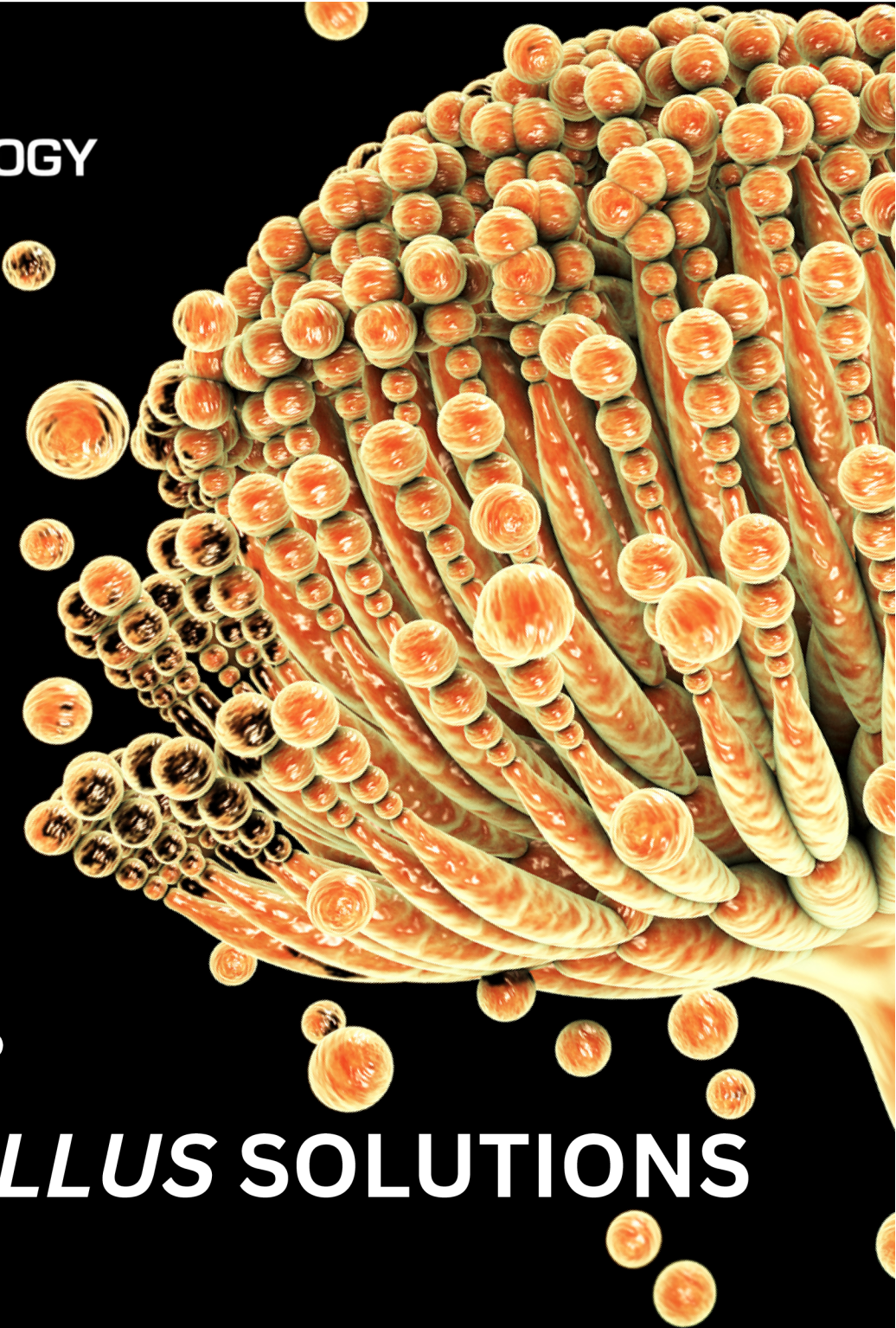




FungiXpert® ***ASPERGILLUS* SOLUTIONS**

Immunochromatographic Tests
for Detecting *Aspergillus*
GM Antigen and IgG Antibody

Obtaining results within 10 mins

FungiXpert® *Aspergillus* Galactomannan Detection K-Set (Lateral Flow Assay)

FungiXpert® *Aspergillus* IgG Antibody Detection K-Set (Lateral Flow Assay)



Aspergillus Galactomannan Detection K-Set (Lateral Flow Assay)



Specification

Specimen	LoD	Shelf Life	Storage
Serum, BAL fluid	0.5 ng/mL	24 months	2-30°C



Main Components

Aspergillus Galactomannan Detection K-Set	1 test/pack × 25
Positive Control	1.0 mL/vial × 1 vial
Negative Control	1.0 mL/vial × 1 vial
Sample Treatment Solution	3.0 mL × 1 vial
Instructions For Use	1



