Professional Supplier In Invasive Fungal Disease Detection

ImTec DIAGNOSTICS NV

ERA BIOLOGY

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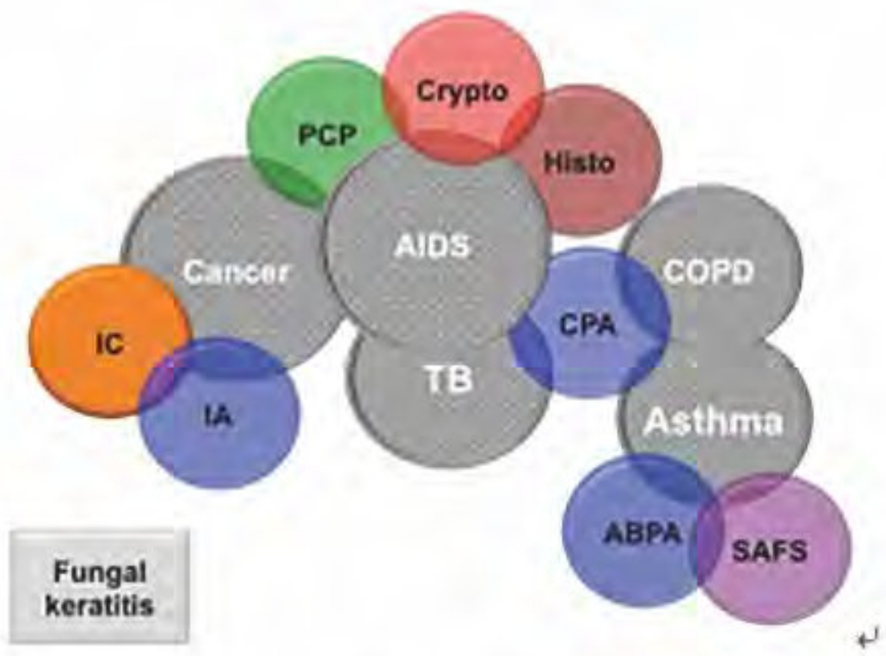
Introduction of Invasive Fungal Disease (IFD)

Overview[1]

Globally, over 300 million people are afflicted with a serious fungal infection and 25 milllion are at high risk of dying or losing their sight. Estimates for the global burden of fungal diseases are based on population and disease demographics. Some fungal diseases are acute and severe (i.e. cryptococcal meningitis and fungal eye infection (keratitis), other recurrent (i.e. Candida vaginitis or oral candidiasis in AIDS) and other chronic (i.e. chronic pulmonary aspergillosis or fungal hair infection (tinea capitis).

Invasive Fungal Disease (IFD) is one of the most severe fungal infection categories. One billion people worldwide are infected with fungal each year, and more than 1.5 million die from IFD[2]. The most common life-threatening fungal infections and estimated overall mortality are shown below.



(ABPA, allergic bronchopulmonary aspergillosis; AIDS, acquired immunodeficiency syndrome; COPD, chronic obstructive pulmonary disease; CPA, chronic pulmonary aspergillosis; Crypto, cryptococcosis; Histo, histoplasmosis; IA, invasive aspergillosis; IC, invasive candidiasis; PCP, Pneumocystis pneumonia; SAFS, severe asthma with fungal sensitization; TB, tuberculosis)

Burden of common life-threatening fungal infections:

~50% mortality in developed world if treated – in non AIDS

Fungal infection	Number affected	Case fatality rate	Estimated deaths	Comments
Cryptococcal meningitis	370,000 in AIDS	15-20% USA >50% developing world	250,000 in AIDS	CDC estimate
Pneumocystis pneumonia	>400,000 in AIDS >100,000 in non-AIDS	~15% in AIDS with best treatment ~50% in non-AIDS	>200,000 in AIDS >50,000 non-AIDS	Most cases in Africa not diagnosed and 100% mortality
Disseminated Histoplasmosis	~100,000	15-30%, if diagnosed and treated	>80,000	Most common in the Americas
Invasive aspergillosis	>300,000	~30% mortality if treated in HIC -in AIDS ~50% non-AIDS, in HIC	>30,000 in AIDS >125,000 in non-AIDS	Many missed diagnoses globally
Invasive candidiasis	>750,000	~40% mortality treated	>350,000	

Fungal infection	Number affected	Case fatality rate	Estimated deaths	Comments
Chronic pulmonary aspergillosis	>3,000,000	~15-40% mortality in HIC ~15% mortality in the developed world	>450,000 in non hospitalised populations	Under-diagnosed and mistaken for tuberculosis
Severe asthma with fungal sensitisation (SAFS)	>6,500,000	<1% but no good figures.	350,000 – 489,000 asthma deaths ~50% related to SAFS	Uncertain
Total	~13,000,000		1,600,000	Probably a significant underestimate

Patients at High Risk for IFD[3]

Immuno-compromised patients are at high risk for developing invasive fungal disease, which is often difficult to diagnose. Vulnerable populations include:

- ICU patients
- HIV patients
- Burn patients
- Respiratory patients
- Stem Cell and Organ Transplant patients
- Cancer patients undergoing chemotherapy
- Central Venous Catheters
- Hemodialysis

The morbidity of IFD is increasing, but due to the lack of obvious clinical manifestations, it often leads to a higher rate of missed diagnosis. The rate of misdiagnosis of pulmonary aspergillosis before the lung surgery was as high as 73%[4]. Another study[5] shows that Aspergillus was detected at autopsy in 59.0% of 46 dead patients. Therefore, the early, rapid and accurate diagnosis of IFD is crucial to improve the grim situation.

Reference

1. Anon.2019. Fungal Disease Frequency. [online] Available at: https://www.gaffi.org/why/fungal-disease-frequency/ [Accessed 10 December 2019]

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4. Zhang, R.R., Wang, S.F., Lu, H.W., Wang, Z.H. and Xu, X.L., 2014. Clinical in vestigation of misdiagnosis of invasive pulmonary aspergillosis in 26 immunocompetent patients. International journal of clinical and experimental medicine, 7(11), p.4139.

5. Meersseman, W., Vandecasteele, S.J., Wilmer, A., Verbeken, E., Peetermans, W.E. and Van Wijngaerden, E., 2004. Invasive aspergillosis in critically ill patients without malignancy. American journal of respiratory and critical care medicine, 170(6), pp.621-625.

Fungus (1-3)-β-D-Glucan Test (Chromogenic Method)

Overview

This product is intended for the screening diagnosis of invasive fungal disease. This product is used to provide rapid diagnosis reference for clinical invasive fungal infection through quantitative detection of (1-3)-β-D-glucan in the serum and Bronchoalveolar Lavage (BAL) fluid.

Product Characteristics

Basic Parameters	***Fungus (1-3)-β-D-Glucan Test (Chromogenic Method)***				
Model	GCT-110T	GKT-25M	GKT-12M	GKT-10M	GKT-5M
Specification	110 tests/kit	50 tests/kit	50 tests/kit	36 tests/kit	30 tests/kit
Number of main reagents	2/4 vials	2 vials	4 vials	3 vials	6 vials
Detection time	40 min	60 min			
Instrument	Microplate Reader	Kinetic Tube Reader			
Method	Chromogenic Method				
Sample type	Serum and BAL fluid				
Linearity range	31.25-500 pg/ml				
Specificity	The cross-reaction rate of 100 pg/ml endotoxin solution is less than 2%				
Inter assay variation	≤10%				

Product Advantages

Convenient
Various specifications satisfy different requirements
Easy
Can be equipped with fully automatic instruments, easy and reduce errors
Early
5-8 days prior to clinical symptoms and imaging
Accurate
Quality control ensures the experiment accuracy
Recommended by the EORTC/MSG Consensus Group
As one of the mycological criteria for the diagnosis of invasive fungal disease

• Screening Test for Invasive Fungal Disease in High-Risk Patients

Bacterial Endotoxin Test (Chromogenic Method)

Overview

Healthcare-associated infections caused by gram-negative bacteria are associated with high morbidity and mortality.In addition, due to the drug abuse, antibiotic resistance rates have been rising during the past 2 decades and the global emergence of multidrug-resistant gram-negative bacteria becomes a growing threat to therapy.The mortality rate has increased for the infected patients without accurate diagnosis and appropriate initial antimicrobial therapy.

