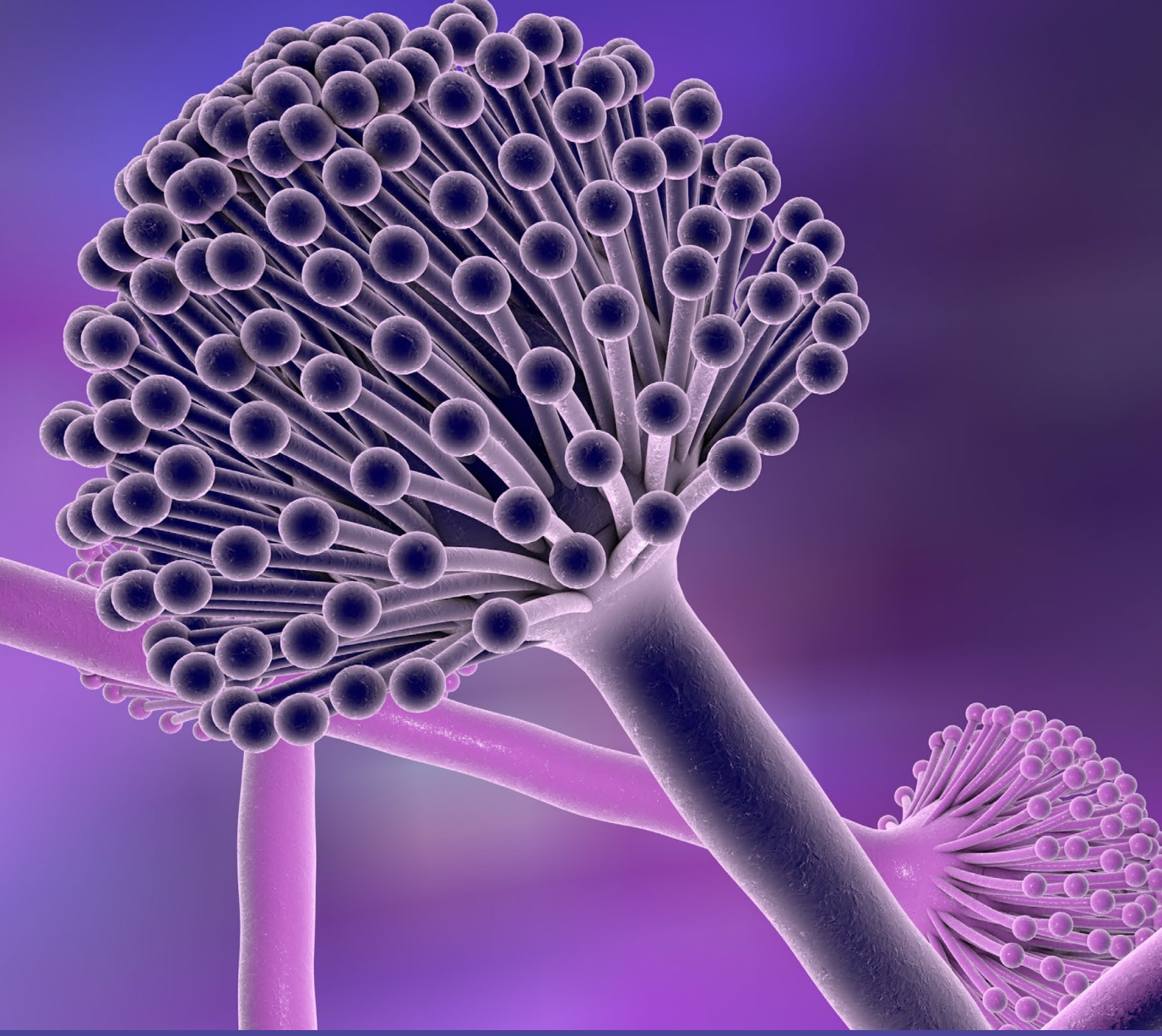


Dynamiker Fungal Solution

Product Portfolio

Specialist in
Invasive Fungal Infection
Diagnostic

丹娜生物 DMK

Dynamiker Biotechnology (Tianjin) Co., Ltd.

Company Profile

Dynamiker Biotechnology, established in 2014, is a Chinese manufacturer of diagnostic kits for Invasive Fungal Disease (IFD), including Invasive Aspergillosis, Invasive Candidiasis, Cryptococcosis, Mucormycosis, PJP, Fusarium, Talaromyces marneffei and Panfungal screening.

All products are CE-IVD under ISO13485, some are listed by US-FDA and Brazil-ANVISA. More than 50 peer-reviewed papers and studies had proved the good quality of Dynamiker's kits.

