

Exeter Initiative for Science and Technology

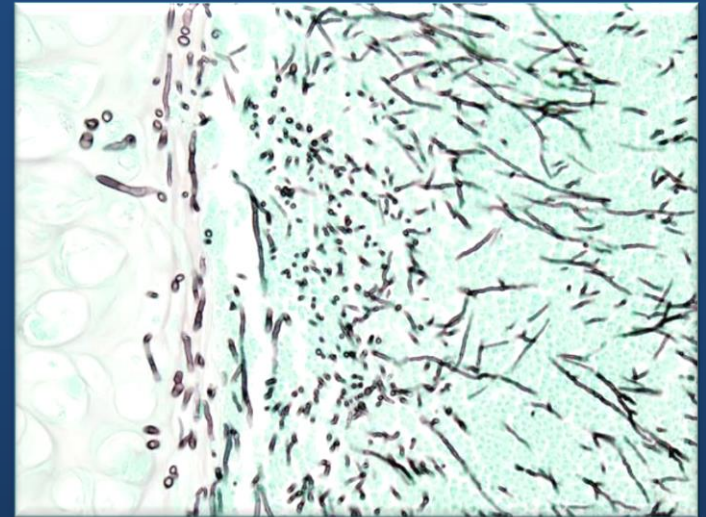
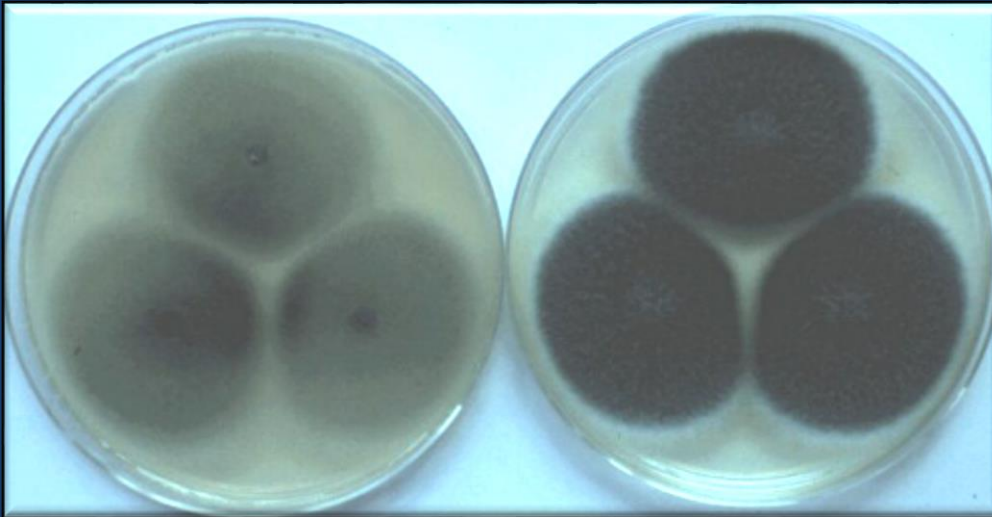
15th February 2018

