丹娜生物
DNK

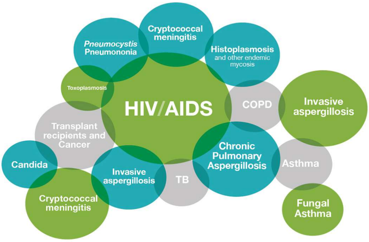
Dynamiker Biotechnology

Specialist in Diagnostics of Invasive Fungal Diseases

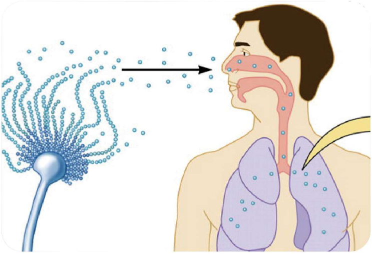
Rapid · Robust · Reliable

1 Global Fungal Burden

Globally, over 300 million people of all ages suffer from serious fungal infections every year resulting in over 1.6 million deaths. Like malaria with 445,000 deaths and tuberculosis with 1,700,000 deaths annually (2016), many deaths from fungal infection are avoidable. Most serious fungal infections are 'hidden', occurring as a consequence of other health problems such as AIDS, cancer, organ transplant, asthma and corticosteroid therapies. All require specialized testing for diagnosis, and delays or missed diagnosis often lead to death, serious chronic illness or blindness.



*From GAFFI Kampala Uganda 2018



*http://www.life-worldwide.org/fungal-diseases/chronic-pulmonary-aspergillosis/

Immunocompromised patients (Haematological malignancy, Transplantation, ICU, Cancer, AIDS, TB, COPD, Long term use of antibiotics/ corticosteroids, flu, etc) are easily infected by fungi. More than 80% of Invasive Fungal Diseases(IFD) are caused by Candida. spp, Aspergillus. spp and Cryptococcus. spp, with the mortality from 40%-100%. The biggest challenge faced by clinicians is late therapy due to late diagnostics. Conventional diagnostics like culture, microscopy and CT scanning is time- consuming and with low sensitivity and specificity. Serological tests (culture-free) provide an early, rapid and more reliable adjunct for IFD diagnosis.

Burden of common life-threatening fungal infections:

~50% mortality in developed world even treated.

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
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	
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
Total	~13,000,000		1,600,000	Probably a significant underestimate

*Data come from https://www.gaffi.org/why/fungal-disease-frequency/

2 Product List

13485:2016

Colorimetric Assay

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

ELISA Assay

DNK-1402-1	Dynamiker Aspergillus Galactomannan Assay
DNK-1403-1	Dynamiker Candida Mannan Assay
DNK-1404-1	Dynamiker Cryptococcus neoformans Antigen Assay
DNK-1405-1	Dynamiker Human Procalcitonin Assay
DNK-1406-1	Dynamiker Aspergillus fumigatus IgM Assay
DNK-1407-1	Dynamiker Aspergillus fumigatus IgG Assay
DNK-1408-1	Dynamiker Candida albicans IgM Assay
DNK-1409-1	Dynamiker Candida albicans IgG Assay

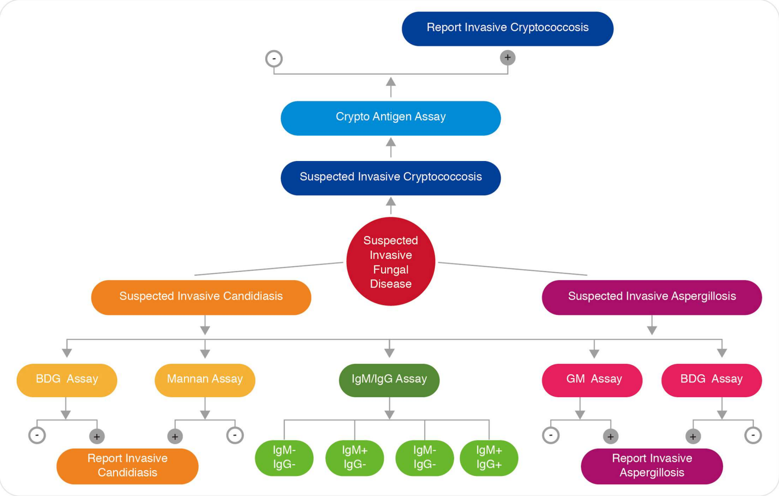
POCT Assay

DNK-1411-1	Dynamiker Cryptococcal Antigen Lateral Flow Assay
DNK-1412-1	Dynamiker Candida IgM Lateral Flow Assay
DNK-1413-1	Dynamiker Candida IgG Lateral Flow Assay
DNK-1414-1	QuicGM™ Aspergillus Galactomannan Ag Lateral Flow Assay
DNK-1415-1	QuicIgG™ Aspergillus IgG Ab Lateral Flow Assay