The Founder and President of Dynamiker, Dr. Zeqi Zhou got his Ph.D. at Ohio University and postdoc in Harvard Medical School. He used to work for Bayer and Wyeth in the USA by leading the R&D team. R&D colleagues are coming from Harvard Medical School USA, Kansas State University USA, Queen Mary University UK, Tsinghua University, Nankai University, etc.

Dynamiker is working with Global Action Fund for Fungal Infection (GAFFI) to promote the diagnosis of IFD. Meanwhile, Dynamiker is the strategic partner of Pfizer to improve the diagnosis and management of IFD.

Until now, Dynamiker kits had been used in more than 80 countries worldwide.






Product Family

Panfungal Screen Test

- DNK-1401-1 **Dynamiker Fungus (1-3)-β-D-Glucan Assay**

ELISA

- DNK-1402-1 **Dynamiker Aspergillus Galactomannan Assay**
- DNK-1403-1 Dynamiker Candida Mannan Assay
- DNK-1407-1 Dynamiker Aspergillus fumigatus IgG Assay
- DNK-1409-1 Dynamiker Candida albicans IgG Assay
- DNK-2201-1 **Dynamiker Fungus (1-3)-β-D-Glucan Assay (ELISA)**

POCT

- DNK-1411-1 **Dynamiker Cryptococcal Antigen Lateral Flow Assay(LFA)**
- DNK-2301-1 **QuicG Fungus (1-3)-β-D-Glucan Lateral Flow Assay**
- DNK-1414-1 **QuicGM Aspergillus Galactomannan Ag Lateral Flow Assay**
- DNK-1415-1 **QuicIgG Aspergillus IgG Ab Lateral Flow Assay**
- DNK-2111-1 QuicIgG Candida IgG Lateral Flow Assay
- DNK-2112-1 QuicMn Candida mannan Ag Lateral Flow Assay
- DNK-2113-1 QuicGXM Cryptococcus neoformans Ag Lateral Flow Assay

PCR

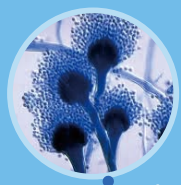
- DNK-1416-1 **MycoMDx Aspergillus PCR Assay**
- DNK-1417-1 **MycoMDx Candida PCR Assay**
- DNK-2107-1 MycoMDx Candida auris PCR Assay
- DNK-2108-1 MycoMDx Mucor PCR Assay
- DNK-2109-1 MycoMDx Pneumocystis jeroveci PCR Assay
- DNK-2110-1 MycoMDx Talaromyces marneffei PCR Assay

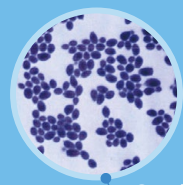
Dynamiker Fungus (1-3)-β-D-Glucan Assay

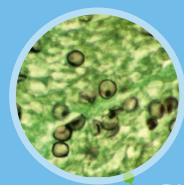
Catalogue No. **DNK-1401-1**

Breakable • **E**arly • **S**ensitive • **T**ime-efficient

It's used for pan-fungal detection. (1-3)-β-D-Glucan is the main cell wall component of most fungi, such as ***Candida***, ***Aspergillus***, ***Fusarium***, etc. By spectrophotometry quantitative detection of (1-3)-β-D-Glucan in serum, this assay offers a diagnostic reference for invasive fungal diseases.


Aspergillus


Candida


PJP


(1-3)-β-D-Glucan

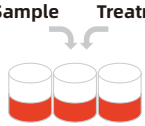
PANFUNGAL SCREENING

Specification

Specimen	Specification	Inter-assay CV	Intra-assay CV	Detection Range	Endotoxin Shielding
Serum	96 tests	≤12%	≤10%	37.5-600pg/ml	1.0 EU/mL

Test Procedure

Serum Sample **Treatment Solution** **Add Main Reagent**



Incubate at 37℃ for 10min

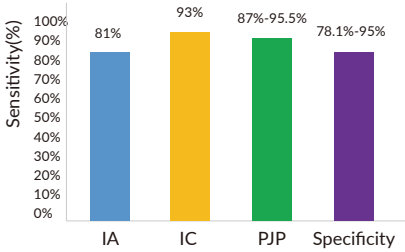
Kinetic reading 37℃ for 40min

Test report

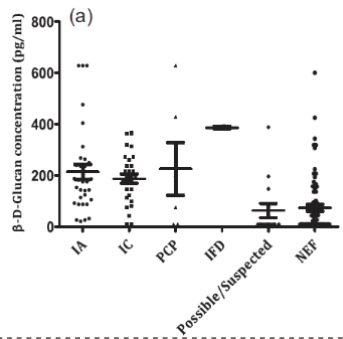
Risk Factors

- Hematology/HSCT
- Prolong Stay in ICU
- Transplantation
- Immunosuppressive therapy
- Oncology
- COPD
- AIDS
- Long-term use of antibiotics/corticosteroids
- Flu

Clinical Performance



IA: Invasive Aspergillosis | **IC:** Invasive Candidiasis
PJP: 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;

*Shabaan AE, et al: Role of serum (1,3)-β-d-glucan assay in early diagnosis of invasive fungal infections in a neonatal intensive care unit. J Pediatr (Rio J). 2017.