Endotoxin, a cell wall component found exclusively in gram-negative bacteria, has been used as a biological marker for the rapid diagnosis of gram-negative bacterial infections.

Product Characteristics

Basic Parameters	***Bacterial Endotoxin Test (Chromogenic Method)***				
Model	EDT-110T	EKT-25M	EKT-12M	EKT-10M	EKT-5M
Specification	110 tests/kit	50 tests/kit	50 tests/kit	36 tests/kit	30 tests/kit
Number of main reagents	2/4 vials	2 vials	4 vials	3 vials	6 vials
Intended use	Quantitative determination of endotoxin in pharmaceutical and biological end-products	Screening diagnosis of gram-negative bacterial infection			
Sample type	Dialysate, Dialysis water	Serum			
Detection time	40 min	60min			
Low detection limit	0.001 EU/ml	1pg/ml (0.005 EU/ml)			
Instrument	Microplate Reader	Kinetic Tube Reader			
Method	Chromogenic Method				
Inter assay variation	≤10%				

Product Advantages

Convenient Various specifications satisfy different requirements
Easy Can be equipped with fully automatic instruments, easy and reduce errors
High Sensitivity The low detection limit totally meets international standards
Accurate Quality control ensures the accuracy of the experiment

• *Screening and Diagnosing Gram-negative Bacterial Infection in High-Risk Patients*

Overview

Kinetic Tube Reader is the auxiliary equipment for Fungus (1-3)-β-D-Glucan Test and Bacterial Endotoxin Test.
We have different models including semi-automatic MB-80 series, and full-automatic IGL series.

Fully Automatic Kinetic Tube Reader

—— Liberate Clinicians From Tedious Work

IGL-200

Instrument Parameters

Name	Fully Automatic Kinetic Tube Reader
Description	Bacterial endotoxin, fungus (1-3)-β-D-glucan detection;30 channels, LAN communication
Analysis method	Photometry
Wavelength range	400-500nm
Size	L602mm×W502mm×H565mm
Weight	46.4 kg

Product Advantages

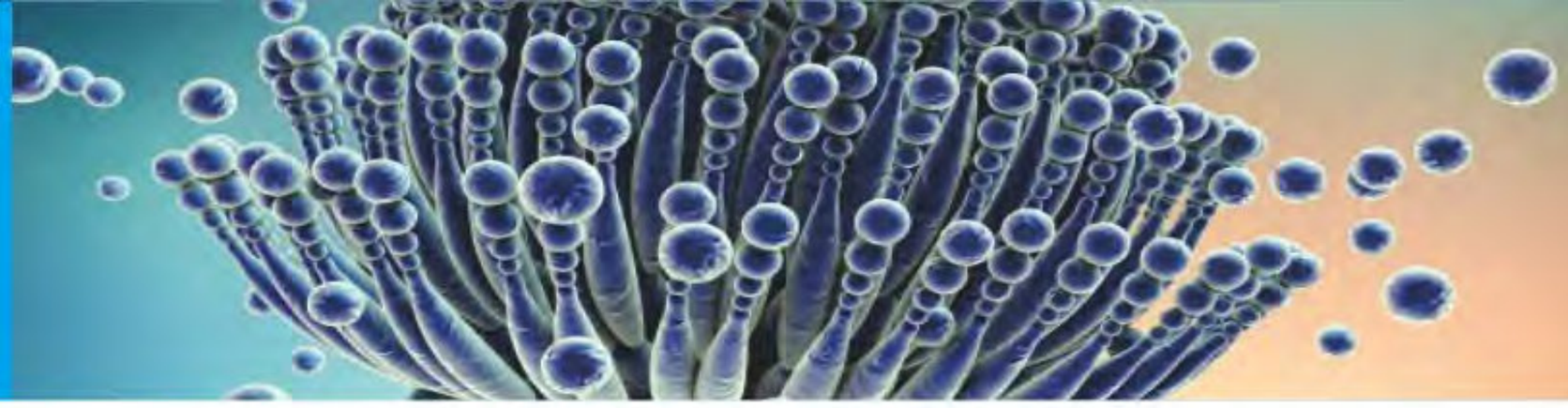
Full automatically operate the whole experiment following the standardized workflow.

Clear legend, indicate the position of each area

With barcode scanning, **intelligently recognize** reagent and sample information

Double way **LIS system** connection

Rapid, detection time is only 1 hour

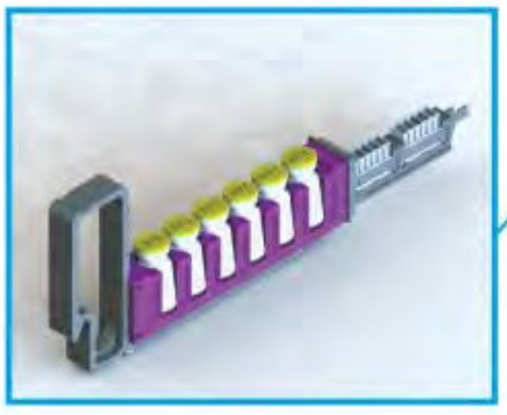


With built-in **screen-touch** computer

Intelligent system with **volume inspection** to improve experimental accuracy

Closed system avoids interference of environment

With built-in **UV lamp** for internal disinfection



Integrated reagent and detection area, highly matched and compact

Support fungus (1-3)-β-D-glucan test and bacterial endotoxin test simultaneously.

Support the addition of **emergency sample**

Specialized for **pyrogen-free** experiments with pyrogen-free consumables

IGL-800

For the hospital with large sample size

IGL-800 with 128 channels is available!

GOLDSTREAM®

Kinetic tube reader MB-80 series

Detection Principle

Photometry: The device is applied to dynamically monitor the absorbance value of the reaction reagent through photoelectric conversion principle. The cut-off absorbance time is linearly correlated with the content of fungus (1-3)-β-D-glucan and endotoxin, rendering the establishment of a standard curve between them. The specific detection value can be obtained by software system analysis.

MB-80M

All-in-one instrument with 32 channels
With built-in screen-touch computer
Each channel is independently collecting data, plug-and-play

MB-80A

High throughput with 128 channels
Applicable to hospitals with large sample size

MB-80X

32 channels
Extensible platform: Support parallel connection of 4 devices

Lateral Flow Assay

Rapid test utilizes lateral flow technique qualitative or quantitatively detects most common fungal pathogens including Aspergillus, Candida and Cryptococcus. Rapid test product line significantly reduces experimental steps to maximize detection efficiency.

Features

- **Rapid**

  Obtain result within 10 min

- **Simple**

  Easy to use, ordinary laboratory staff can operate without training

- **Intuitive result**

  Qualitative: There is no need for calculation, visual reading result

  Quantitative: Matching "Rapid Lateral Flow Reader" to obtain quantitative results

- **Economic**

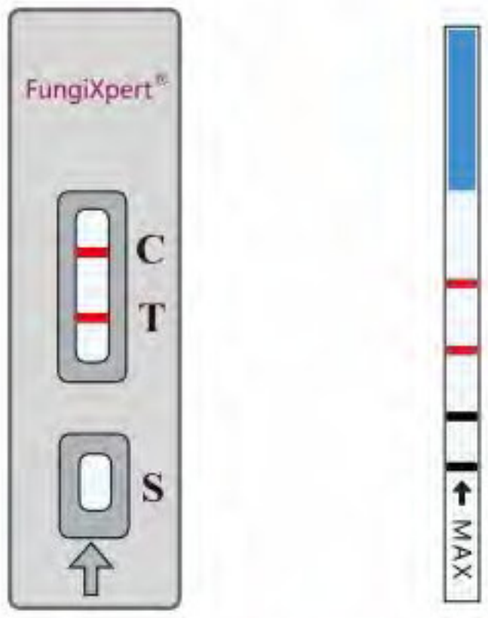
  Product can be transported and stored at room temperature, reducing costs

FungiXpert®

Cryptococcal Capsular Polysaccharide Detection K-Set (Lateral Flow Assay)

Overview

This product is used for the detection of Cryptococcal capsular polysaccharide antigen in serum or CSF, the K-Set is mainly used in the clinical diagnosis of Cryptococcal infection. Cryptococcal infection can occur in several parts of the body, most commonly in the central nervous system and lungs. An estimated mortality of cryptococcal infection was 625,000 persons annually.