Molecular Assay

DNK-1416-1	MycoMDx Aspergillus PCR Assay

3 Panel Testing



Report Invasive Cryptococcosis

-
+

Crypto Antigen Assay

Suspected Invasive Cryptococcosis

Suspected Invasive Fungal Disease

Suspected Invasive Candidiasis

Suspected Invasive Aspergillosis

BDG Assay

Mannan Assay

IgM/IgG Assay

GM Assay

BDG Assay

-
+
+
-

Report Invasive Candidiasis

IgM- IgG-

IgM+ IgG-

IgM- IgG-

IgM+ IgG+

-
+
+
-

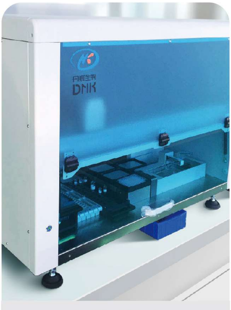
Report Invasive Aspergillosis

4 Platforms

sunrise
TECAN.

TECAN SUNRISE™

Multiskan FC



4 Guideline

1. EORTC/MSG guideline 2008

Table 1. Criteria for proven invasive fungal disease except for endemic mycoses

Analysis and specimen	Moldsa	Yeastsa
Serological analysis: CSF	Not applicable	Cryptococcal antigen in CSF indicates disseminated cryptococcosis

Table 2. Criteria for probable invasive fungal disease except for endemic mycoses.

Aspergillosis

Galactomannan antigen detected in plasma, serum, bronchoalveolar lavage fluid, or CSF Invasive fungal disease other than cryptococcosis and zygomycoses

B-D-glucan detected in serum.

2.Practice Guidelines for the Diagnosis and Management of Aspergillosis: 2016 Update by the Infectious Diseases Society of America

(1)How Should Galactomannan and (1 → 3)-β-D-Glucan Be Used for the Diagnosis of Aspergillosis?

Recommendations

Serum and BAL GM is recommended as an accurate marker for the diagnosis of IA in adult and pediatric patients when used in certain patient subpopulations (hematologic malignancy, HSCT) (strong recommendation; high-quality evidence).

GM is not recommended for routine blood screening in patients receiving mold-active antifungal therapy or prophylaxis, but can be applied to bronchoscopy specimens from those patients (strong recommendation; high-quality evidence).

GM is not recommended for screening in SOT recipients or patients with CGD (strong recommendation; high-quality evidence).

Serum assays for (1 → 3)-β-D-glucan are recommended for diagnosing IA in high-risk patients (hematologic malignancy, allogeneic HSCT), but are not specific for Aspergillus (strong recommendation; moderate-quality evidence).

(2)How Can Biomarkers Be Used to Assess Patient Response to Therapy?

Recommendations

Serial monitoring of serum GM can be used in the appropriate patient subpopulations (hematologic malignancy, HSCT) who have an elevated GM at baseline to monitor disease progression and therapeutic response, and predict outcome (strong recommendation; moderate-quality evidence).

(1 → 3)-β-D-glucan has not been extensively studied in IA to predict outcome (weak recommendation; low-quality evidence).

(3)How Can Chronic Cavitary Pulmonary Aspergillosis Be Diagnosed?

The **Aspergillus IgG** antibody test is the most sensitive microbiological test (strong recommendation; moderate-quality evidence).

3.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 pre-emptive 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).

4.Other Mycology Guidelines

Guideline	Test Diseases	Description	Recommendation	QOE
ESCMID-EC-MM-ERS Guideline 2017	To diagnosis IA	GM in serum	A	II
		GM in BAL	A	II
	To diagnosis of IFD	Serum 1-3 β-D Glucan	B	II
ESCMID guideline 2012	Candidaemia, invasive candidiasis, chronic disseminated candidiasis	Serum (1-3)-β-D-Glucan	Recommended	II

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For the Benefit of Human Health

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