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

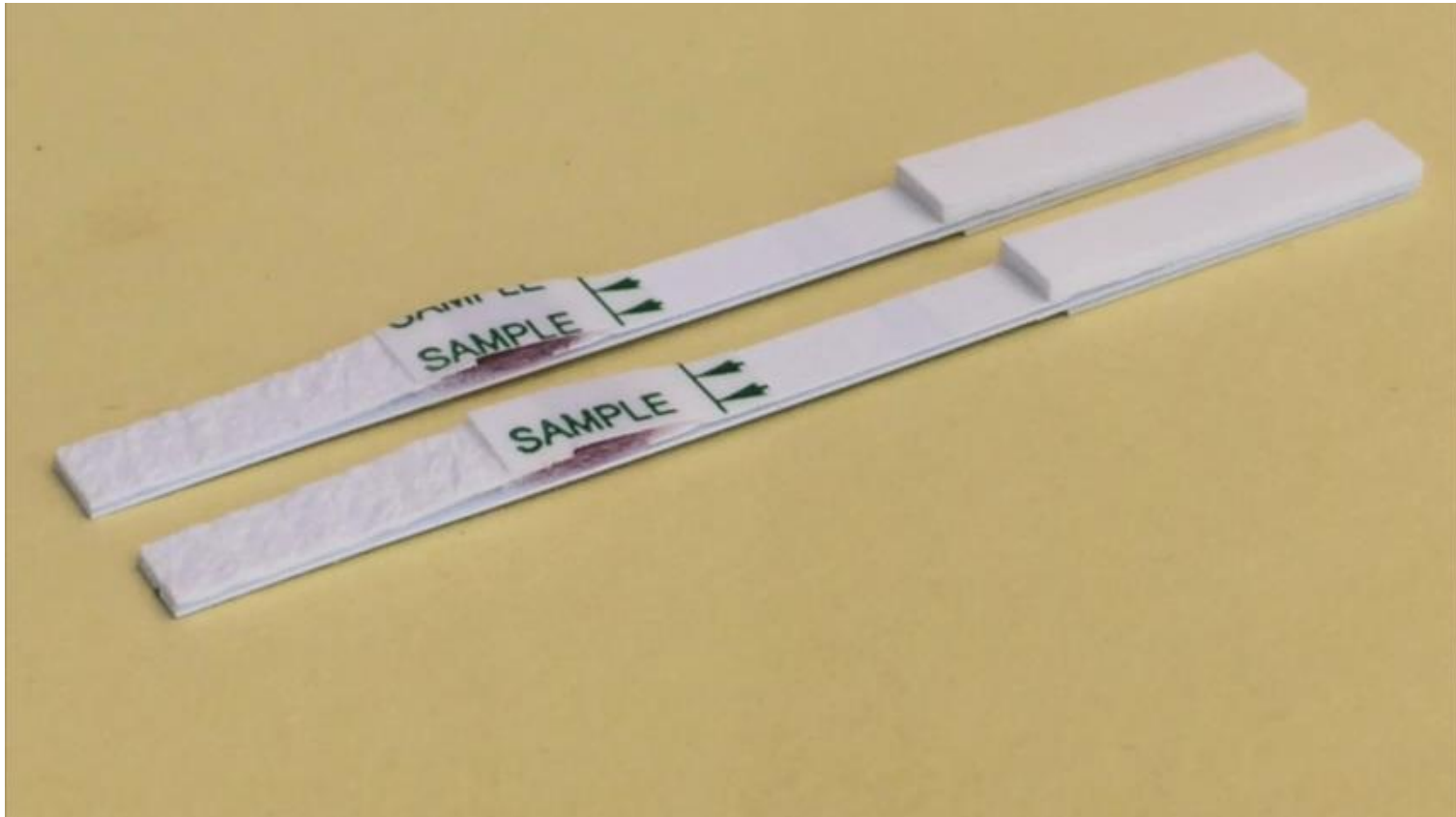
Treatment typically 'fever-driven' or by non-specific chest CT
- proven diagnosis typically only at autopsy (but rarely conducted)

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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1. (WO2010082034) ANTIBODY

PCT Biblio. Data Description Claims National Phase Notices Drawings Documents

Latest bibliographic data on file with the International Bureau

Pub. No.: WO/2010/082034 International Application No.: PCT/GB2010/000064
Publication Date: 22.07.2010 International Filing Date: 18.01.2010

IPC: C07K 16/14 (2006.01), G01N 33/568 (2006.01)

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Inventors: THORNTON, Christopher; (GB)

Agent: WALLIS, Naomi Rachel; WITHERS & ROGERS LLP Goldings House 2 Hays Lane London SE1 2HW (GB)

Priority Data: 61/145,282 16.01.2009 US

Title: (EN) ANTIBODY
(FR) ANTICORPS

Abstract: (EN) The invention relates to antibodies to *Aspergillus* species and to methods of producing those antibodies. The invention also relates to the use of such antibodies in identifying the presence of the *Aspergillus* species and to methods of treating an infection with the *Aspergillus* species.
(FR) La présente invention concerne des anticorps contre l'espèce *Aspergillus* et des méthodes de production de ces anticorps. L'invention porte également sur l'utilisation desdits anticorps dans l'identification de la présence de l'espèce *Aspergillus*, et sur des méthodes de traitement d'une infection au moyen de l'espèce *Aspergillus*.