High-Risk Patients

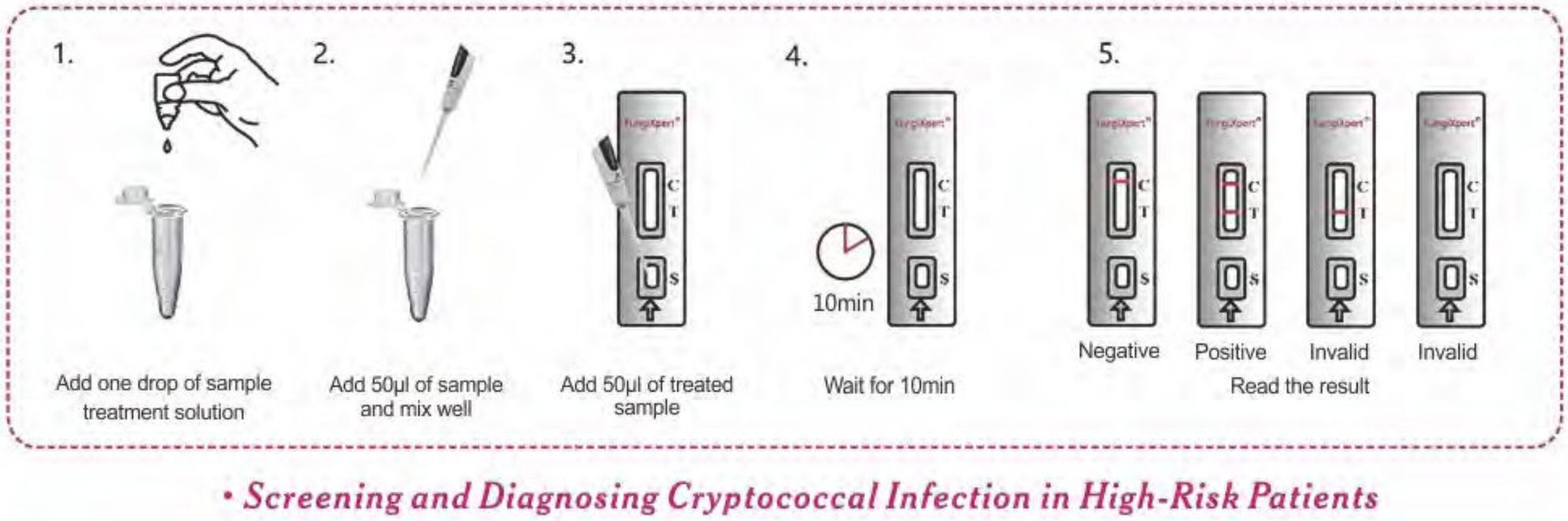
- HIV patients
- ICU patients
- Organ transplant recipients
- Cancer patients
- Diabetes patients
- Leukemia patients

Product Characteristics

Basic Parameters	***Cryptococcal Capsular Polysaccharide Detection K-Set(Lateral Flow Assay)***	
Method	Lateral Flow Assay	
Specification	25 tests/kit	50 tests/kit
Sample type	CSF, Serum	
Detection time	10 min	
Detection objects	*Cryptococcus spp.*	
Stability	The K-Set is stable for 2 years at 2℃-30℃	
Low detection limit	0.5 ng/ml	

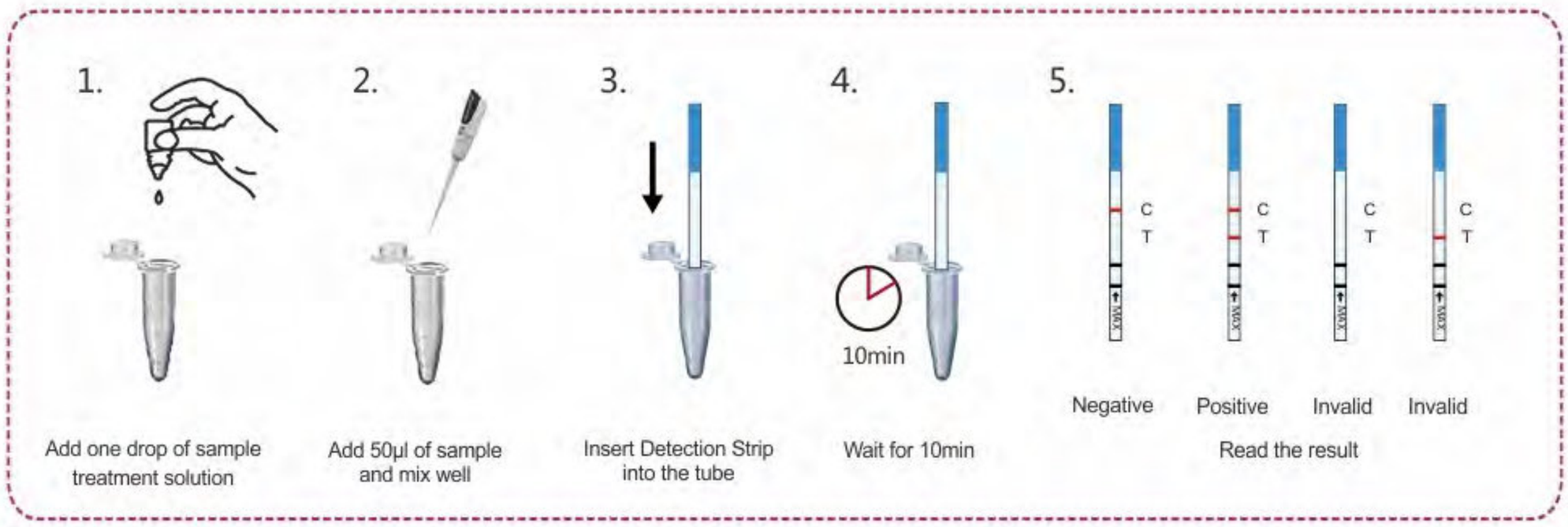
Operation Method

Cassette type (25 Tests/Kit)



• *Screening and Diagnosing Cryptococcal Infection in High-Risk Patients*

Strip type (50 Tests/Kit)



Clinical Performance

- **Low detection limit**

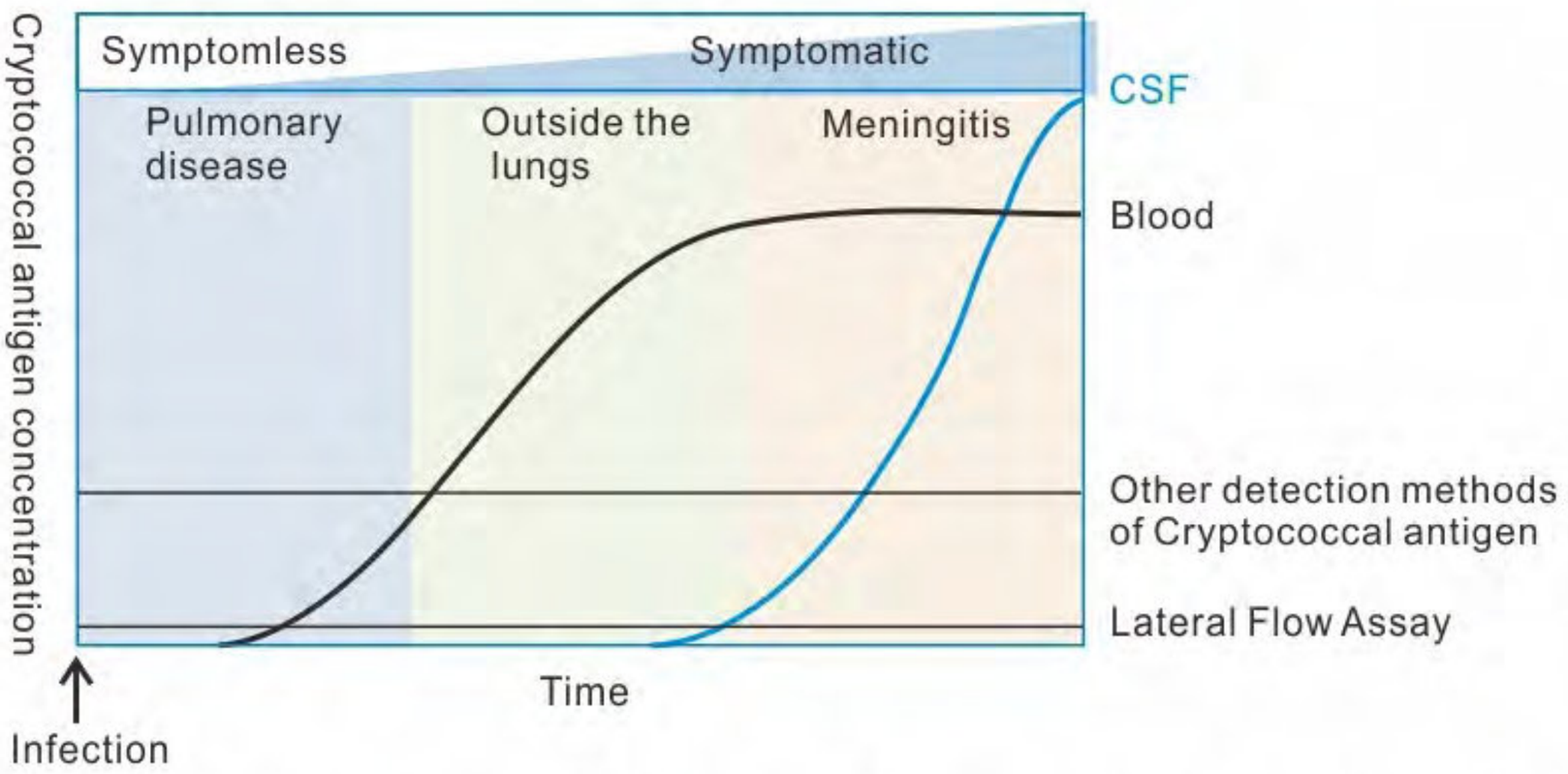
  The low detection limit is **0.5ng/ml**.

