

# FungiXpert™ CLIA Assays

Comprehensive solutions for the detection of

## THE MOST COMMON FUNGAL PATHOGENS & OTHER BIOMARKERS

Pan-fungal Screening/(1-3)- $\beta$ -D-Glucan

*Aspergillus* Infection

*Candida* Infection

*Cryptococcus* Infection

Bacterial Endotoxin

Inflammation Biomarkers

# EMPOWERING YOUR LABORATORIES WITH

## FungiXpert™

### Era Biology's CLIA Panel Assays

#### OUR UNIQUE MONOTEST

- All needed reagents and consumables in just one strip
- Costly Effective: 1 monotest  $\Leftrightarrow$  1 result, no hidden cost
- On-demand testing for urgent samples, no need for sample cumulation
- Suitable for laboratories of all sizes: no need for outsourcing testings



#### CLIA METHOD

- High sensitivity and specificity
- Excellent turnaround time



#### RAPID

- Obtains results from sample loading to data analysis within 60 mins



#### FULLY AUTOMATED WORKFLOW

- All our FungiXpert CLIA reagent kits are compatible with our instrument FACIS (Full-Automatic Chemiluminescence Immunoassay System).
- Full automatic operation from sample pretreatment to data analysis, minimizing the risks of sample contamination and manual errors



**ANY TIME, ANY WHERE, ANY VOLUME**

# Pan-Fungal Screening

Detecting (1-3)- $\beta$ -D-Glucan (BDG),  
a predominant and specific constituent of the cell wall in most fungi.

## (1-3)- $\beta$ -D-Glucan Assay

- **High negative predictive value**, aiding in ruling out fungal infections
- Short TAT of **1 hour** from sample loading to result analysis
- Earlier Diagnosis
  - 4 days prior to clinical symptoms
  - 5 days prior to fever
  - 10.7 days prior to respiratory symptoms
  - 9.3 days prior to the HRCT examination[1]
- Continuous Monitoring
  - Indicates disease progression
  - Evaluates treatment efficacy

## Specification

Specimen	Sensitivity	Specificity	LoD	Shelf Life	Storage
Serum, BAL fluid	91.7%, 92.2%	96.3%, 96.9%	0.05 ng/mL	12 months	2-8°C

## Main Components

Fungus (1-3)- $\beta$ -D-Glucan Detection Strip	1 test/strip × 12
Positive Control	1.0 mL/vial × 1 vial
Negative Control	1.0 mL/vial × 1 vial
Control Solution	1.5mL/vial × 2 vials
Instructions For Use	1

REF: BG012-CLIA

High Mortality

IFI

High Infection

Low Diagnostic

Low Recovery

## Invasive Fungal Infections

Invasive fungal infections (IFIs) are life-threatening opportunistic infections in immunocompromised or critically ill people.[2] Infectious fungal diseases (IFDs) are responsible for at least 13 million infections and 1.5 million deaths globally per year.[3] Timely detection and treatment of IFIs are crucial to minimize morbidity and mortality in these vulnerable populations.

### IFI mortality rate [3]

Mycosis	Mortality rate (%)
Invasive candidiasis	~40
Invasive aspergillosis	30-70
Pneumocystis pneumonia	10-60
Disseminated histoplasmosis	10-60

- **Broad Coverage:** BDG is a component of the cell walls of many fungal species, including **common pathogens** like *Candida*, *Aspergillus*, and *Pneumocystis jirovecii*.
- **High Sensitivity:** Our BDG test can detect even small amounts of BDG present in the serum of infected individuals. This sensitivity allows for the early detection of IFIs, even **before clinical symptoms may manifest**.
- **High Negative Predictive Value (NPV):** The NPV in the context of a BDG test refers to the probability that a patient with a negative test result does not have IFI. Our BDG test exhibits a **high NPV**, providing reassurance to clinicians that the likelihood of a false-negative result is low. This NPV shows that the accuracy of the negative test result can be valuable in clinical decision-making.

## BDG, the ultimate benchmark in IFI screening

**BDG tests play a key role in detecting these infections and enable proficient diagnosis and treatments.** So the question is, why did the BDG test outbid the other testing tools (including tissue biopsy, radiography, and culture examination)?



