Exeter Initiative for Science and Technology 15th February 2018

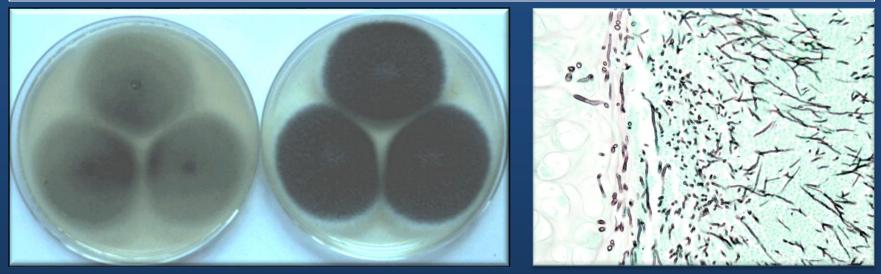
ISCA Diagnostics

Professor Christopher Thornton





Aspergillus Diseases



Aspergillus fumigatus

Most important opportunistic mould pathogen of immuno-compromised humans esp. haematological malignancy and bone marrow transplant patients

Invasive Pulmonary Aspergillosis >200,000 cases/year worldwide with 30-95% mortality

Chronic Pulmonary Aspergillosis ~3 million cases worldwide in patients with underlying lung diseases including asthma

Allergic Bronchopulmonary Aspergillosis ~4 million cases worldwide in patients with asthma and cystic fibrosis

1. Identify a need

Diagnosing IPA

Notoriously difficult - no single 'gold standard' test for diagnosis

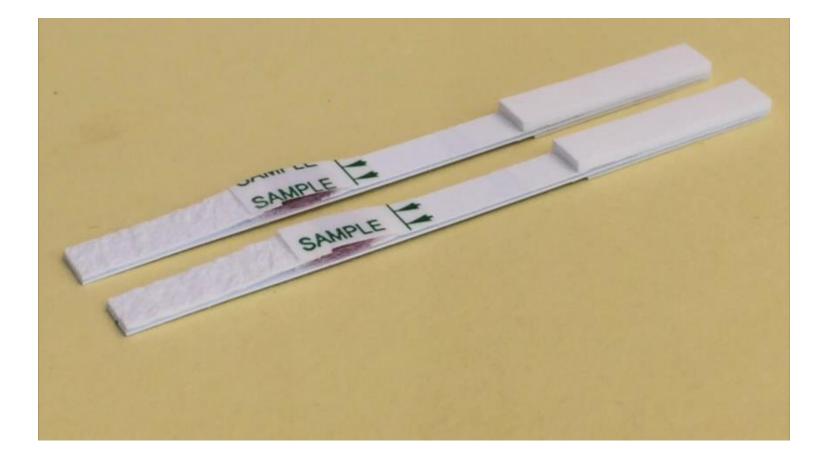
Treatment typically 'fever-driven' or by non-specific chest CT - proven diagnosis typically only at autopsy (but rarely conducted)

Imperative that diagnosis is made without delay (days not weeks) - prognosis worsens significantly in the absence of recognition and effective treatment

Many patients receive inappropriate treatment with costly and toxic azole drugs - typically adds an additional £25k to hospital stay

Widespread azole resistance in clinical strains of Aspergillus

2. Provide a *simple* solution



Lateral-Flow Device demo

- Uses a highly specific monoclonal antibody (JF5)
- Diagnosis now **minutes** rather than days or weeks

3. Protect your IP

Intellectual Property and Patenting

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Applicants:	THORNTON, Christopher [GB/GB]; (GB) (For US Only). UNIVERSITY OF EXETER (GB/GB); Northcote House The Queen's Drive Exeter Devon EX4 4QJ (GB) (For All Designated States Except US)					
Inventors:		Christopher; (GB)				
Agent:	WALLIS, Nao (GB)	mi Rachel; WITHERS & ROGER:	S LLP Goldings House 2 Hay	s Lane London SEI 2HW		
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Aspergillus LFD and Clinical Studies