- **Sensitivity and specificity**

  Sensitivity 100% Specificity 100%

Serum/CSF		Culture and/or India-Ink	
		Positive	Negative
FungiXpert®	Positive	66	0
K-Set	Negative	0	11

a.Methodology comparison



Adapted from Kozel and Bauman, Expert Opin. Med. Diagn. (2012) 6:245

b.Product comparison

Product	*FungiXpert*	*IMMY*
Detection limit	0.5ng/ml	1.0ng/ml

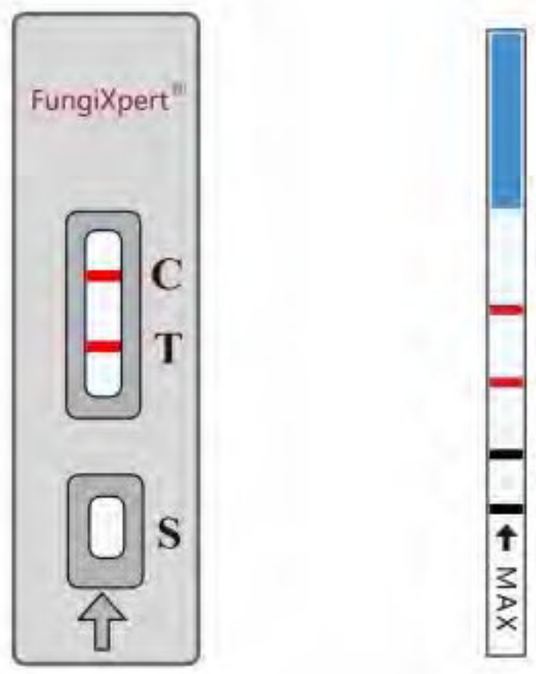
Aspergillus Galactomannan Detection K-Set (Lateral Flow Assay)

Overview

The incidence of Invasive Aspergillosis (IA) in immunosuppressed patients is rapidly increasing due to antibiotic abuse. *Aspergillus fumigatus* is one of the most common pathogens that cause severe aspergillus infection in patients with immunosuppressive disease, followed by *Aspergillus flavus, Aspergillus niger* and *Aspergillus terreus*. Due to lack of typical clinical manifestations and effective early diagnosis methods, IA has a high mortality rate of 50% to 100%. Early rapid detection is a key factor in the effective treatment and reduction of death in IA.

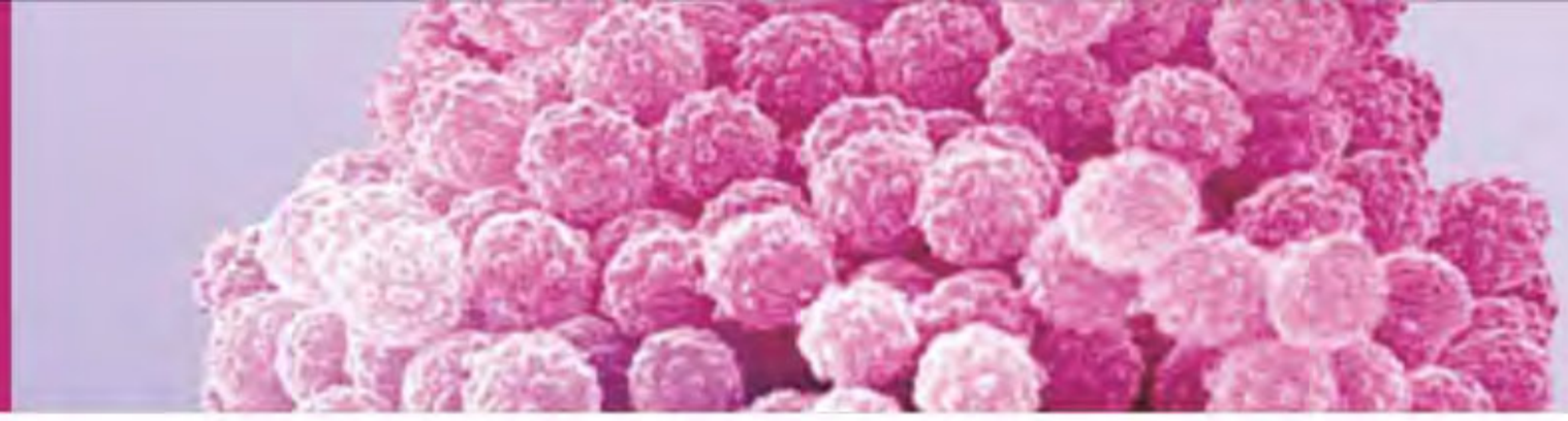
Product Characteristics

Basic Parameters	***Aspergillus Galactomannan Detection K-Set (Lateral Flow Assay)***
Method	Lateral Flow Assay
Sample type	Serum, BAL fluid
Specification	25 tests/kit, 50 tests/kit
Detection time	10 min
Detection objects	*Aspergillus spp.*
Stability	The K-Set is stable for 2 years at 2℃-30℃.
Low detection limit	5 ng/ml
Sensitivity	89%
Specificity	95%



Clinical performance

- ***Low detection limit***
  Limit of Detection (LoD) is 5 ng/ml
- ***Support the diagnosis of invasive aspergillosis in early stage***
  GM is 5-8 days earlier than the clinical symptoms of invasive aspergillosis (IA);
  GM is 7.2 days earlier than high-resolution CT scans;
  GM is on average 12.5 days earlier than starting empirical antifungal treatment.
- ***Recommendations***
  Recommended by IDSA guideline for Aspergillosis 2016 and ESCMID-ECMM-ERS guideline for Aspergillosis 2018



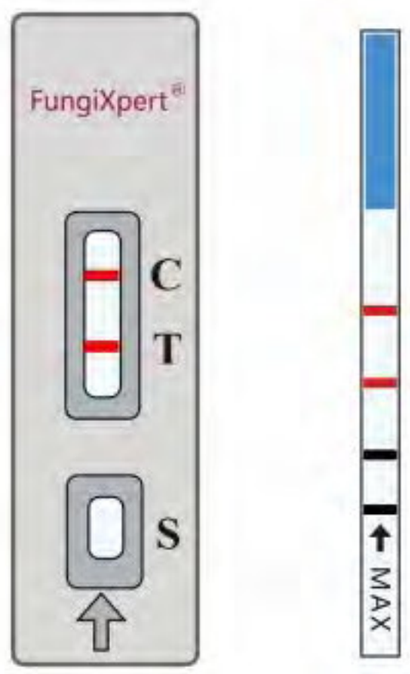
Aspergillus IgG/IgM Antibody Detection K-Set (Lateral Flow Assay)

Overview

The products use colloidal gold immunochromatography technology to detect aspergillus-specific IgG, IgM antibody in human serum, providing a rapid and effective auxiliary aid for the diagnosis of susceptible populations. Chronic and allergic forms of pulmonary aspergillosis are estimated to affect over three million people worldwide. Antibody testing is central to diagnosis of these conditions. Furthermore, an antigen-antibody combined test has been recommended. When combining the results of GM and Aspergillus-antibody, the sensitivity would be increased to 96.3%.