CFDA

CE IVD

Platform

The BDG Assay is working on a microplate reader with kinetic reading at 405nm and temperature control at 37℃.

Recommend microplate readers are Tecan Sunrise or BioTek ELX808iu, with incubator and kinetic reading at 405nm.

Dynamiker Aspergillus Galactomannan Assay

Catalogue No. **DNK-1402-1**

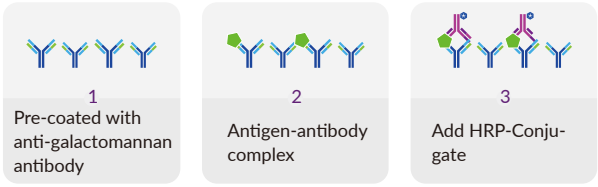
CFDA CE IVD

It is used for the detection of Aspergillus galactomannan antigen in human serum and bronchoalveolar lavage fluid (BALF), offering a diagnostic reference for Aspergillus infection.

Specification

Specimen	*Serum/ BALF*
Specification	*96 tests*
Sensitivity	*75%-90%*
Specificity	*85%-95%*
Time to answer	*2 hours*
Method	*Sandwich ELISA*
Intra-assay CV	*≤10%*
Inter-assay CV	*≤12%*
Used for	*Invasive Aspergillosis*

Sandwich principle



Dynamiker Aspergillus Galactomannan Assay is based on sandwich Enzyme-linked Immunosorbent Assay (ELISA).

Panel Testing: BDG Assay+GM Assay

Fungus (1-3)-β-D-Glucan Assay **Aspergillus Galactomannan Assay** **BDG+GM Panel Testing**

Guideline

Guideline	Diseases	Description	Recommendation	QOE
EORTC/MSG guideline 2008	Aspergillosis	One of the diagnostic criteria for probable diagnosis; GM antigen detected in plasma, serum, BALF ,or CSF		
IDSA guideline for aspergillosis 2016	IA3 in adult and paediatric patients with hematologic malignancy, HSCT	Serum and BALF GM	Strong	High
	IPA	Routine BALF test by non-culture-based methods (eg, GM)	Strong	Moderate
	IA in patients with hematologic malignancy, HSCT	Serial monitoring of serum GM; disease progression and therapeutic response and predict out come	Strong	Moderate
	Empiric and preemptive antifungal therapy	Serum or BALF GM guide antifungal therapy in asymptomatic or febrile high-risk patients to reduce unnecessary antifungal therapy	Strong	Moderate
ERS and ESCMID guideline 2015	CPA	BALF GM	Moderate	II

Dynamiker Cryptococcal Antigen Lateral Flow Assay (LFA)

Catalogue No. **DNK-1411-1**

More than 30% HIV patients get infected by **Cryptococcal Meningitis**.

- **C**ryptococcus neoformans/gattii
- **CM** Screening

It is used for diagnosis of Cryptococcosis by detecting capsular polysaccharide antigens of Cryptococcus species complex (Cryptococcus neoformans and cryptococcus gatti) in human serum, plasma and cerebral spinal fluid(CSF).

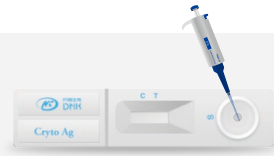
CN LFA

Specification

Lateral Flow Assay	Serum/Plasma/CSF	0.5-1ng/mL	18 month	15 min	40/50 tests/kit
Method	Sample	LOD	Shelf life	Detection Time	Specification

Test Procedure

1 Serum, Plasma and cerebral spinal fluid(CSF)



2 Add 80μL

3 15 mins

Positive

Negative

Invalid

4 Interperation of result

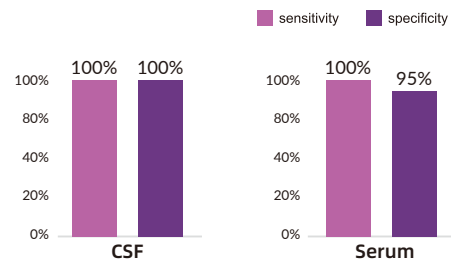
Guideline

WHO guidelines for the Diagnosis, Prevention, and Management of Cryptococcal Disease in Hiv-Infected Adults, Adolescents, and Children, 2018