High NPV,  
High Specificity



Rapid in 1 hr



Broad Spectrum



Non-invasive

# Aspergillus Panel Assays

## 🧪 Aspergillus Galactomannan Antigen Assay

- Galactomannan (GM) is an antigen marker on the cell wall of *Aspergillus* species.
- Strongly recommended as high quality-evidence in the diagnosis of **Invasive Aspergillosis (IA)** in adult and pediatric patients with hematologic malignancy, HSCT [4]
  - Provides diagnosis 7-14 days earlier than nonspecific clinical symptoms and radiological evidence [5]
- Monitoring of galactomannan aids in assessing response to antifungal therapy

### Specification

Specimen	Sensitivity	Specificity	LoD	Shelf Life	Storage
Serum, BAL fluid	94.29%, 94.64%	95.07%, 95.92%	0.07 µg/L	12 months	2-8°C

### Main Components

Aspergillus Galactomannan Detection Strip	1 test/strip × 12
Positive Control	1.0 mL/vial × 1 vial
Negative Control	1.0 mL/vial × 1 vial
Control Solution	1.5 mL/vial × 2 vials
Instructions For Use	1

REF: FAGM012-CLIA

## 🧪 Aspergillus IgG Antibody Assay

- IgG is a marker of **long-term infection** and is used to diagnose **pre-existing or chronic** infection-related diseases.
- The most sensitive microbiology test in diagnosing chronic cavitary pulmonary aspergillosis (CCPA) [4]
- An effective screening and diagnostic method for non-neutropenic patients with invasive pulmonary aspergillosis (IPA) [6]

### Specification

Specimen	Shelf Life	Storage
Serum	12 months	2-8°C

### Main Components

Aspergillus IgG Antibody Detection Strip	1 test/strip × 12
Positive Control	0.2 mL/vial × 1 vial
Negative Control	0.2 mL/vial × 1 vial
Instructions For Use	1

REF: FAIgG012-CLIA

## 🧪 Aspergillus IgM Antibody Assay

- IgM is the first-line defence in response to initial exposure IA.
- Elevated IgM antibody levels indicate **active Aspergillus infection**.

### Specification

Specimen	Shelf Life	Storage
Serum	12 months	2-8°C

### Main Components

Aspergillus IgM Antibody Detection Strip	1 test/strip × 12
Positive Control	0.2 mL/vial × 1 vial
Negative Control	0.2 mL/vial × 1 vial
Instructions For Use	1

REF: FAIgM012-CLIA

## Global Burden

The airborne fungus *Aspergillus fumigatus* poses a serious health threat to humans by causing numerous invasive infections and a notable mortality in humans. IA is responsible for 600,000 deaths annually worldwide [7].

## How to prevent Aspergillosis?



Avoiding mold exposure



Be careful with dusts and soil



Proper food storage



**EARLY DETECTION**

## Apply the adequate testing for better result :

### Radiological Evidence

- ✗ Limited specificity
- ✗ Non-specific Findings by observations
- ✗ Radiation Exposure
- ✗ Slow radiology report TAT
- ✗ High-Cost Examination

### Culture Testing

- ✗ Low sensitivity [8]
- ✗ Slow TAT: incubation of at least 5 days required by IDSA guideline
- ✗ Labor-intensive and Skill-dependent
- ✗ Contamination Issues

### FUNGIXPERT

- ✓ Higher sensitivity & specificity
- ✓ Full-automatic operation
- ✓ Shorter TAT: < 1 hr
- ✓ Lower labor cost
- ✓ Antigen+Antibody = HIGHER ACCURACY

# Candida Panel Assays

7 days earlier than culture results for candidemia

16 days earlier than radiological evidence for the patients with chronic disseminated candidiasis [9]

## Candida Mannan Antigen Assay

- Detects mannan, the main cell wall constituents in *Candida* species
- Promotes the fast initiation of appropriate antifungal treatment
- Capable of detecting various *Candida* species, including ***C.albicans*, *C.glabrata*, *C.auris*, *C.krusei*, *C.tropicalis*, *C.parapsilosis* and *C.guilliermondii***

### Specification

Specimen	Sensitivity	Specificity	LoD	Shelf Life	Storage
Serum, BAL fluid	87.6%, 91.57%	91.28%, 93.88%	20 pg/mL	12 months	2-8°C

### Main Components

Candida Mannan Detection Strip	1 test/strip × 12
Positive Control	1.0 mL/vial × 1 vial
Negative Control	1.0 mL/vial × 1 vial
Control Solution	1.5 mL/vial × 2 vials
Instructions For Use	1

REF: FCMN012-CLIA

## Candida IgG Antibody Assay

- Detects anti-mannan IgG antibody in human serum
- Reflects an **ongoing or previous infection** of Invasive Candidiasis (IC)
- A significant increase in IgG level indicates an acute infection or a re-infection
- High NPV [10]