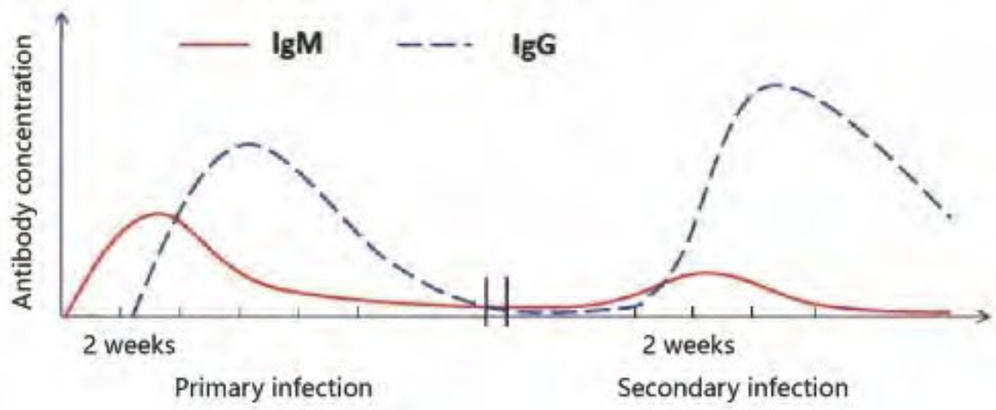
Product Characteristics

Basic Parameters	***Aspergillus IgG Antibody Detection K-Set (Lateral Flow Assay)***	***Aspergillus IgM Antibody Detection K-Set (Lateral Flow Assay)***
Method	Lateral Flow Assay	
Sample type	Serum	
Specification	25 Tests/Kit, 50 Tests/Kit	
Detection time	10 min	
Detection objects	*Aspergillus spp.*	
Stability	The K-Set is stable for 2 years at 2℃-30℃.	
Low detection limit	5 AU/ml	
Sensitivity	95%	95%
Specificity	92%	92%



Clinical performance

- ***Low detection limit***
  Limit of Detection (LoD) is 5 AU/ml
- ***Support the diagnosis of aspergillosis in early stage***
- ***Detection of single immunoglobulin subtype demonstrate the infection stage***



- ***Recommended by ESCMID/ECMM/ERS/IDSA etc***

  • *Screening and Diagnosis Invasive Aspergillosis in High-Risk Patients*

FungiXpert®

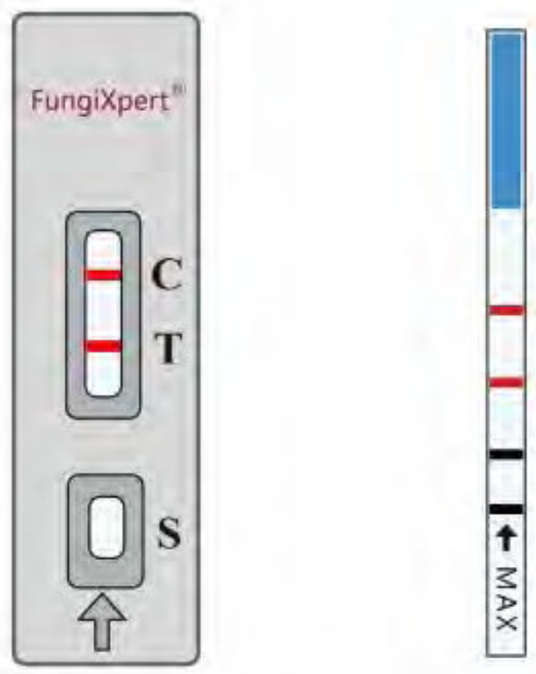
Candida Mannan Detection K-Set (Lateral Flow Assay)

Overview

With the wide application of antibiotics, immunosuppressants and corticosteroids in clinical practice, the incidence of deep fungal infection is increasing year by year. Deep fungal infection invades the organs and causes systemic infection. Mannan is a component of the cell wall of Candida albicans and filamentous fungi. Systemic fungal infection lacks specific clinical symptoms and early rapid detection method. Our products use colloidal gold immunochromatography technology to detect mannan antigen in human serum, providing a rapid and effective auxiliary aid for the diagnosis of susceptible populations.

Product Characteristics

Basic Parameters	***Candida Mannan Detection K-Set (Lateral Flow Assay)***
Method	Lateral Flow Assay
Sample type	Serum
Specification	25 tests/kit, 50 tests/kit
Detection time	10 min
Detection objects	*Candida spp.*
Stability	The K-Set is stable for 2 years at 2℃-30℃.
Low detection limit	**0.5 ng/ml**
Sensitivity	89.5%
Specificity	94%



Clinical performance

- ***Low detection limit***
  Limit of Detection (LoD) is 0.5 ng/ml
- ***Early diagnosis***
  Early before the culture results about 6 days for Candidaemia
- ***Recommended by ESCMID***
  Summary of recommendations by Candida disease, specimen and test evaluated[2]

Disease	Specimen	Test	Recommendation	Level of evidence
Candidaemia	Blood/Serum	Mannan/anti-mannan	Recommended	II
Chronic disseminated candidiasis	Blood/Serum	Mannan/anti-mannan	Recommended	II

Candida Mannan IgG/IgM Antibody Detection K-Set (Lateral Flow Assay)

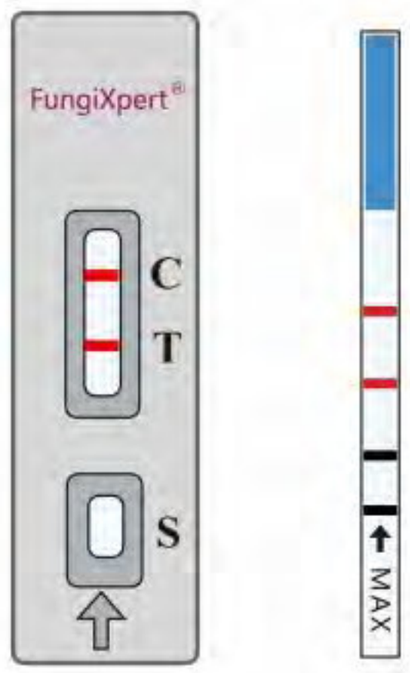
Overview

Our products use colloidal gold immunochromatography technology to detect manna-specific IgG, IgM antibody in human serum, providing a rapid and effective auxiliary aid for the diagnosis of susceptible populations.

During systemic fungal infection, mannan and its metabolic components persist in the body fluids of the host, which stimulates the humoral immune response of the host and produces specific antibodies against mannan. For invasive candidiasis detection, the best-studied test is a combined mannan/antimannan antibody assay. Antigen-antibody combined detection can increase sensitivity by 40% compared to single detection.

Product Characteristics

Basic Parameters	***Candida Mannan IgG Antibody Detection K-Set (Lateral Flow Assay)***	***Candida Mannan IgM Antibody Detection K-Set (Lateral Flow Assay)***
Method	Lateral Flow Assay	
Sample type	Serum	
Specification	25 Tests/Kit, 50 Tests/Kit	
Detection time	10 min	
Detection objects	*Candida spp.*	
Stability	The K-Set is stable for 2 years at 2℃-30℃.	
Low detection limit	4 AU/ml	
Sensitivity	94%	>99%
Specificity	>99%	>99%



Clinical performance

- ***Low detection limit***
  Limit of Detection (LoD) is 4 AU/ml
- ***Early diagnosis***
  Early before the culture results about 6 days for Candidaemia
  Early before radiological detection about 16 days for the patients with hepatosplenic IC
- ***Fast initiation of appropriate antifungal treatment***
  It can help physicians in initiating prompt and appropriate antifungal therapy,
  resulting in life saving and decreased morbidity

