aliquot of the same sample (serum) be repeated.

- Concentration value < 135 AU/mL is considered to be negative for Candida IgG antibody.
  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.

Test Performance

Diagnostic Sensitivity and Specificity

The *Fast* Candida IgG Ab LFA uses a clinical research method that compares the assessment reagents with a reference method on the same serum samples and compares the consistency of the results. The clinical agreement study evaluated a total of 222 serum samples (94 positive, 128 negative)**.**

The coincidence rate of the assessment reagent and the reference method was evaluated:
The clinical sensitivity (positive compliance rate) of the test is 86.2% and the clinical specificity (negative compliance rate) is 95.3%. The total accuracy rate is 91.4%.

LFA result	Reference method result		Total
	Positive	Negative	
Positive	81	6	87
Negative	13	122	135
Total	94	128	222

Sensitivity

To evaluate the lowest Limit of Detection (LOD), first the Limit of Blank (LOB) was determined. 5 blank references (sample dilution solution) were tested with each of the 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 5.0 AU/ml, and 2 negative sera were spiked with the concentration of the LOB for LOD determination. The maximum LOD value for the three batches of kits was 7.0 AU/mL, so the limit of detection was set at 7.00 AU/mL.

Precision
(Intra and Inter assays)

4 clinical samples (1 negative, 1 critical positive, 1 medium positive and 1 strong positive) 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 reproducibility, indoor precision, and inter-batch precision for medium-positive and strongly positive samples in the three instruments assays were: Reproducibility CV ≤ 9.5%, indoor precision CV ≤ 13 %, inter-batch CV ≤ 13.5%); the positive detection rate of critical positive samples was ≥ 96%, the negative detection rate of negative samples was 100%.

Interferences

Controlled tests of potential interfering substances showed that there was no interference for the under-mentioned concentrations:

Substance	Concentration
Hemoglobin	<5 mg/mL
Bilirubin	<300 mg/L
Cholesterol	<10 mg/mL
Triglycerides	<7.5 mmol/L
Voriconazole	40 µg/mL
Amphotericin b	1 mg/mL
Caspofungin	0.27 mg/mL

Rheumatoid factor, anti-nuclear antibody, and anti-double-stranded DNA antibody did not interfere with the test results.

Cross reaction

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

Cross reactant (Virus/Bacteria)	Result
Aspergillus positive IgG antibody	Negative
Cryptococcal positive antigen	Negative
Mycoplasma pneumoniae positive IgG antibody	Negative
Chlamydia pneumoniae positive IgG antibody	Negative

Hook effect

Candida IgG humanized monoclonal antibody at a concentration of 1500 AU/mL was taken and diluted with negative serum matrix to different concentrations of 10 AU/mL, 50 AU/mL, 100 AU/mL, 200 AU/mL, 500 AU/mL, 1000 AU/mL, and 1500 AU/mL, and the fluorescence values were detected with three batches of reagents. The assay was repeated three times to check whether there is a hook effect. Fluorescence intensities are shown in relative fluorescent units (RFU).

Candida IgG Ab concentration (AU/mL)	Batch Nr 191101 (RFU)	Batch Nr 191102 (RFU)	Batch Nr 191103 (RFU)
10	1198	1109	1297
50	4864	5005	4812
100	11754	12115	11909
200	24493	22667	20035
500	51911	50173	42284
1000	72033	70756	73621
1500	82173	81469	81221

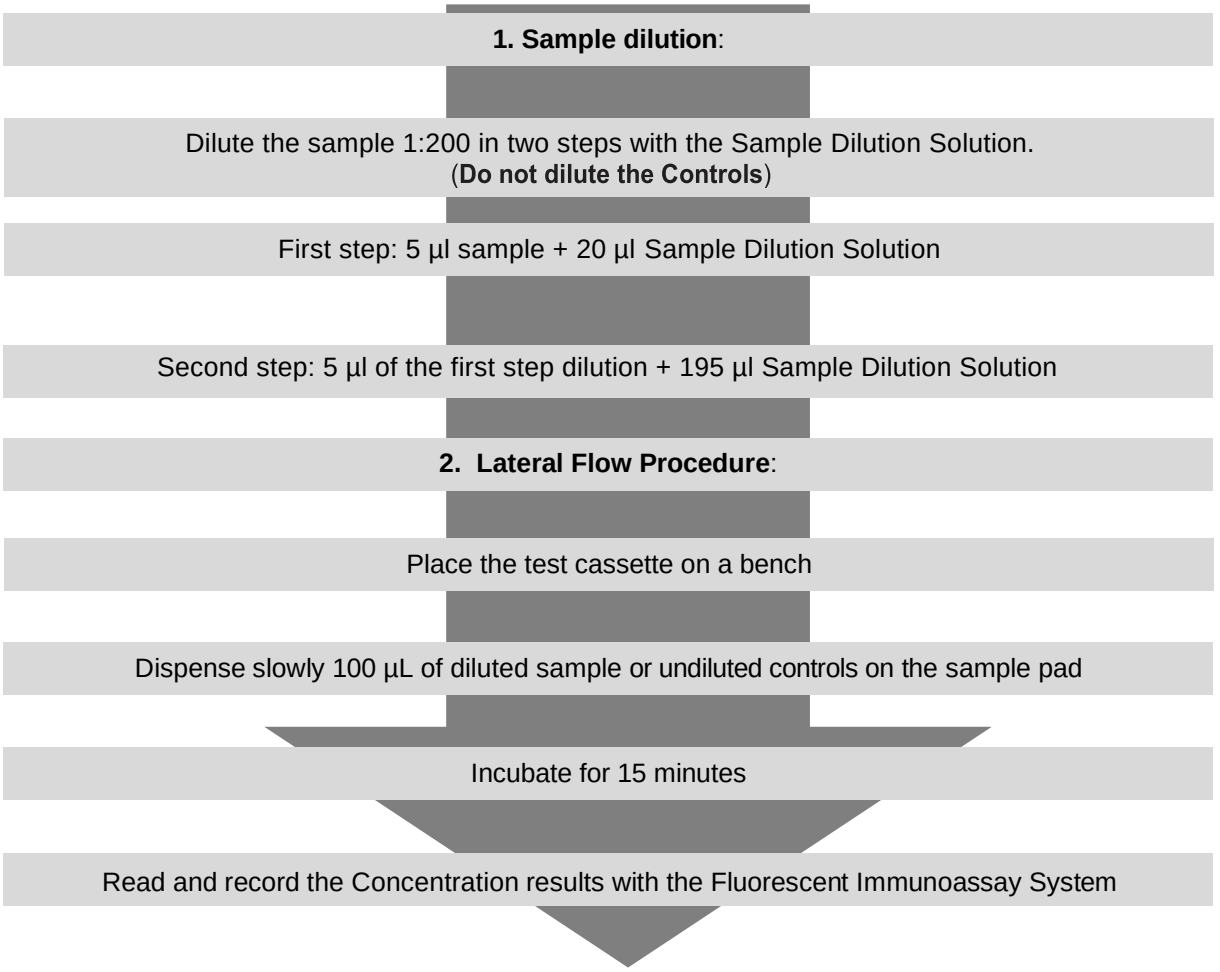
From the results of these tests, it is clear that there was no Hook effect for a Candida IgG antibody concentration of 1500 AU/mL, and higher concentrations were not validated.

Notes:

TECO® *Fast* Candida IgG Ab 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