Designated States: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
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African Intellectual Property Organization (OAPI) (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Publication Language: English (EN)
Filing Language: English (EN)

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PCT Biblio. Data Description Claims National Phase Notices Drawings Documents

Available information on National Phase entries (more information)

Office	Entry Date	National Number	National Status
European Patent Office (EPO)	16.08.2011	201070049	Published: 23.11.2011
United States of America	07.11.2011	13144872	Published: 15.03.2012

European Patent Register

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EP2387585

About this file: EP2387585

Legal status: ST36

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EP2387585 - ANTIBODY [Right-click to bookmark this link]

Status: Examination is in progress
Database last updated on: 04.07.2013

Most recent event: 03.05.2013 New entry: Additional fee for renewal fee: payment of fee

03.05.2013 New entry: Renewal fee paid

Applicant(s): For all designated states
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[2011/47]

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[2011/47]

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[2013/11]

Application number, filing date: 10700449.1 18.01.2010

Priority number, date: WO2010GB00064
US20090145282P 16.01.2009 Original published format: US 145282 P
[2011/47]

Filing language: EN

Procedural language: EN

Publication: Type: A1 Application with search report
No.: WO2010082034
Date: 22.07.2010
Language: EN
[2010/29]

Type: A1 Application with search report
No.: EP2387585
Date: 23.11.2011
Language: EN

The application has been published by WIPO in one of the EPO official languages on 22.07.2010
[2011/47]

International and Supplementary search report(s): International search report - EP 22.07.2010 published on:

Classification: International: C07K16/14, G01N33/568 [2011/47]

Designated contracting states: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR

Title: German: ANTIKÖRPER [2011/47]
English: ANTIBODY [2011/47]
French: ANTICORPS [2011/47]

Biological material: This application mentions deposited biological material, check the file for details

Entry into regional phase: 16.08.2011 National basic fee paid
16.08.2011 Designation fee(s) paid
16.08.2011 Examination fee paid

Examination procedure: 16.08.2011 Amendment by applicant (claims and/or description)
16.08.2011 Examination requested [2011/47]
17.07.2012 Despatch of a communication from the examining division (Time limit: M06)
25.01.2013 Reply to a communication from the examining division
09.04.2013 Despatch of a communication from the examining division (Time limit: M04)

4. Prove that it works

Aspergillus LFD and Clinical Studies

13 clinical studies conducted since 2008

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

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

6 more clinical studies published since 2015

JMM Journal of Medical Microbiology

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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

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.

This Article

Published online ahead of print May 22, 2015, doi: 10.1099/jmm.0.000092
J Med Microbiol May 2015
jmm.0.000092

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What's this?

5. Exploit your IP


Commercialisation of *Aspergillus* LFD



www.iscadiagnostics.com

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



 Spin-out company

Incorporated: 29 March 2012

- Company N° 8010751
- HMRC SEIS tax relief

University - 25% ownership

C.R.Thornton - 41%

Angel investors (each a %
of remaining 66%)

Commercialisation



Institute to Industry



www.iscadiagnostics.com

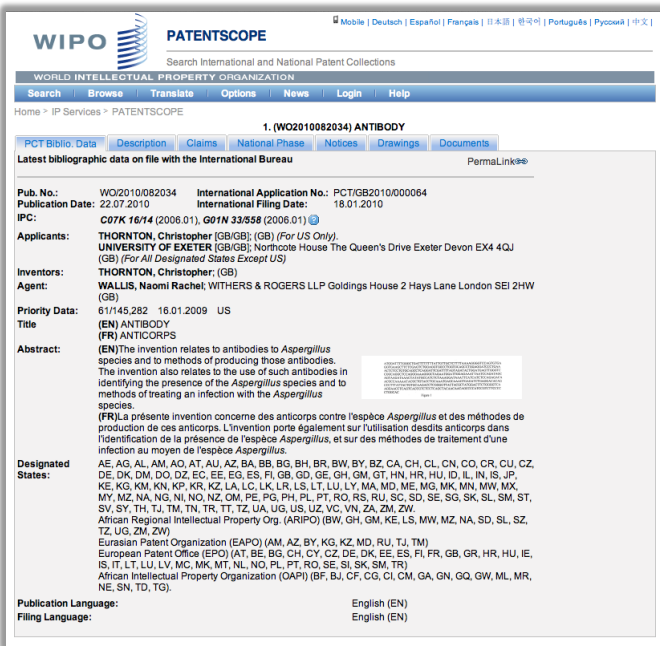
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IP to ISCA