FungiXpert®

Aspergillus Galactomannan ELISA Detection Kit

Overview

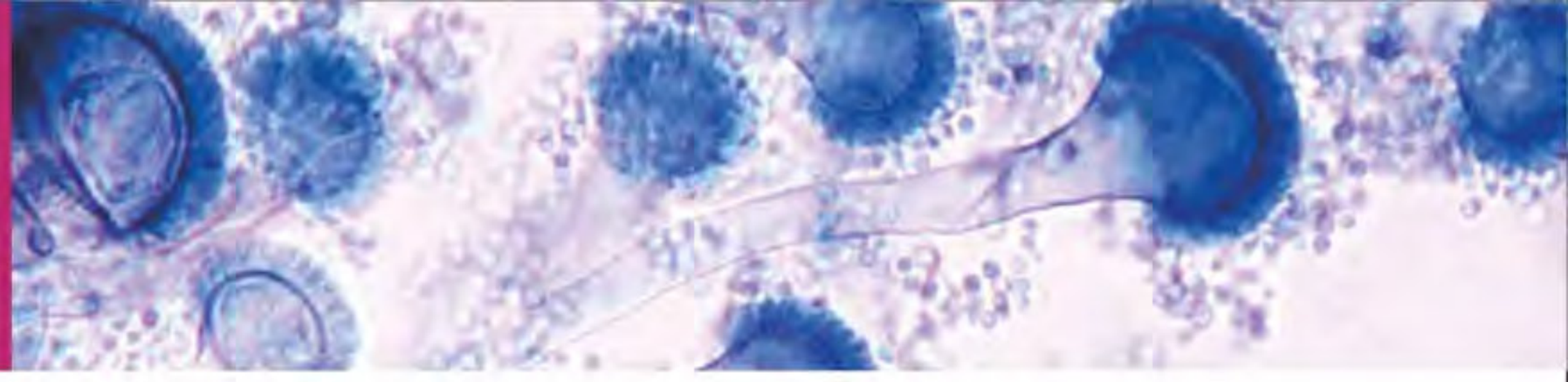
Aspergillus Galactomannan ELISA Detection Kit is an immunoenzymatic sandwich microplate assay for the detection of Aspergillus galactomannan antigen in adult and pediatric serum samples and bronchoalveolar lavage (BAL) fluid samples.

Product Characteristics

Basic Parameters	***Aspergillus Galactomannan ELISA Detection Kit***
Method	ELISA
Sample type	Serum, BAL fluid
Specification	96 tests/kit
Detection objects	*Aspergillus spp.*
Detection time	2 h
Low detection limit	1 ng/ml
Sensitivity	86%
Specificity	90%

Product Advantages

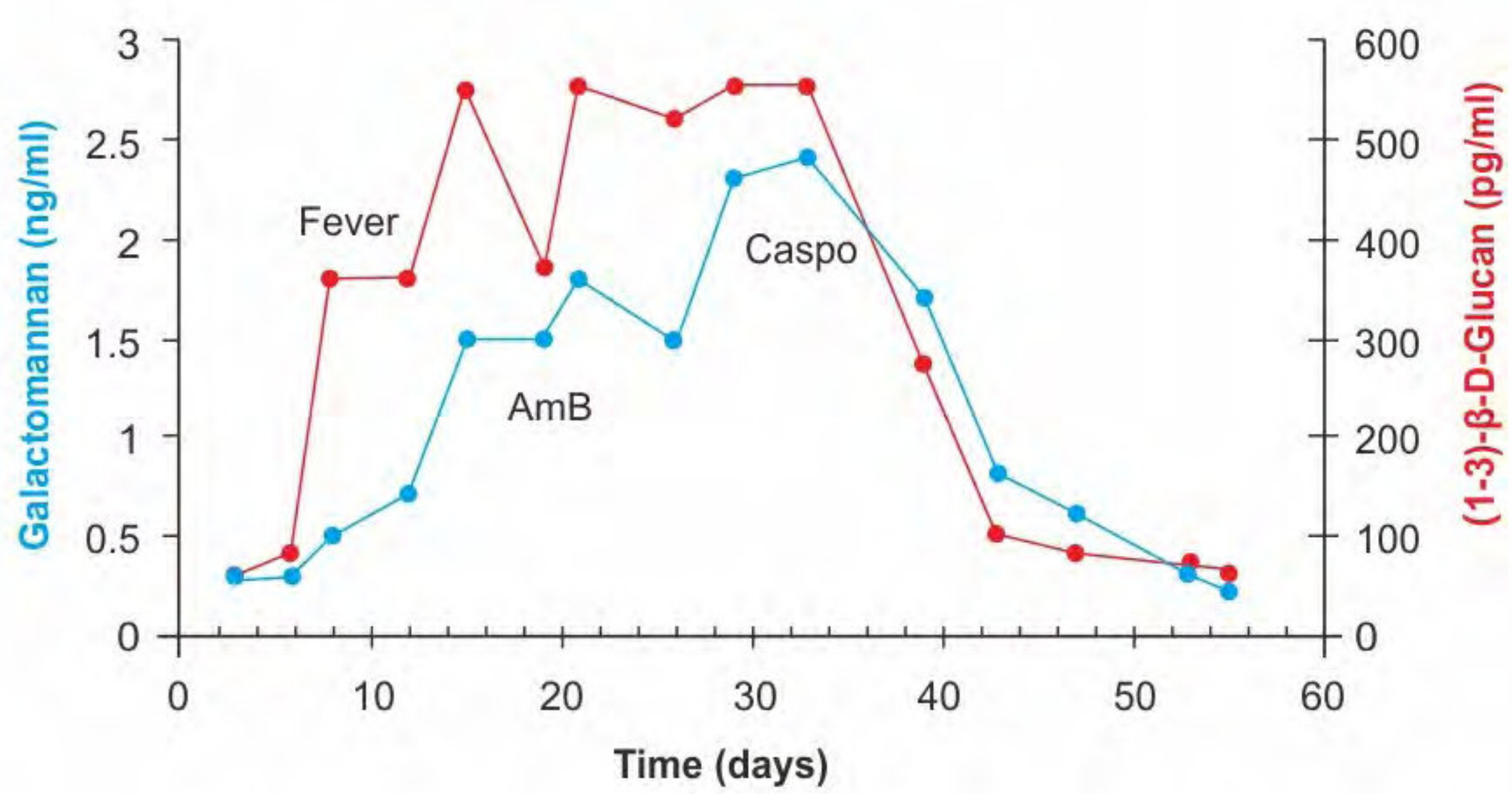
- ***More Advance***
  International leading edge detection method, high sensitivity and specificity.
- ***More Accurate***
  Optimize the operation process. Reduce the risk of contamination during the experiment



- ***Faster***
  One-step detection, reducing the number of incubation and washing time
  Obtain results within 2h
- ***More Economical***
  Split microplate, cost saving

Clinical performance

- ***Low detection limit***
  Limit of Detection (LoD) is 1 ng/ml
- ***Support the diagnosis of invasive aspergillosis in early stage***
  GM is 5-8 days earlier than the clinical symptoms of invasive aspergillosis (IA);
  GM is 7.2 days earlier than high-resolution CT scans;
  GM is on average 12.5 days earlier than starting empirical antifungal treatment.
- ***Monitor disease progression and therapeutic response, and predict outcome***[1]



- ***Recommendations***
  Recommended by IDSA guideline for Aspergillosis 2016 and ESCMID-ECMM-ERS guideline for Aspergillosis 2018

More ELISA products

- **Cryptococcal Capsular Polysaccharide ELISA Detection Kit**
- **Candida Mannan ELISA Detection Kit**

