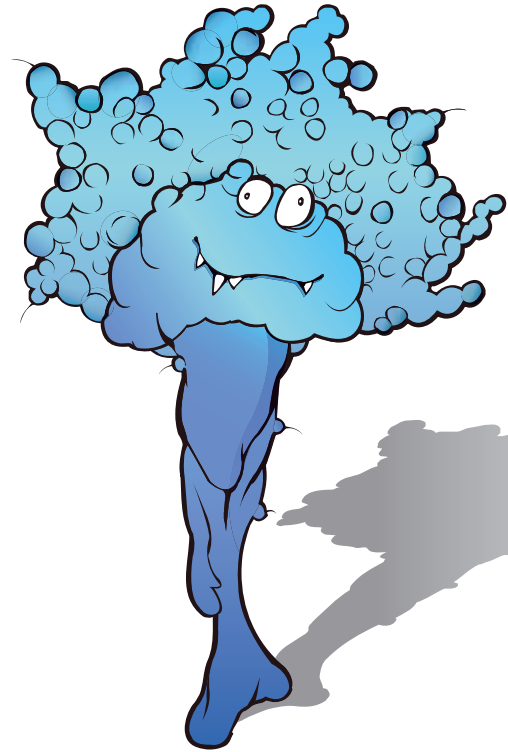


MycAssay™

Aspergillus

Rapid detection of Aspergillus DNA from lower respiratory tract samples using Real-Time PCR

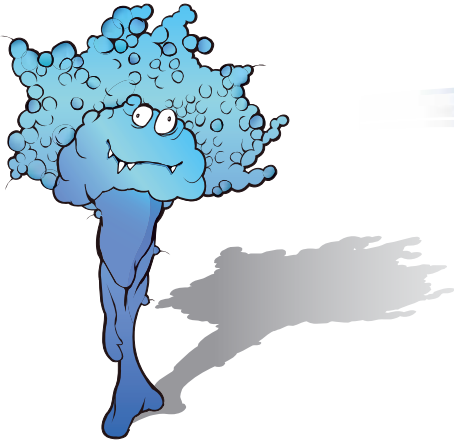


MycAssay™ Aspergillus is a CE marked, Real-Time PCR assay for the detection of *Aspergillus* DNA in lower respiratory tract samples.

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 Myconostica's fungal extraction system, **MycXtra®**, a result can be obtained within 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

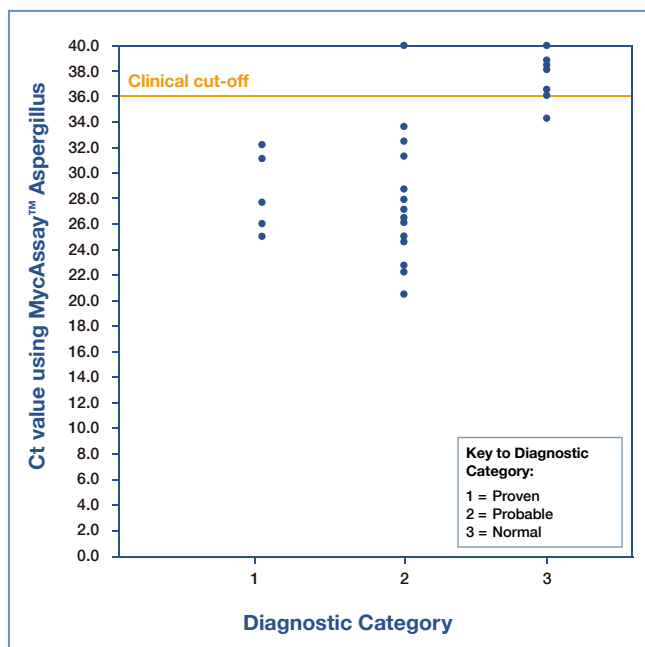


Figure 1.
CT of 36.0 set as clinical cut-off and based on probability of disease.

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
- Clinical cut-off
- Provides highly reproducible data
- Has an internal amplification control in every reaction to highlight false negative results
- Consists of closed tube reactions and single use reagents to reduce the risk of contamination

Experimental data

Clinical lower respiratory tract samples were extracted using **MycXtra®** and subsequently screened using **MycAssay™ Aspergillus** on the Cepheid SmartCycler®. The results obtained with **MycAssay™ Aspergillus** were compared to the clinical and culture diagnoses available for the samples.

When compared to the clinical diagnoses **MycAssay™ Aspergillus** provides a sensitivity and specificity of 94% and 91% respectively, with positive and negative probability values of 97% and 83%.

Comparing **MycAssay™ Aspergillus** results with Aspergillus culture positive data provides a sensitivity and specificity of 94% and 77% respectively, with positive and negative probability values of 91% and 83%.

These data compare favourably with traditional methods for diagnosing infections caused by Aspergillus spp. indicating that the use of **MycAssay™ Aspergillus** can enable the accurate diagnosis of invasive aspergillosis.

Product is
CE marked