TECOmedical Group

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Information

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TECO® Fungus (1-3)-β-D-Glucan Assay

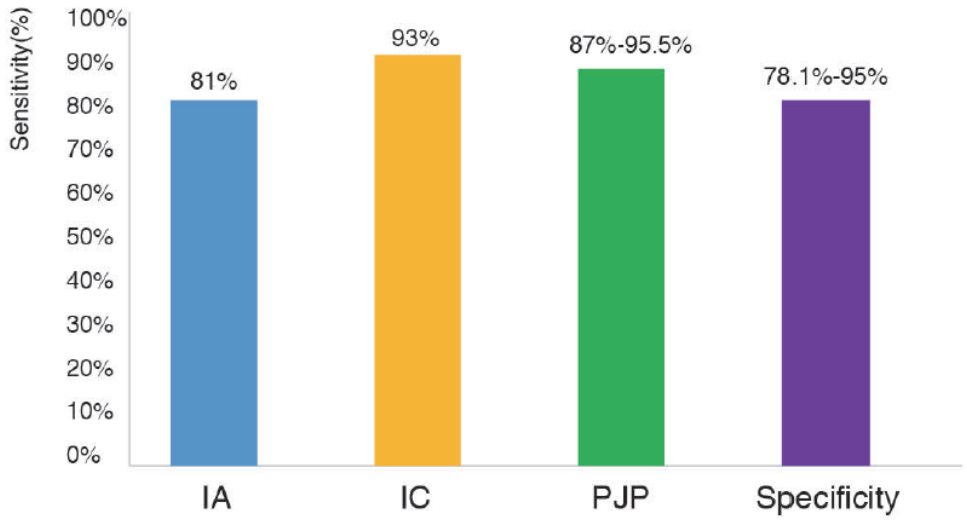
IVD CE

(1-3)-β-D-glucan is an integral part of the cell wall of most fungi and is not found in bacteria, viruses, or human cells. For this reason, the detection of (1-3)-β-D-glucan in human serum is a diagnostic indicator of invasive fungal diseases.

Assay Description	Kinetic test on spectrophotometer, 405 nm at 37°C
Time to Result	Approx. 60 minutes
Interpretation	< 70 pg/mL negative ≥ 95 pg/mL positive
Diagnostic Sensitivity	86.55% (n=119)
Diagnostic Specificity	89.07% (n=183)
Intra Assay CV	4.62% (n=80)
Inter Assay CV	4.30% (n=20)
Kit Design	Test kit contains the following components and can be split: 12 x 8 Microtiter Plate Test Strips 4 vials each - Reaction Solutions 5 vials each - Standards 5 vials each - Controls
Manufacturer	TECOmedical AG Gewerbestrasse 10 CH-4450 Switzerland
Catalogue No.	TE1068

TECO® Fungus (1-3)-β-D-Glucan Assay

Sensitivity and specificity of the TECO® Fungus (1-3)-β-D-Glucan Assay in different clinical pictures



IA: Invasive Aspergillosist I ***IC:*** Invasive Candidiasis I ***P JP:*** Pneumocystis Jiroveci Pneumonia

*White PL, et al: An evaluation of the performance of the Dynamiker® Fungus (1-3)-β-D-Glucan Assay to assist in the diagnosis of invasive aspergillosis, invasive candidiasis and Pneumocystis pneumonia. Med Mycol. 2017 Nov 1;55(8):843-850;

Recommendations before Starting the (1-3)-β-D-Glucan Assay

- ✓ Allow test kit to come to room temperature for 30 minutes
- ✓ Check programming of the reader; allow to come to 37°C
- ✓ Change the pipette tip for each pipetting step (also duplicate determination)
- ✓ Use pyrogen-free tubes and pipette tips:
  - Eppendorf BIOPUR 2-200 uL, Order No. 0030 075.234
  - Eppendorf BIOPUR 50-1000 uL, Order No. 0030 075.250
  - Safe Lock Tubes 1,5 mL, Catalogue No. TECO-1401-1-4
- ✓ The **Main Reagent R1** should be frozen at -20°C immediately after use and is then stable for 5 days. ***Only one thawing cycle possible!***

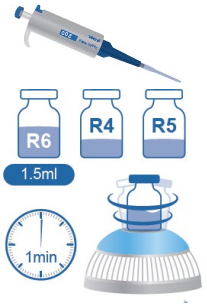
Brief Description of Assay Procedure

Assay Step 1: Standard and Control Solutions

Add 1.5 mL Diluent R6 to Standard R4 (Standard A).