### Specification

Specimen	Shelf Life	Storage
Serum	12 months	2-8°C

### Main Components

Candida IgG Antibody Detection Strip	1 test/strip × 12
Positive Control	0.2 mL/vial × 1 vial
Negative Control	0.2 mL/vial × 1 vial
Instructions For Use	1

REF: FCIGG012-CLIA

## Candida IgM Antibody Assay

- Detects anti-mannan IgM antibody in human serum
- IgM antibody production increases significantly with the exposure to *C.albicans*.
- Reflects an **active infection** of Candidemia
- IgM antibodies are among the earliest responders to *Candida* infections

### Specification

Specimen	Shelf Life	Storage
Serum	12 months	2-8°C

### Main Components

Candida IgM Antibody Detection Strip	1 test/strip × 12
Positive Control	0.2 mL/vial × 1 vial
Negative Control	0.2 mL/vial × 1 vial
Instructions For Use	1

REF: FCIGM012-CLIA

Globally, in every 10 patients infected by candidemia



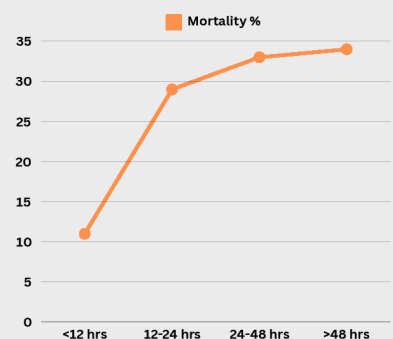
2.5 of them will die from candidiasis!!

### TEST CANDIDA EARLY!!!

Invasive infections due to *Candida* species lead to high morbidity and mortality of up to 30% [11]. Studies show that early detection is vital for providing clinicians with adequate treatments and saving lives.

The five most common lethal pathogens—***C. albicans*, *C. glabrata*, *C. tropicalis*, *C. parapsilosis*, and *C. krusei***—account for over 90% of these infections among at least 15 distinct *Candida* species, **which can be detected by our *Candida* assays.**

### Hospital Mortality Rate Associated With Delayed Therapy [12]



# Cryptococcus

A prevalent opportunistic infection in patients with HIV/AIDS

## Cryptococcal Capsular Polysaccharide Antigen Assay

- Detects the antigen of *Cryptococcus*, capsular polysaccharide
- Covering **variants of *Cryptococcus***:
  - *Cryptococcus gattii* (serotype B and C)
  - *Cryptococcus neoformans* (serotype A, serotype D, serotype A and D)
- Up to 2 weeks earlier than the presence of clinical symptoms [13]

### Specification

Specimen	Sensitivity	Specificity	LoD	Shelf Life	Storage
Serum, CSF	93.22%, 96.77%	98.48%, 96.55%	0.07µg/L	12 months	2-8°C

### Main Components

Cryptococcal Capsular Polysaccharide Detection Strip	1 test/strip × 12
Positive Control	1.0 mL/vial × 1 vial
Negative Control	1.0 mL/vial × 1 vial
Control Solution	1.5 mL/vial × 2 vials
Instructions For Use	1

REF: FCrAg012-CLIA

# Bacteria

Also known as lipopolysaccharide detection

## Bacterial Endotoxin Assay

- Endotoxins are lipopolysaccharides (LPS) found in the outer membrane of **Gram-negative bacteria**. Endotoxins can elicit severe immune responses in humans, leading to fever, shock, and even death.
- Dynamic monitoring indicates the degree of infection and prognosis
  - Endotoxin activity (EA) level and mortality are positively correlated; the higher the EA level, the higher the mortality rate (> 40% with the ICU and hospital mortality data combined)[14]
  - EA level gives an early indication for specific intensive therapy and facilitates the evaluation of treatment effectiveness [15]
- Monitoring indicator for blood dialysis contamination among hemodialysis patients [16]

### Specification

Specimen	LoD	Shelf Life	Storage
Serum	0.5 pg/mL	12 months	2-8°C

### Main Components

Bacterial Endotoxin Detection Strip	1 test/strip × 12
Positive Control	1.0 mL/vial × 1 vial
Negative Control	1.0 mL/vial × 1 vial
Control Solution	1.5 mL/vial × 2 vials
Instructions For Use	1

REF: BE012-CLIA

# Inflammation

## 🧪 Serum Amyloid A (SAA) Assay

- Serum amyloid A (SAA) is an acute-phase protein that is a sensitive biomarker in a wide spectrum of inflammatory diseases (rheumatic, systemic lupus erythematosus, and rheumatoid arthritis).[17]
- SAA levels increase during **viral infections**, correlating positively with the severity of the infection.
- **Panel testing with CRP** to differentiate viral infection and bacterial infection

