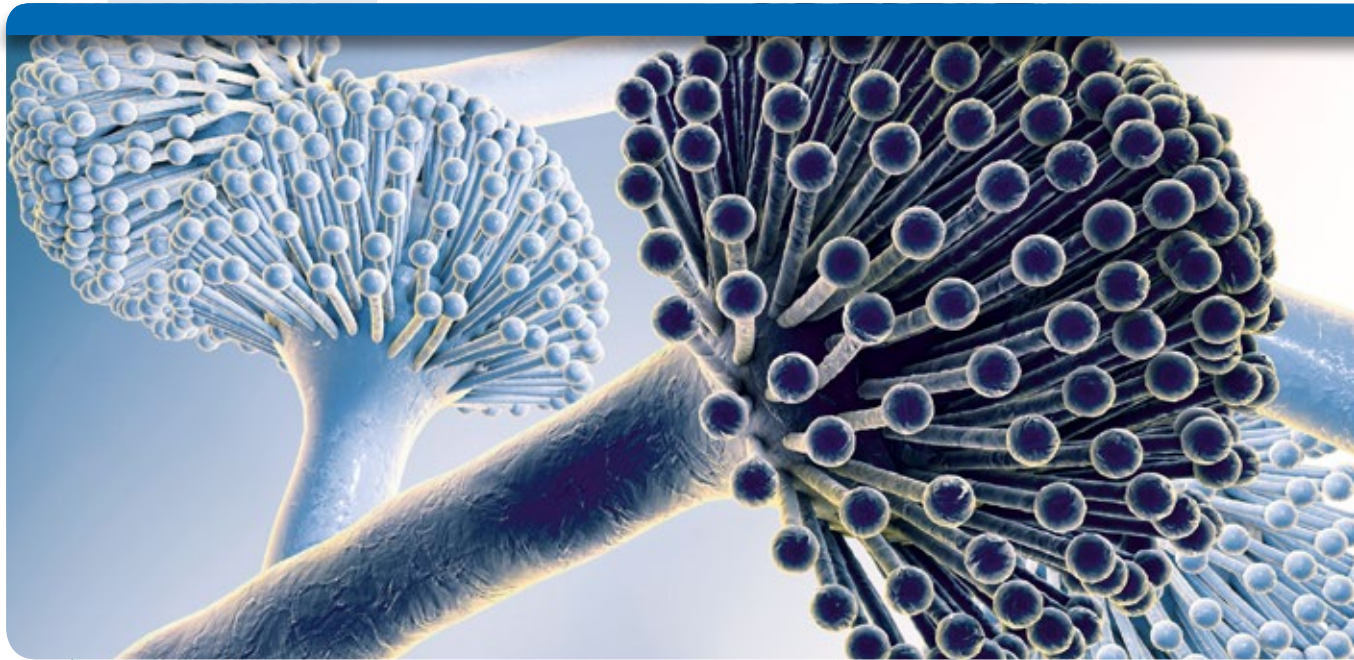


IVD



Fungiplex[®] Aspergillus Azole-R

● IVD Real-Time PCR

Fungiplex Aspergillus Azole-R

Fungiplex Aspergillus Azole-R is a real-time PCR test which identifies the **most common mutations of the Cyp51 gene associated with resistance to the azole class of antifungal drugs**. It provides rapid results with high sensitivity and specificity **without culture**.

Azole antifungal drugs are the primary option for the prophylaxis and treatment of invasive aspergillosis (IA). Resistance to azoles in *Aspergillus fumigatus* is emerging as a global health problem through both the use of azoles in the environment and their prolonged use in the management of patients with IA.

Delayed diagnosis, and limited treatment options for azole-resistant invasive aspergillosis results in poor patient outcomes, with mortality reported as high as 88%.¹ Early detection of resistance is crucial to ensure patients receive effective treatment quickly.

Resistance in *Aspergillus fumigatus* is caused by known mutations in the *Cyp51* gene that threaten the role of the azole class of antifungals:

- Tandem Repeat 34 (TR₃₄) and the associated amino acid substitution L98H
- Tandem Repeat 46 (TR₄₆) and the associated amino acid substitutions T289A and Y121F.

The Fungiplex Aspergillus Azole-R assay can rapidly detect the presence of the **tandem repeat sequences TR₃₄ and TR₄₆** to inform patient management. The assay is validated against DNA extracted from **serum, plasma and bronchoalveolar lavage (BAL)** fluid.

Sample	Limit of detection TR ₃₄ (ge)	Limit of detection TR ₄₆ (ge)	Thermocyclers (validated)	Time to result
Serum	50	50	√ ABI 7500	< 2 h from extraction (1-25 samples)
Plasma	50	50	√ ABI Quant Studio 5	
BAL	50	50	√ Bio-Rad CFX	
			√ Hain FluoroCycler XT	
			√ Mic qPCR Cycler	
			√ Roche Lightcycler 480 II	
			√ QIAGEN RotorGene	

LOD refers to 100% detection of simulated samples (genomic DNA) at the stated concentration.
'ge' = 'genome equivalents' per 500 µL of sample.

Fungiplex Aspergillus Azole-R

- provides **early detection** of the most **common mutations** associated with **azole resistance**
- has been designed to work as a **companion test to Fungiplex Aspergillus** and runs on the same conditions
- is provided in a **user-friendly format** that is compatible with **existing laboratory equipment** and produces results from extracted DNA in **less than 2 hours**.

¹Van der Linden et al. *Emerg Infect Dis* 2015; **21**(6): 1041-44.

Order Information: Part-No. 1858553 Fungiplex Aspergillus Azole-R PCR IVD Kit

The kit provides all necessary reagents for 25 tests.

Please contact your Bruker sales representative for availability of the IVD product in your country.

Fungiplex is a registered trademark of Bruker in the European Union and in the USA.

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