Operating Procedure

REF: FGM025-001

1. Sample pre-treatment

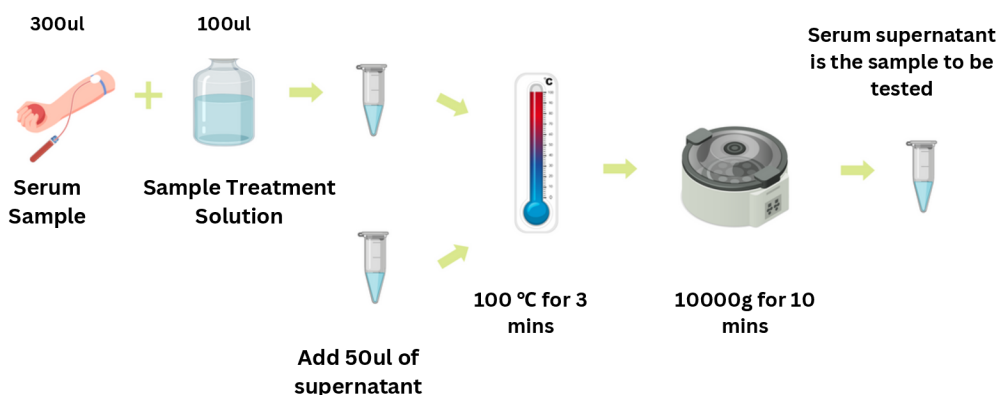
Option #1



Full-automatic pretreatment

*note: new product
contact us for more
information

Option #2



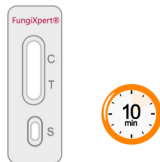
2. Detection

a.



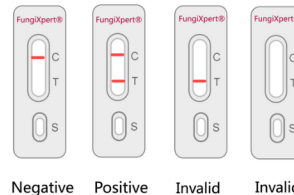
Add 50ul of supernatant

b.



Wait for 10 minutes

c.



Read the results

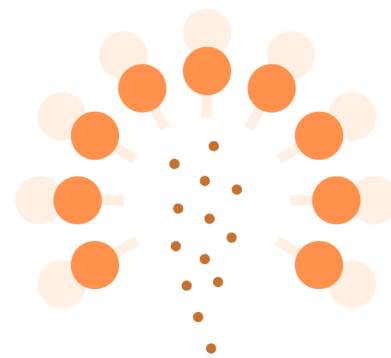


Clinical Performance

- Low detection limit
 - Limit of Detection (LoD) is 0.5 ng/ml
- Support the diagnosis of aspergillosis in the early stage[1]
 - 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[2] and ESCMID-ECMM-ERS guideline for Aspergillosis 2018 [3]

Aspergillus Infections

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



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

Specification

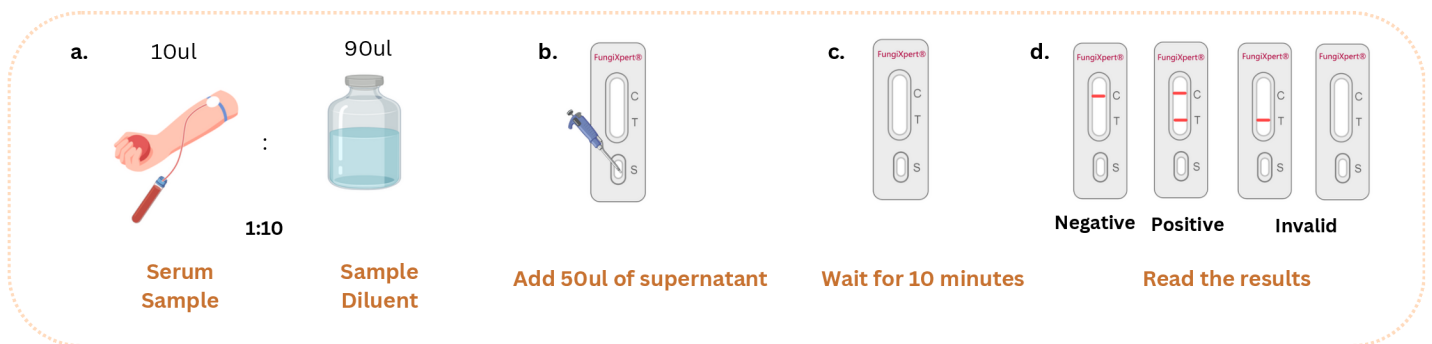
Specimen	Shelf Life	Storage
Serum	24 months	2-30°C

Main Components

Aspergillus IgG Antibody Detection K-Set	1 test/pack × 25
Sample diluent	3.0 mL
Instructions For Use	1