Full-Automatic Chemiluminescence Immunoassay System

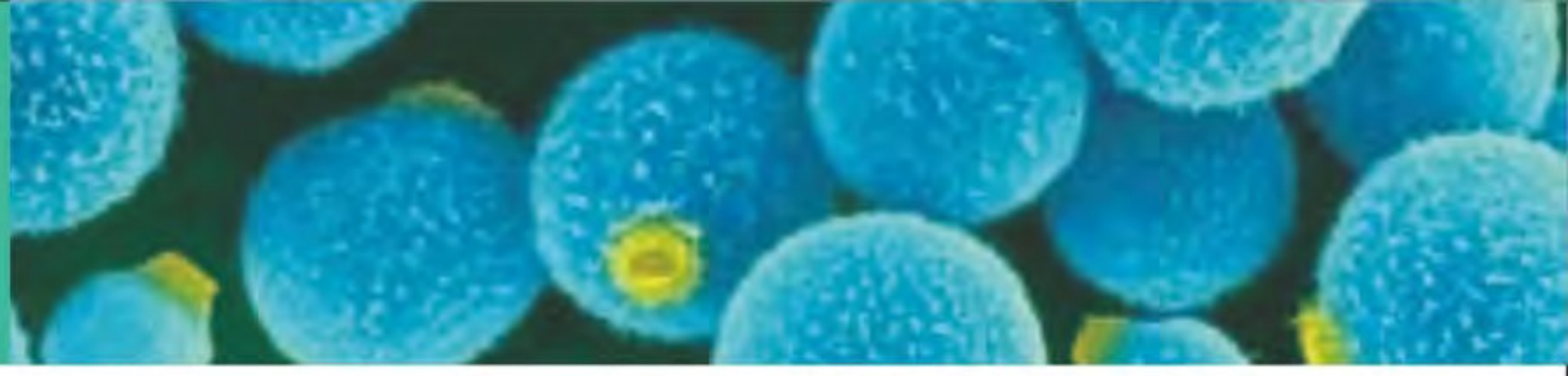
FACIS is an exclusively developed open detection system, which **in possession of independent intellectual property rights and 10 patents.**

Overview

Full-Automatic Chemiluminescence Immunoassay System（FACIS） is an open system. Experiment whose methodology is chemiluminescence or photometry can be performed on this instrument.

Instrument Parameters

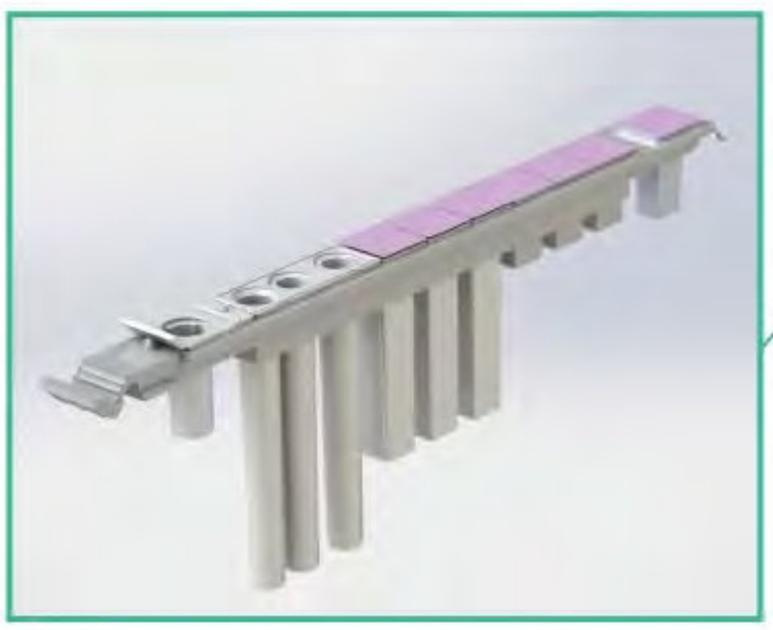
Basic Parameters	***Full-Automatic Chemiluminescence Immunoassay System***	
Model	FACIS-I	FACIS-II
Model description	Host system, could complete the detection task voluntarily	Slave system, could connect with the host system to complete the detection task
Standard configuration	Built-in tablet computer and special software	None
Analysis method and test menu	Photometry:(1-3)-ß-D-glucan etc. Chemiluminescence: Aspergillus galactomannan, Aspergillus IgG/IgM, Candida mannan,Candida mannan IgG/IgM, Cryptococcal capsular polysaccharide etc.	
Wavelength range	405nm, 450nm	
Number of channels	12	
Size	L603mm×W500mm×H548mm	
Weight	41 kg	



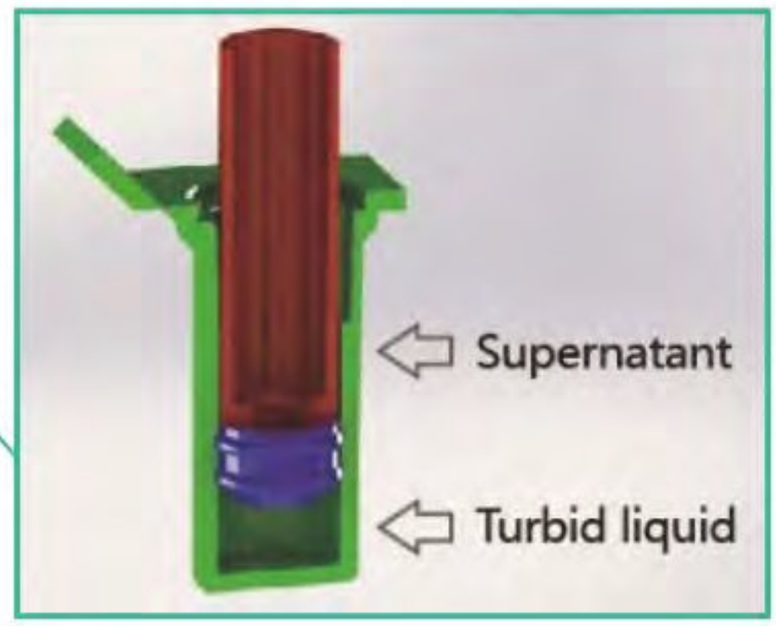
Product Advantages

- ***Fully automatic***
  Automatically perform sample treatment, sample separation, reagent distribution, detection, data analysis
- ***Multi-function***
  Support two optical system, photometry and chemiluminescence at the same time
- ***Intelligent***
  Single independent reagent, convenient and economical
  Software can be re-edit to adapt new detection items
- ***Extensible***
  Each host system can connect with slave system which satisfy the hospital with different sample size
- ***Compact***
  Save lab space

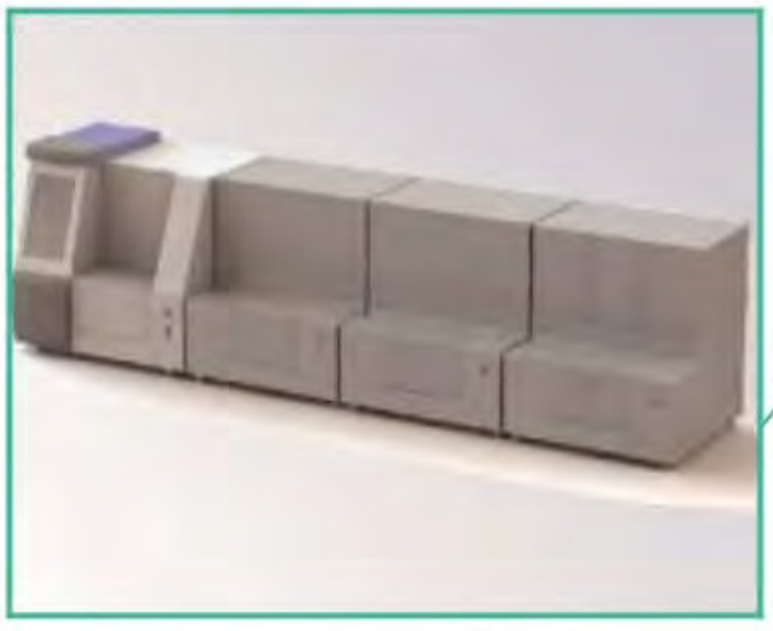
Instrument function features



Monotest: Integrated reagents and consumables together, more convenient



Unique sample pretreatment system using micron film with invention patent



Extensible platform: Support parallel connection of multiple devices

FungiXpert®

Aspergillus Galactomannan Detection Kit (CLIA)

Overview

FungiXpert® Aspergillus Galactomannan Detection Kit (CLIA) is the **world's first and only** quantitative reagent for the early detection of invasive Aspergillus infection with chemiluminescence integrated reagent strip. It is fully automated with FACIS to complete sample pretreatment and experimental testing, fully liberating the hands of laboratory physician and greatly improve detection accuracy.

Product Characteristics

Basic Parameters	***Aspergillus Galactomannan Detection Kit (CLIA)***
Model	Chemiluminescence immunoassay
Sample type	Serum, BAL fluid
Specification	12 Tests/kit
Applicable instrument	Full-Automatic Chemiluminescence Immunoassay System(FACIS)
Time	40 min
Detection objects	*Aspergillus spp.*
Stability	The kit is stable for 1 year at 2℃-8℃.
Low detection limit	0.1 μg/L
Sensitivity	86.7%
Specificity	91.3%

Product Advantages

Saving time is saving life! Obtain result within 40 min.