Add 1.5 mL Diluent R6 to Control R5 (Positive Control).

Mix on the vortex mixer for at least 1 minute.

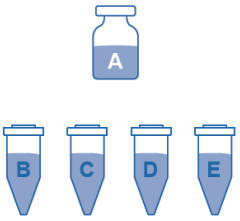


Assay Step 2: Preparation of Standard Solutions

Label tubes B to E.

Add 0.3 mL Diluent R6 to each tube.

Prepare Standard series (see table).



Standard ID	Concentration	Dilution
Standard A	600 pg/mL	See Assay Step 1
Standard B	300 pg/mL	0.3 mL Diluent(R6) + 0.3 mL Standard A Vortex: 30 sec
Standard C	150 pg/mL	0.3 mL Diluent(R6) + 0.3 mL Standard B Vortex: 30 sec
Standard D	75 pg/mL	0.3 mL Diluent(R6) + 0.3 mL Standard C Vortex: 30 sec
Standard E	37.5 pg/mL	0.3 mL Diluent(R6) + 0.3 mL Standard D Vortex: 30 sec

Assay Step 3: Treatment Solution

One vial of Treatment Solution R3 is sufficient for 30 samples.

Assay Step 4: Sample Preparation

<u>Pipette into the Microtiter Plate:</u>

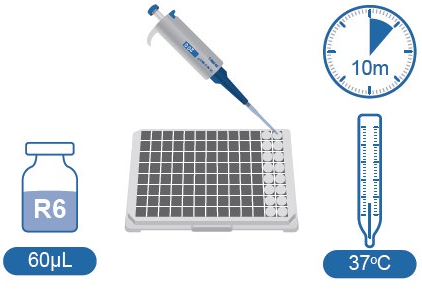
60 µL Diluent R6 as Negative Control;

60 µL Standard Solutions (A-E);

20 µL Positive Control or samples **PLUS**

40 µL Treatment Solution R3 (= 60 µL).

Shake plate for 10 seconds and incubate at 37°C for 10 minutes.

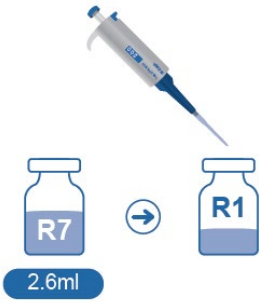


Assay Step 5: Main Reagent

Always prepare fresh!

Pipette 2.6 mL Reconstitution Buffer into the vial containing the Main Reagent R1 (sufficient for 24 wells).

Mix thoroughly and carefully – *do not vortex!*

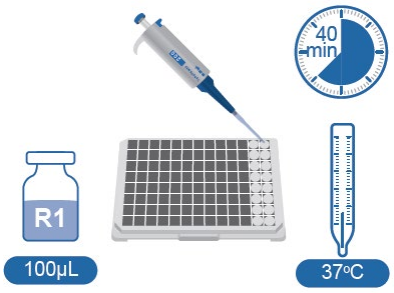


Assay Step 6: Detection

Immediately after Assay Step 4:

Add 100 µL Main Reagent to each well of the Microtiter Plate.

Shake Microtiter Plate for 5-10 seconds.



Assay Step 7: Data Analysis

Kinetic measurement of OD values at 37°C for 40 minutes at 405 nm and 490 nm.

Check of Controls and report of results.

Für weitere Informationen wenden Sie sich bitte an:
For further information please contact:
Pour plus d'information, veuillez contacter:

www.tecomedical.com

Certified Quality System ISO 13485 mdc

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