13 clinical studies conducte since 2008

UK, US, Australia, Austria, Chile, China, Germany, Turk

2015 meta-analysis in China using data from 8 of these

6 more clinical studies published since 2015



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Diagnostic Accuracy of a Novel Lateral-Flow Device in Invasive Aspergillosis: a Meta-Analysis

Zhijie Pan¹, Mengjiao Fu², Jiaojiao Zhang³, Hua Zhou⁴, Yiqi Fu⁵ and Jianying Zhou (zjyhz@zju.edu.cn)6

+ Author Affiliations

Received 18 October 2014. Revised 18 May 2015. Revised 15 April 2015. Accepted 19 May 2015.

Abstract

A novel lateral-flow device (LFD) has been invented for use as a diagnostic tool for invasive aspergillosis (IA). We conducted a meta-analysis to assess the diagnostic accuracy of the device. The published studies that used the European Organization of the Research and Treatment of Cancer/Mycoses Study Group (EORTC/MSG) criteria and provided sufficient data were included. Two reviewers independently collected the data of each study and assessed the risk bias using the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2). The pooled sensitivity, specificity and diagnostic odds ratio (DOR) were computed and reported with a 95% confidence interval (CI). Seven studies published between 2008 and 2014 were included. The pooled sensitivity, specificity and DOR for the proven/probable versus no IA cases were 0.86 (95% CI, 0.76-0.93), 0.93 (95% CI, 0.89-0.96) and 65.94 (95% CI, 27.21-159.81) in LFD test using bronchoalveolar lavage (BAL) fluid, and 0.68 (95% CI, 0.52-0.81), 0.87 (95% CI, 0.80-0.92) and 11.90 (95% CI, 3.54-39.96) in LFD test using serum. We concluded that the Aspergillus-LFD had a great diagnostic value in immunocompromised patients at risk of IA. The BAL-LFD might have a better performance than the serum-LFD test.

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This Article

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5. Exploit your IP

Commercialisation of Aspergillus LFD



www.iscadiagnostics.com

JF5 IP (diagnostics/therapeutics) licenced to ISCA May 2013



EXETER Spin-out company

Incorporated: 29 March 2012

Company Nº 8010751
HMRC SEIS tax relief

University - 25% ownership

C.R.Thornton - 41%

Angel investors (each a % of remaining 66%)

Commercialisation



UNIVERSITY OF

Institute to Industry



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Applicants:	THORNTON, Christopher [GB/GB]; (GB) (For US UNIVERSITY OF EXETER [GB/GB]; Northcote Ho (GB) (For All Designated States Except US)	
Inventors:	THORNTON, Christopher; (GB)	
Agent:	WALLIS, Naomi Rachel; WITHERS & ROGERS I (GB)	LLP Goldings House 2 Hays Lane London SEI 2HW
Priority Data:	61/145,282 16.01.2009 US	
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Publication Lang		English (EN)
Filing Language:		English (EN)
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UoE licences IP to ISCA

