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TECO® FungiLine

Routine diagnostics for the detection of fungal diseases

TECOmedical Group

www.tecomedical.com

TECO® FUNGILINE FOR RELIABLE DIAGNOSTICS

TECO® FungiLine *Fast* Fluorescence System

> *Fast* Fungus (1-3)-β-D-Glucan Antigen Assay

> *Fast* Aspergillus Galactomannan Antigen Assay

> *Fast* Aspergillus IgG Antibody Assay

> *Fast* Candida Mannan Antigen Assay

> *Fast* Candida IgG Antibody Assay

> *Fast* Cryptococcus Antigen Assay

Screening Tests

> TECO® Aspergillus Galactomannan Assay

> TECO® Fungus (1-3)-β-D-Glucan Assay

TECO® FUNGILINE

Innovative tests for the detection of fungal infections

"It is estimated that invasive fungal infections are only diagnosed in 50% of cases during the patient's lifetime and are the most frequently overlooked causes of death in intensive care patients. The low detection rate is due, among other things, to the complexity of the diagnostics, for which clinical, radiological and micro-biological findings have to be taken into account." (Lilienfeld-Toal et al., 2019)

The TECO® FungiLine includes a large number of innovative tests for the detection of a wide variety of fungal infections based on methods such as ELISA, kinetic determination and immunofluorescence tests, which can be classified as follows:

Screening assays in 96-well format for higher throughput routine laboratories

The screening methods are based on the detection of fungal cell wall components.

TECO® Aspergillus Galactomannan Assay

Aspergillus galactomannan is a component of the cell wall of Aspergillus species and is primarily used to detect invasive aspergillosis or to screen high-risk patients.

- ELISA with 2 patented monoclonal antibodies against galactomannan
- Simplified sample preparation without heating and centrifugation
- Validated for serum and bronchoalveolar lavage (BAL)

TECO® Fungus (1-3)-β-D-Glucan Assay

(1-3)-β-D-glucan is a cell wall component of various fungi and is used as a pan marker for invasive fungal infections. Pneumocystis, Aspergillus, and Candida infections are particularly well documented. The test does not differentiate between the individual fungi.

- Kinetic test
- Kit assembly allows multiple approaches without loss of activity
- Validated for serum

Fluorescence system for quick and easy fungus diagnosis (TECO® FungiLine *Fast*)

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

- (1-3)-β-D-glucan detection in 15 minutes
- Validated for serum and plasma

Fast Aspergillus Galactomannan Antigen Lateral Flow Assay

- Aspergillus galactomannan antigen detection in 20 minutes
- Validated for serum and bronchoalveolar lavage (BAL)

Fast Aspergillus IgG Antibody Lateral Flow Assay

- Detection of Aspergillus IgG in 15 minutes
- Validated for serum

Fast Candida Mannan Antigen Lateral Flow Assay

- Detection of Candida mannan antigen in 20 minutes
- Validated for serum

Fast Candida IgG Antibody Lateral Flow Assay

- Detection of Candida IgG in 15 minutes
- Validated for serum

Fast Cryptococcus Antigen Lateral Flow Assay

- Detection of Cryptococcus antigen in 20 minutes
- No sample preparation step needed
- Validated for serum and CSF

TIMELY DIAGNOSIS AND RAPID TREATMENT ARE LIFE-SAVING

Most invasive fungal infections are caused by Aspergillus spp., Candida spp. and Cryptococcus spp. Affected patients have a poor prognosis and a high mortality rate. The timely, targeted treatment of invasive fungal infections is life-saving (see Figure 1) and depends on a quick and reliable diagnosis.

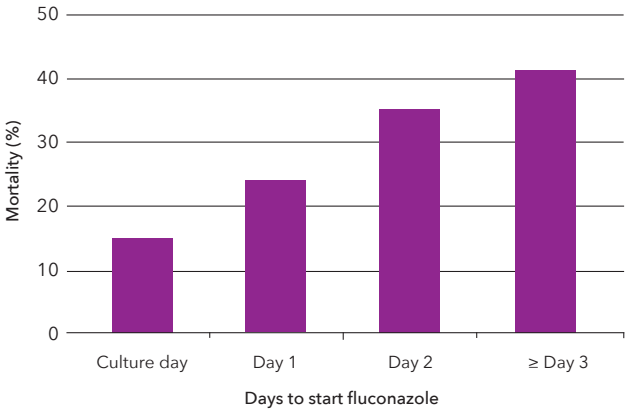


Figure 1:
Relationship between hospital mortality and the number of days to initiation of fluconazole therapy. We calculated the days to the start of fluconazole therapy by subtracting the start date of fluconazole therapy from the culture date of the first blood sample positive for yeast (Garey et al., 2006).

Laboratory tests are often done in batches to make best use of the 96-well format, either in-house, or after being sent to external laboratories. But sample collection or sample shipment means life-saving time can be lost.

Test results of individual patients are usually available within a few days, depending on the number of samples in-house and the testing frequency in external laboratories.