Patent to Product

Marketing, Sales
& Distribution

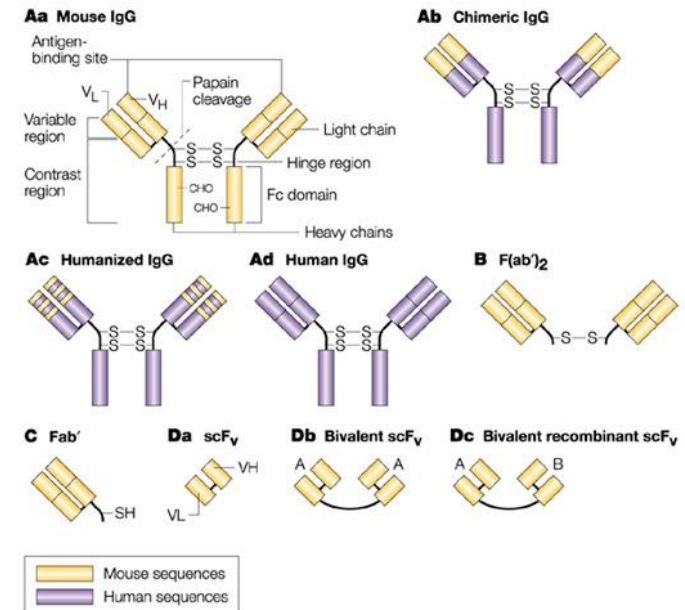
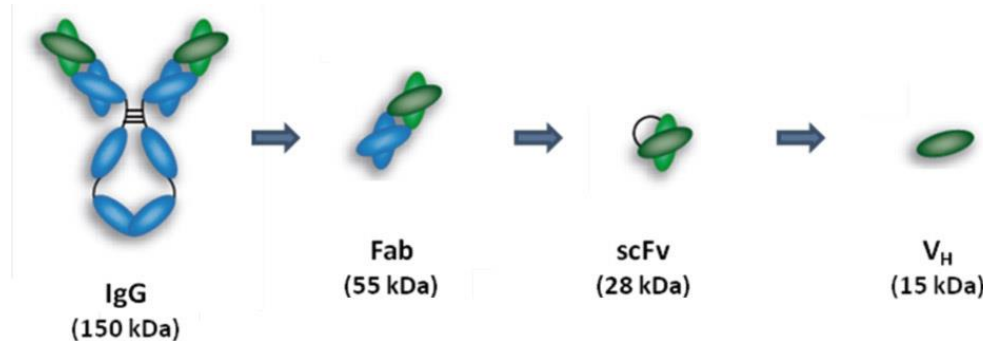
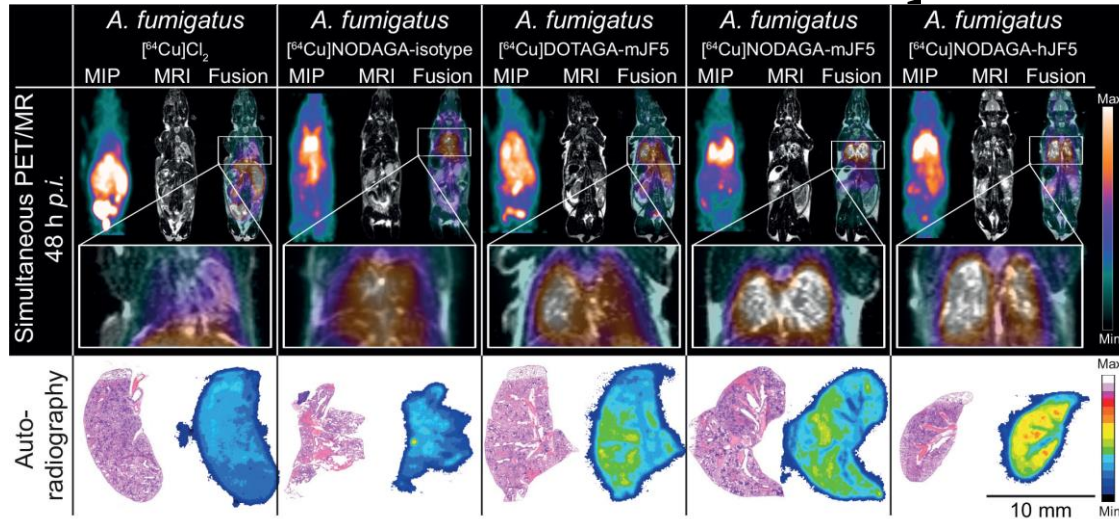