Patent to Product

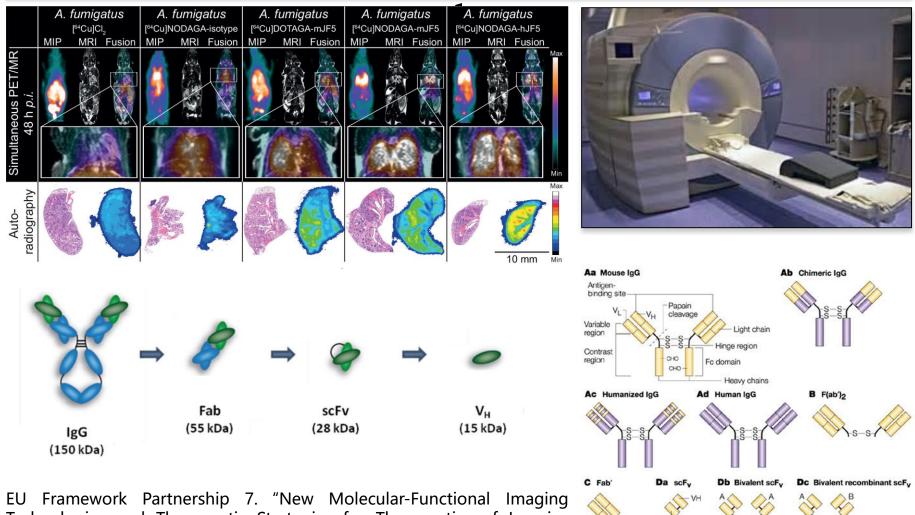
Marketing, Sales & Distribution



Bench to Bedside

6. Broaden your Horizons

ISCA Diagnostics as European SME



Technologies and Therapeutic Strategies for Theranostics of Invasive Aspergillosis". HEALTH.2013.1.2-1: Development of imaging technologies for therapeutic interventions in rare diseases. 2013 – 2018.

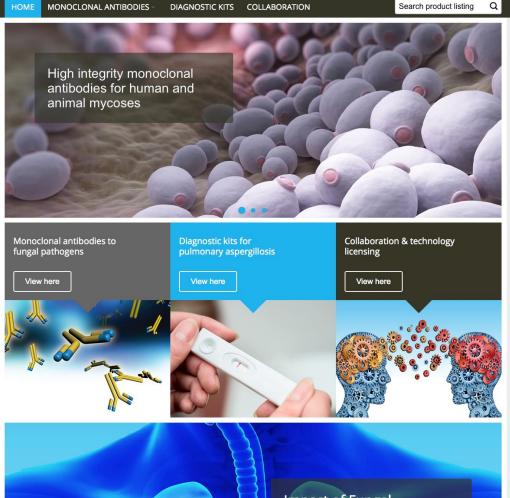
Mouse sequences

Human sequences

7. Expand your Empire



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Impact of Fungal Pathogens

Infectious diseases caused by viruses, bacteria, and fungi remain a leading cause of death worldwide.

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Fungi are responsible for superficial in and genital tract, especially vulvovagi wordwide every year. Environmental exacerbate respiratory diseases such immunocompromised individuals such transplants. While the indence of im unacceptably high mortality rates. Co- worldwide each year with mortality rat Trichoderma, and Trichosporon add to	nal candidiasis (or thrush). Togethe fungi such as Alternaria, Cladospo as asthma. Fungi are also respons n as haematological malignancy pa rasive infections is much lower that neverative estimates show that invi es of between 30-95%. Emerging i	r, these superficial infections are the rium, and Penicillium are allergenic sible for life-treatening invasive infe tients, and recipients of solid organ n superficial infections, they are of g asive pulmonary aspergillosis alone fungal pathogens of humans such as	sught to affect ~1.7 billion humans species found in the home and ctions, especially in and allogeneic stem cell reater concern because of the affects >200,000 humans
Alternaria, monocional antibody (cione PC3)	Approximate Approx	Candida, moute monocional antibody (cione MC3)	Cladosporium, monocional antibody (clone CH1)
View here	View here	. View here .	View here
Fusatium, monocional antibody idone ED7	Lomentospora prolificans, monecinal antibody (elone	par-Asomycete, monoconal antibody (tope IE3)	Pseudallescheria / Scedosportum complex,
View here	CA4] View here	View here	monoclonal antibody [clone GA3] View here
	0	Y	
Pseudallescheria/Scedosporium complex, monoclonal antibody [clone HG12]	Trichoderma, monoclonal antibody [clone MF2]	Trichosporon asahii and T. asteroides, monoclonal antibody [clone CA7]	Trichosporon asahii and T. asteroides, monoclonal antibody [clone TH1]
View here	View here	View here	View here
Selected images courtesy of Y. E. Am	atnieks (Fun with Microbiology).		
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Big thanks to...

ISCA Shareholders! Genna Davies (ISCA R&D scientist)

Paul Sheppard Neil Hayes Rachael Baird Tori Hammond Sean Fielding Nick Talbot



New Molecular-Functional Imaging Technologies and Therapeutic

Strategies for Theranostic of Invasive Aspergillosis