### Specification

Specimen	LoD	Shelf Life	Storage
Serum, Plasma	1.0 mg/L	12 months	2-8°C

### Main Components

Serum Amyloid A (SAA) Detection Strip	1 test/strip × 12
Positive Control	0.1 mL/vial × 1 vial
Negative Control	0.1 mL/vial × 1 vial
Control Solution	0.5 mL/vial × 1 vial
Instructions For Use	1

REF: SAACLIA-01

## 🧪 C Reactive protein (CRP) Assay

- C-reactive protein is a compound that the liver produces in response to inflammation throughout the body.
- The dynamic monitoring of CRP is crucial to assess treatment efficacy and prognosis.
- CRP **significantly increases 2 hours after infection and peaks around 24-48 hours**, which makes it a key indicator for early detection of **bacterial infection**. [18]

### Specification

Specimen	LoD	Shelf Life	Storage
Serum, Plasma	0.2 mg/L	12 months	2-8°C

### Main Components

C Reactive protein (CRP) Detection Strip	1 test/strip × 12
Positive Control	0.1 mL/vial × 1 vial
Negative Control	0.1 mL/vial × 1 vial
Control Solution	0.5 mL/vial × 1 vial
Instructions For Use	1

REF: CRPCLIA-01

## 🧪 Interleukin-6 (IL-6) Assay

- IL-6 is a cytokine, a signaling molecule that plays a crucial role in the immune response and inflammation.
- IL-6 levels **rise earlier than those of PCT and CRP**, making it a pivotal indicator for the early detection of acute infections.
- IL-6 **peaks around 2 hours post-infection**, correlating positively with the severity of the infection. [19]

### Specification

Specimen	LoD	Shelf Life	Storage
Serum, Plasma	2.0 pg/mL	12 months	2-8°C

### Main Components

Interleukin-6 (IL-6) Detection Strip	1 test/strip × 12
Positive Control	0.5 mL/vial × 1 vial
Negative Control	0.5 mL/vial × 1 vial
Control Solution	1.5 mL/vial × 1 vial
Instructions For Use	1

REF: IL6CLIA-01

## 🧪 Procalcitonin (PCT) Assay

- PCT is a precursor hormone of calcitonin and is a key biomarker for diagnosing bacterial infections.
- PCT levels are stable during viral infections, aiding in **distinguishing bacterial** from viral infections.
- PCT levels are **unaffected by hormones or antibiotics**. PCT's high sensitivity and specificity in detecting infections also surpass traditional markers. [20]

### Specification

Specimen	LoD	Shelf Life	Storage
Serum, Plasma	0.05 ng/mL	12 months	2-8°C

### Main Components

Procalcitonin (PCT) Detection Strip	1 test/strip × 12
Positive Control	0.5 mL/vial × 1 vial
Negative Control	0.5 mL/vial × 1 vial
Control Solution	1.5 mL/vial × 1 vial
Instructions For Use	1

REF: PCTCLIA-01



PANEL TESTING  
BETTER PREVENTION

## References

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## Order Information

Product Name	REF #	Test Volume
Fungus (1-3)- $\beta$ -D-Glucan Detection Kit(CLIA)	BG012-CLIA	12 tests/kit
Aspergillus Galactomannan Detection Kit (CLIA)	FAGM012-CLIA	
Aspergillus IgG Antibody Detection Kit (CLIA)	FAIgG012-CLIA	
Aspergillus IgM Antibody Detection Kit (CLIA)	FAIgM012-CLIA	
Candida Mannan Detection Kit (CLIA)	FCMN012-CLIA	
Candida IgG Antibody Detection Kit (CLIA)	FCIgG012-CLIA	
Candida IgM Antibody Detection Kit (CLIA)	FCIgM012-CLIA	
Cryptococcal Capsular Polysaccharide Detection Kit (CLIA)	FCrAg012-CLIA	
Bacterial Endotoxin Detection Kit(CLIA)	BE012-CLIA	
Procalcitonin (PCT) Detection Kit (CLIA)	PCTCLIA-01	
Serum Amyloid A (SAA) Detection Kit (CLIA)	SAACLIA-01	
Interleukin 6 (IL-6) Detection Kit (CLIA)	IL6CLIA-01	
C Reactive Protein (CRP) Detection Kit (CLIA)	CRPCLIA-01	

## Instrument

Full-Automatic Chemiluminescence Immunoassay System	FACIS-I
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## Consumables

Disposables for FACIS-I (with micron films)	XHCHD12H	12 tests/kit
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