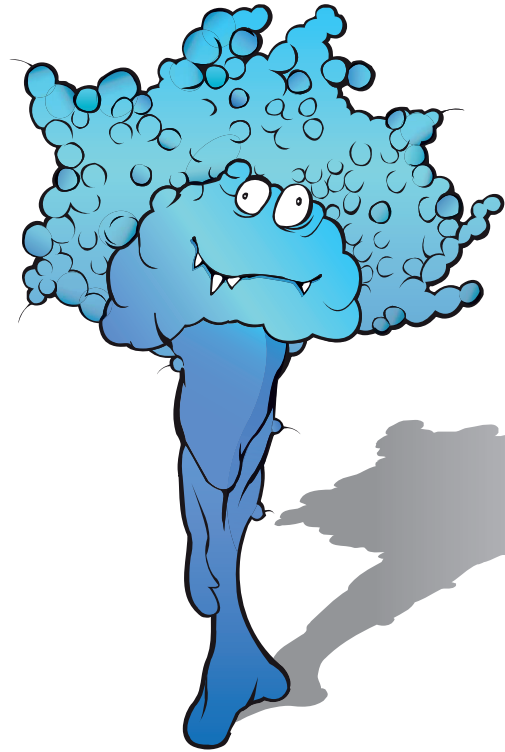


MycAssay™

Aspergillus

Rapid detection of
Aspergillus DNA from
serum samples using
Real-Time PCR

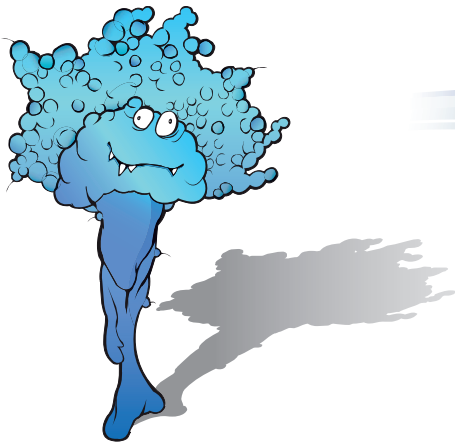


MycAssay™ Aspergillus is a CE marked, Real-Time PCR assay for the detection of *Aspergillus* in **serum** samples.

The kit is designed to be used by qualified laboratory professionals; the results provided by **MycAssay™** Aspergillus aid physicians to make a diagnosis in immunocompromised patients suspected of having an infection caused by *Aspergillus* spp.

When **MycAssay™** Aspergillus is used in conjunction with a recommended extraction system, a result can be obtained in less than 3 hours of sample receipt. **MycAssay™** Aspergillus provides rapid and accurate results to physicians, **enabling appropriate drug treatments to be administered thereby improving patient outcomes.**





Aspergillus spp.

- Are filamentous fungi or moulds that are ubiquitous in the atmosphere
- May cause severe respiratory and systemic infections to those who are immunocompromised e.g. transplant recipients, leukaemics, patients on ICU, but pose no threat to healthy individuals

Traditional methods used in the diagnosis of aspergillosis infections have limitations associated with poor sensitivity and specificity. **MycAssay™ Aspergillus** offers increased sensitivity, specificity and speed of diagnosis, all of which are key factors in improving patient survival rates.

Respiratory vs Serum

MycAssay™ Aspergillus gave a sensitivity and specificity of 94% and 91% respectively compared to clinical diagnosis on clinical lower respiratory tract samples which were extracted using **MycXtra®**.

However, lower respiratory tract samples have limitations due to the invasive nature of the bronchoalveolar lavage procedure. A meta analysis by Mengoli *et al.* reported on >10,000 blood, serum and plasma samples from 1618 patients at risk for invasive aspergillosis (IA). They calculated the sensitivity and specificity of a single PCR positive blood sample to be 0.88 and 0.75 respectively and the diagnostic odds ratio for proven and probable cases to be 16.41. **These data support the use of blood (including serum) as a diagnostic matrix for IA.**

Mengoli C. *et al.* The Lancet ID 2009; 9; 86-96

Myconostica Ltd, part of Lab21
184 Cambridge Science Park, Cambridge CB4 0GA
Tel: +44 (0) 1223 395 450 Fax: +44 (0) 1223 395 451
www.Lab21.com myco@lab21.com

Features of **MycAssay™ Aspergillus**

- Highly sensitive – has a Limit of Detection of approximately one genome
- Provides highly reproducible data
- Has an internal amplification control in every reaction to highlight false negative results
- Easy experimental set-up
- Consists of closed tube reactions to reduce the risk of contamination

Experimental data

To determine the Limit of Detection for the entire procedure, serum samples spiked with Aspergillus DNA were extracted using a modified Roche High Pure PCR Template Preparation Kit and subsequently tested using **MycAssay™ Aspergillus** on the Cepheid SmartCycler®. The Limit of Detection of the entire procedure was 5 genome equivalents in 0.5 mL serum. Drugs anticipated to be present in a patient sample were tested for their ability to interfere in the **MycAssay™ Aspergillus** reaction. None of the drugs tested were found to interfere. (Figure 1).

Substances tested for interference

Amoxicillin with clavulanic acid, atovaquone, azathioprine, azotreonam, ceftazidime, ciproflaxacin, chlorphenamine maleate, clindamycin phosphate, co-trimoxazole, creatinine, dapsone, dexamethasone sodium phosphate, fluconazole, meropenam, metoclopramide hydrochloride, paracetamol, primaquine phosphate, prednisone sodium phosphate, prednisone, prochlorperazine vancomycin and voriconazole

Figure 1 Substances tested for interference. Full details are found in the IFU

Product is
CE marked