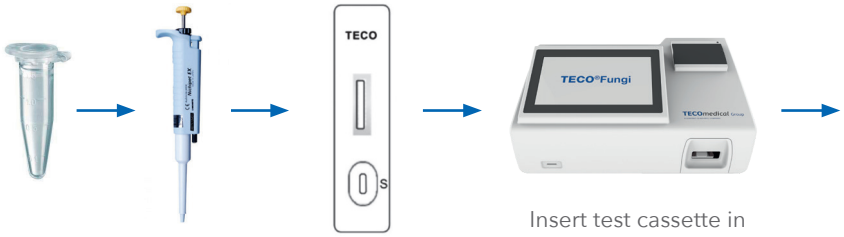
For cases with low throughput and a need for fast results, the TECO® FungiLine *Fast* was developed to avoid this loss of time and to enable every hospital laboratory to establish fast in-house fungal diagnostics.

TECO® FUNGILINE *FAST*

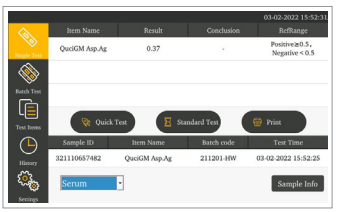
The TECO® FungiLine *Fast* consists of a fluorescence analyzer (FIC-Q100N) and fluorescence-based rapid tests (TECO® *Fast* Lateral Flow Assays) for the detection of the most common invasive fungal infections. The combination of analyzer and *Fast* LFAs can be established in every laboratory.

The TECO® FungiLine *Fast* is a monotest procedure and enables the quick and easy detection of fungal antigens and associated antibodies within less than 60 minutes.

General test sequence from (pretreated) sample to result:



Insert test cassette in FIC-Q100N analyzer

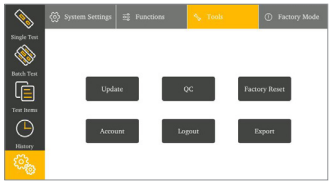
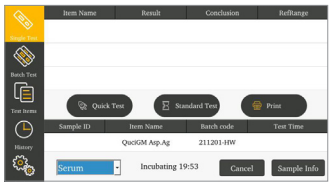
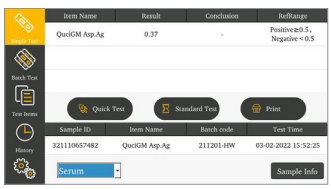


Results available in 15-20 minutes, report via:
- Printer
- csv file (USB export)
- LIS
- Internal data storage

FUNGILINE FIC-Q100N ANALYZER & SOFTWARE

The fluorescence system with excellent sensitivity and specificity

FIC-Q100N Analyzer - Hardware	Properties
	Bench-top fluorescence analyzer for quantitative / qualitative measurement and calculation of test results • Dimensions: 285 mm (L) x 240 mm (W) x 130 mm (H) • Weight: 2 kg • Detection unit: reliable LED / LD technology
	Various connection options: • LIS connection via ethernet or RS-232 port for direct transfer of results • 2 USB connections for barcode reader and data backup (csv files)
	• Low maintenance: annual performance check recommended (performance check set available upon request) • Standard curve import via barcode reader (QR-code based) • Loading rail for test cassette (front right)
	• Touch screen monitor • On-board printer

FIC-Q100N Analyzer - Software	Properties
	• User-friendly interface on touch screen monitor
	Flexible adaptation to individual work processes: • Quick test (instant readout after incubation) • Standard test (with incubation on board) **Use of different sample-specific calibration curves in one test is possible:** • Selection of different sample types (e.g. serum, BAL etc.) per test cassette
	• Objective measurement of *Fast* Tests • 4000 results are saved on the internal card • Storage on external USB stick • Results are displayed on the screen, can be printed and / or sent to the LIS

TECO® FUNGILINE AT A GLANCE

Product	Procedure	Determination	Catalogue No.
TECO® Aspergillus Galactomannan Assay	ELISA	Aspergillus galactomannan antigen	TE 1067
TECO® Fungus (1-3)-β-D-Glucan Assay	Kinetic	(1-3)-β-D-glucan	TE 1068
TECO® *Fast* Aspergillus Galactomannan Antigen (Ag) Assay	Lateral Flow	Aspergillus galactomannan antigen	TE 1069
TECO® *Fast* Aspergillus IgG Antibody (Ab) Assay	Lateral Flow	Aspergillus IgG	TE 1070
TECO® *Fast* Candida Mannan Antigen (Ag) Assay	Lateral Flow	Candida mannan antigen	TE 1081
TECO® *Fast* Candida IgG Antibody (Ab) Assay	Lateral Flow	Candida IgG	TE 1083
TECO® *Fast* Cryptococcus Antigen (Ag) Assay	Lateral Flow	Cryptococcus antigen	TE 1085
TECO® *Fast* Fungus (1-3)-β-D-Glucan Antigen (AG) Assay*	Lateral Flow	(1-3)-β-D-glucan antigen	TE 1088

* manufactured for TECOmedical by Dynamiker Biotechnology, Tianjin, China

REF.:

von Lilienfeld-Toal M, Wagener J, Einsele H, Cornely OA, Kurzai O: Invasive fungal infection–new treatments to meet new challenges. Dtsch Arztebl Int 2019; 116: 271–8. DOI: 10.3238/arztebl.2019.0271

Garey KW, Rege M, Pai MP, Mingo DE, Suda KJ, Turpin RS, Bearden DT: Time to Initiation of Fluconazole Therapy Impacts Mortality in Patients with Candidemia: A Multi-Institutional Study. Clinical Infectious Diseases 2006; 43: 25-31. DOI: 10.1086/504810

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Certified Quality System ISO 13485 mdc

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