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The evaluation of real-time PCR assays for aiding the diagnosis of invasive fungal disease: real-time Aspergillus, and real-time Candida

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Background: Invasive fungal diseases (IFD) are a significant cause of mortality and morbidity, posing a risk to those patients that are immunosuppressed, such as those undergoing solid organ transplant, allogeneic haematopoietic stem cell transplant, or with prolonged stay in the intensive care unit. Difficult to diagnose, and with poorer patient outcomes directly attributable to delayed treatment, IFD is combatted in many healthcare settings by employing prophylaxis, and empiric therapy. In recent years PCR has been shown, in combination with other biomarkers, to be a promising tool in the development of diagnostic algorithms that drive pre-emptive, rather than empiric treatment. Bruker are developing a suite of multiplex Real Time PCR assays for the most common causative a123gents of IFD. The first two assays developed are for Invasive Aspergillosis (IA) and Invasive Candidiasis (IC), detecting the most common causative agents and differentiating those species resistant to first line treatment (Table 1). The assays have been designed to run under the same conditions, allowing case based selection of the most appropriate diagnostic tests.

Material/methods: A range of simulated samples were prepared from plasmid material and genomic DNA for known *Aspergillus* and *Candida* species over a dynamic range of 20 – 2 $\times 10^6$ ipc for plasmids and 10 CFU / 600 fg for genomic DNA. An internal control was included within each sample and samples were tested using either the Bruker Real Time *Aspergillus* assay, or the Bruker Real Time *Candida* assay, as required. Samples were divided across five verified thermocycler platforms to ensure accuracy across all systems. Data were collected to report analytical performance characteristics.

Results: The results from the Bruker Real Time PCR assays are summarized in Table 1.

Table 1: No. of IFD simulated samples detected by Bruker Real Time PCR

Real Time *Aspergillus* Targets	Tested	Detected	Real Time *Candida* Targets	Tested	Detected
Aspergillus spp. *(A. fumigatus, A. flavus, A. niger)*	360	359	***Candida spp.*** *(C. albicans, C. parapsilosis, C. tropicalis, C. dubliniensis)*	288	281
A. terreus	240	237	***C. glabrata***	72	72
			C. krusei	72	72
Total detected	**600**	**596**	**Total detected**	**432**	**425**
False positives		10	False positives		0
False negatives		4	False negatives		7
True negatives		668	True negatives		864
True positives		596	True positives		425
Sensitivity / Specificity (%)	**99.33 / 98.53**		**Sensitivity / Specificity (%)**	**98.38 / 100**	

Conclusions: The Bruker Real Time *Aspergillus* PCR, and Bruker Real Time *Candida* PCR exhibit excellent analytical performance when tested against *Aspergillus* or *Candida* species. A multi-centered diagnostic accuracy study will evaluate the utility of these assays in clinical laboratories.