Monotest! Integrated reagents and consumables together, more convenient.

• *Screening and Diagnosing Invasive Aspergillosis in High-Risk Patients*

Unique sample pretreatment system using micron film with invention patent

Fully automatically perform experiment process & data analysis.

Clinical performance

- ***Low detection limit***

  Limit of Detection (LoD) is 0.1 μg/L

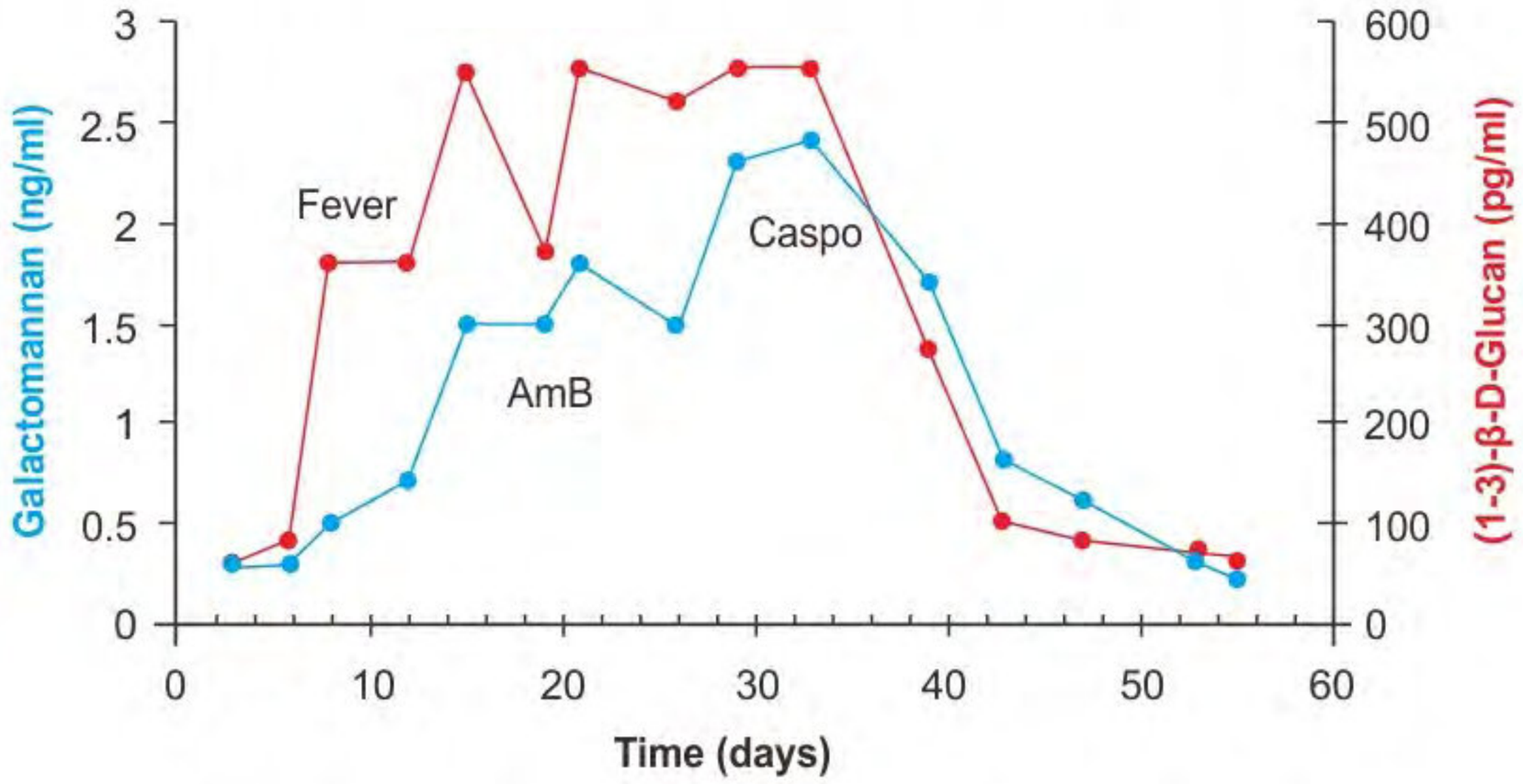
- ***Support the diagnosis of invasive aspergillosis in early stage***

  GM is 5-8 days earlier than the clinical symptoms of invasive aspergillosis (IA);

  GM is 7.2 days earlier than high-resolution CT scans;

  GM is on average 12.5 days earlier than starting empirical antifungal treatment.

- ***Monitor disease progression and therapeutic response, and predict outcome***



- ***Recommendations***

  Recommended by IDSA guideline for Aspergillosis 2016 and ESCMID-ECMM-ERS guideline for Aspergillosis 2018

More CLIA products

- **Aspergillus IgG Antibody Detection Kit（CLIA）**
- **Aspergillus IgM Antibody Detection Kit（CLIA）**
- **Candida Mannan Detection Kit (CLIA)**
- **Candida IgG Antibody Detection Kit (CLIA)**
- **Candida IgM Antibody Detection Kit (CLIA)**
- **Cryptococcal Capsular Polysaccharide Detection Kit (CLIA)**

FungiXpert®

Cryptococcus/ Aspergillus, Candida Albicans Molecular Detection Kit (Real-time PCR)

Product Characteristics

Basic Parameters	*Cryptococcus Molecular Detection Kit (Real-time PCR)*	*Aspergillus, Candida Albicans Molecular Detection Kit (Real-time PCR)*
Sample type	CSF	BAL fluid
Specification	48 sample tests/kit	
Detection time	2 h	
Detectable range	1.0×10^{2}~1.0×10^{8}copies	
Linearity range	5.0×10^{2}~5.0×10^{6}copies	
Inter assay variation	≤5%	
Stability	The kit is stable for 12 months at 2-8℃	
Machine to operate on	Fluorescence quantitative PCR instrument with VIC and ROX fluorescence groups is applicable to 0.2 ml octubule.	Fluorescence quantitative PCR instrument with VIC, FAM and ROX fluorescence groups is applicable to 0.2 ml octubule.
Result interpretation	Ct value of sample Positive: ≤38 The smaller of the Ct value, the severer of infection is indicated. When the Ct value of the test result is less than the Ct value of the weak positive reaction solution, it means that the infection is severe. Negative: >38	Ct value of sample Positive: ≤36.5 The smaller of the Ct value, the severer of infection is indicated. When the Ct value of the test result is less than the Ct value of the weak positive reaction solution, it means that the infection is severe. Negative: >36.5
Sensitivity	92%	*Aspergillus spp.*: 99% *Candida albicans*: 92.4%
Specificity	97%	*Aspergillus spp.*: 92.2% *Candida albicans*: 93%

Product Advantages

- ***Convenient***

  Sample pretreatment simplifies nucleic acid extraction.

- ***Economic***

  Product can be transported at 2-8℃, reducing the transportation costs.

- ***Accurate***

  1. The reagent is stored in PCR tube in the form of freeze-dried powder to reduce the possibility of contamination.
  2. The reagent powder is stable at 2-8℃, reducing the influence of temperature on the product quality.
  3. Strictly control the experiment quality with three quality controls.
  4. Dynamic monitoring results reflect the degree of infection.

Pyrogen-free Vacuum Blood Collection Tube (Serum)

No Additive

Clot Activator

Application

The product is especially for the detection of fungus (1-3)-β-D-glucan, bacterial endotoxin, interleukin, tumor necrosis factors, CRP, chemokines, leucocyte induced element and other cytokines. And it also improve detection accuracy of other normal clinical experiments.

Unique Benefits

★ ***Pyrogen-free***

Product Characteristics

Basic Parameters	***Pyrogen-free Vacuum Blood Collection Tube***	
Specification	No Additive	Clot Activator
Cap color	Red	Orange
Tube size	Φ13*75 mm	
Draw volume	4 ml	
Agglutination time	≤15 min (20-25℃)	
Recommended relative centrifugal force	1300g	
Recommended centrifugal time	10 min (horizontal centrifuge). It can be appropriately extended for 3-5 min when using angle type centrifuge.	
Storage condition	4-25℃(or 40-77℉). Avoid direct sunlight.	

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