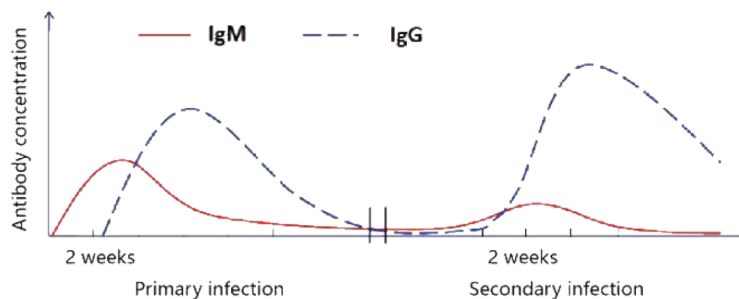
REF: FGM025-002

Operating Procedure



Clinical Performance

- Support the diagnosis of aspergillosis in the early stage
- Aspergillus*-specific IgG antibodies take a mean of 10.8 days to appear in acute illness. [4]
- Detection of a single immunoglobulin subtype demonstrates the infection stage:



Relationship between antibody concentration and *Aspergillus* infection

- Recommended by ESCMID/ECMM/ERS/IDSA etc.:
 - IgG antibody response to *Aspergillus spp.* is one of the characteristics required for the diagnosis of CPA[5].
 - Aspergillus* IgG antibody elevated or other microbiological data is one of the necessary evidence for the diagnosis of chronic cavitary pulmonary aspergillosis (CCPA)[6].

Antibody diagnosis of chronic pulmonary aspergillosis (CPA) [7]

Population	Intention	Intervention	SoR*	QoE*
Cavitary or nodular pulmonary infiltrate in non-immunocompromised patients	Diagnosis or exclusion of CPA	<i>Aspergillus</i> IgG antibody	A	II

*SoR: strength of recommendation; QoE: quality of evidence



Advantages



Room Temperature Storage



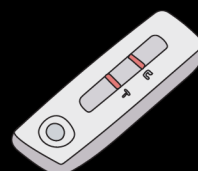
Assisting in Medication Optimization



Rapid



Accurate



Visual-reading

- **Rapid**
 - Results in < 10 mins
- **Smooth Workflow**
 - Offers convenient operation with minimal training
 - No supporting equipment is needed
 - Smoothly incorporates into existing microbiology lab workflow
- **Cost-effective**
 - Remaining stable at room temperature with a two-year shelf life.
 - No hidden costs, 1 test = 1 reportable result
- **User-Friendly**
 - Easy-to-use and simple operating procedure
 - No need for calculation, visual reading result

Order Information

Product Name	REF #	Test Volume
Aspergillus Galactomannan Detection K-Set (Lateral Flow Assay)	FGM025-001	25 Tests/Kit
Aspergillus IgG Antibody Detection K-Set (Lateral Flow Assay)	FGM025-002	

References

1. Pazos C, Pontón J, Del Palacio A. Contribution of (1→3)-β-d-glucan chromogenic assay to diagnosis and therapeutic monitoring of invasive aspergillosis in neutropenic adult patients: a comparison with serial screening for circulating galactomannan[J]. *Journal of clinical microbiology*, 2005, 43(1): 299-305.
2. Patterson T F, Thompson III G R, Denning D W, et al. Practice guidelines for the diagnosis and management of aspergillosis: 2016 update by the Infectious Diseases Society of America[J]. *Clinical Infectious Diseases*, 2016, 63(4): e1-e60.
3. Ullmann A J, Aguado J M, Arikan-Akdagli S, et al. Diagnosis and management of Aspergillus diseases: executive summary of the 2017 ESCMID-ECMM-ERS guideline[J]. *Clinical Microbiology and Infection*, 2018, 24: e1-e38.
4. Cornillet A, Camus C, Nimubona S, et al. Comparison of epidemiological, clinical, and biological features of invasive aspergillosis in neutropenic and nonneutropenic patients: a 6-year survey, *Clin Infect Dis*, 2006, vol. 43 5(pg. 577-584)
5. Ullmann A J, Aguado J M, Arikan-Akdagli S, et al. Diagnosis and management of Aspergillus diseases: executive summary of the 2017
6. Patterson T F, Thompson I G R, Denning D W, et al. Practice guidelines for the diagnosis and management of aspergillosis: 2016 update by the Infectious Diseases Society of America(J). *Clinical Infectious Diseases*, 2016, 63(4): e1-e60.
7. Denning DW, Cadranet J, Beigelman-Aubry C, et al. Chronic pulmonary aspergillosis: rationale and clinical guidelines for diagnosis and management. *Eur Respir J* 2016;47:45-68.



www.era-bio.com

LINKEDIN: @Era Biology

E-MAIL: marketing@era-bio.com

ADDRESS: Tianjin: 2-1, 2, 3-101, No. 2 Zone, Binlv

Industrial Park, Binhai Tourism Area, Binhai New Area,
Tianjin, P.R. China

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VERSION: July, 2024

CE NMPA