Screening for cryptococcal antigen followed by preemptive antifungal therapy among cryptococcal antigen-positive people to prevent the development of invasive cryptococcal disease is recommended before initiating or reinitiating ART for adults and adolescents living with HIV who have a CD4 cell count <100 cells/mm3 (strong recommendation; moderate-certainty evidence) and may be considered at a higher CD4 cell count threshold of <200 cells/mm3 (conditional recommendation; moderate-certainty evidence).

CE IVD CFDA

Clinical Performance



* Evaluation of the Dynamiker cryptococcal antigen Lateral Flow Assay (LFA) in comparison with IMMY LFA and Meridian latex agglutination test. Poster no 1197.

QuicGM™ Aspergillus Galactomannan Ag LFA

QuicIgG™ Aspergillus IgG Ab LFA

Catalogue No. **DNK-1414-1/DNK-1415-1**

- **POCT** for Invasive Aspergillosis

20	50	Serum & BALF
min	tests/kit	
Detection Time	Specification	Sample

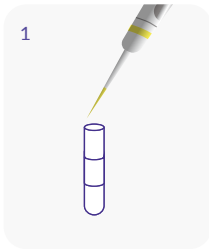
QuicGM / QuicIgG

QuicGM™ Aspergillus Galactomannan Ag Lateral Flow Assay is used to detect galactomannan (GM) in human serum samples, mainly for the auxiliary diagnosis of Invasive Aspergillosis (IA).

QuicIgG™ Aspergillus IgG Ab Lateral Flow Assay is used for detection of Aspergillus galactomannan IgG antibodies in human serum samples, mainly for the auxiliary diagnosis of Chronic Pulmonary Aspergillosis (CPA).

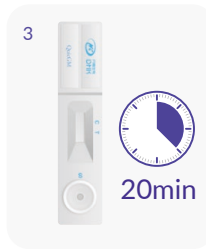
QuicIgE™ Aspergillus IgE Ab Lateral Flow Assay is used for detection of Aspergillus fumigatus m3 allergen-specific IgE antibodies in human serum samples, mainly for Allergic Bronchopulmonary Aspergillosis (ABPA).

Test Procedure



Process Samples

Add 90-100 µl



Incubate for 20 minutes

Read Data

FIC-Q100N Dry Fluorescent Immunoanalyzer

- Standard curve built-in
- LIS Connectivity, Data storage
- Semi-quantitative detection
- Auto-identification for item, Auto-printing
- All-in-one instrument
- 280*240*130(mm), 2Kg

Agreement between QuicGM and GM Assay

		ELISA		Total
		Negative	Positive	
POCT	Negative	94	2	96
	Positive	6	27	33
Total		100	29	129
Positive agreement rate		93.10%		
Negitive agreement rate		94.00%		
Total agreement rate		93.80%		

CE IVD CFDA

Clinical value of Culture-free diagnosis of IFD

The biggest challenge of IFD is the time for diagnosis. It could take several weeks for filamentous fungi. The patients may die already before the clinician get the result from the lab.

Serological tests, using biomarkers of fungal cell wall, provide non-culture, early, and more accurate tests for IFD. Normally it will get results 7-10 days earlier than culture. This could drive the anti-fungal therapy in due time to save lives.

Guidelines recommend Serological tests for IFD:

- Revision and Update of the Consensus Definitions of Invasive Fungal Disease From EORTC/MSG 2019
- IDSA guideline for aspergillosis 2016
- ESCMID guideline 2012
- WHO guideline for HIV-Related Cryptococcal disease
- ERS and ESCMID guideline 2015

Background of Invasive Fungal Disease

- It belongs to Microbiology
- Mortality: 100% without treatment, 75% survival with treatment
- Risk factor: Immunocompromised patients
- Target patients: Hematological malignancy, ICU, Transplantation, AIDS, Using of steroids, long term use of antibiotics, TB, COPD, etc
- Infection site: Bloodstream, lung, CNS, etc.
- Traditional diagnostic method: Culture (time-consuming), Microscopy (depends on experience)
- Biggest challenge of clinicians: Time of diagnosis for IFD
- Epidemiology worldwide:
- Invasive Candidiasis: 12.5 million cases/year
- Invasive Aspergillosis: 11 million cases/year
- Invasive Cryptococcosis: 1.1 million cases/year

CONTACT US

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