Bench to Bedside



6. Broaden your Horizons

ISCA Diagnostics as European SME



EU Framework Partnership 7. "New Molecular-Functional Imaging 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.

7. Expand your Empire



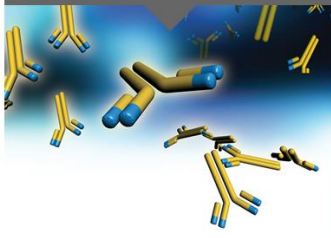
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Monoclonal antibodies to fungal pathogens

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Diagnostic kits for pulmonary aspergillosis

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Collaboration & technology licensing

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Impact of Fungal Pathogens

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



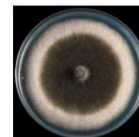
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Home - Monoclonal antibodies - Human mycoses

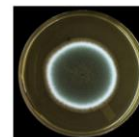
Human mycoses

Fungi are responsible for superficial infections of the skin and nails, causing athlete's foot and ringworm of the scalp, and infections of the oral and genital tract, especially vulvovaginal candidiasis (or thrush). Together, these superficial infections are thought to affect ~1.7 billion humans worldwide every year. Environmental fungi such as *Alternaria*, *Cladosporium*, and *Penicillium* are allergenic species found in the home and exacerbate respiratory diseases such as asthma. Fungi are also responsible for life-threatening invasive infections, especially in immunocompromised individuals such as haematological malignancy patients, and recipients of solid organ and allogeneic stem cell transplants. While the incidence of invasive infections is much lower than superficial infections, they are of greater concern because of the unacceptably high mortality rates. Conservative estimates show that invasive pulmonary aspergillosis alone affects >200,000 humans worldwide each year with mortality rates of between 30-95%. Emerging fungal pathogens of humans such as *Fusarium*, *Scedosporium*, *Trichoderma*, and *Trichosporon* add to the disease burden in these high-risk patient groups.



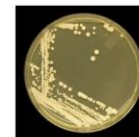
Alternaria, monoclonal antibody [clone PC3]

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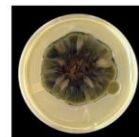
Aspergillus and *Penicillium*, monoclonal antibody [clone JF5]

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Candida, mouse monoclonal antibody [clone MC3]

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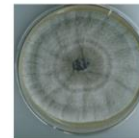
Cladosporium, monoclonal antibody [clone CH1]

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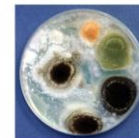
Fusarium, monoclonal antibody [clone ED7]

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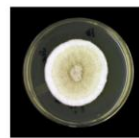
Lomentospora prolificans, monoclonal antibody [clone CA4]

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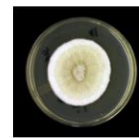
pan-Ascomycete, monoclonal antibody [clone IE3]

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Pseudallescheria / Scedosporium complex, monoclonal antibody [clone GA3]

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Pseudallescheria/Scedosporium complex, monoclonal antibody [clone HG12]

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Trichoderma, monoclonal antibody [clone MF2]

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Trichosporon asahii and *T. asteroides*, monoclonal antibody [clone CA7]

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Trichosporon asahii and *T. asteroides*, monoclonal antibody [clone TH1]

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Selected images courtesy of Y. E. Amatrieks (Fun with Microbiology).

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