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Fungal Diagnostic Assays That Clinicians Need in Resource-Limited Countries

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Fungal diseases pose a significant global health challenge, affecting over 1 billion individuals annually and causing more than 2.5 million deaths worldwide each year. The rising incidence of fungal infections is driven by factors such as population growth, environmental changes, increased global travel and trade, and the emergence of antifungal resistance (AFR), which complicates treatment and leads to higher rates of morbidity and mortality. Pathogens from genera such as *Aspergillus*, *Candida*, *Cryptococcus*, and *Pneumocystis* account for more than 90% of fungal-related deaths. Additionally, diseases like mucormycosis, which surged during the COVID-19 pandemic, contribute significantly to morbidity and mortality in specific clinical contexts (1).

The true prevalence of fungal diseases is often underestimated due to inadequate diagnostic capabilities. To address this, the WHO introduced the model list of in vitro diagnostics in 2018 to improve access to diagnostics, particularly in low- and middle-income countries (LMICs). This list includes tests for microscopy, fungal culture, blood culture, histopathology, and various PCR assays for fungal antigens and infections (2).

Despite these efforts, many LMICs face significant barriers to accessing essential diagnostic tools. Antifungal susceptibility testing (AST) and therapeutic monitoring, which are common in high-income countries, are rarely practiced in LMICs. The lack of mycology laboratories, limited expertise, and low awareness of fungal diseases among healthcare providers further exacerbate the problem. In many middle-income countries, the incidence of healthcare-associated infections like candidemia is disproportionately high, likely due to inadequate infection control measures, overuse of antifungals, and the absence of robust stewardship programs (3).

A survey conducted across 50 institutions in the Balkans revealed that traditional diagnostic methods, such as microscopy (96%) and culture (100%), were widely available. However, access to modern diagnostic tools like molecular assays (61%) was often limited and typically reliant on outsourced services. The use of matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) was less common in these countries compared to the rest of Europe, likely due to its high initial cost, despite its established reliability, speed, and cost-effectiveness. Fluorescent dyes, such as calcofluor white for diagnosing *Aspergillus* and *Mucorales* infections, were used in only about one-third of centers, primarily in high-income countries. While imaging techniques like ultrasound (100%) and CT scans (93%) were universally accessible, more advanced modalities such as PET CT and PET MRI were less commonly available, though they remain critical for specific clinical scenarios. These findings underscore the need for more equitable access to diagnostic resources in LMICs. Expanding access to molecular diagnostic technologies could greatly enhance the management of fungal infections in these regions (4).

The rapid and precise diagnosis of superficial, semi-invasive, and invasive aspergillosis is particularly important in resource-limited settings, where laboratory testing is either costly or unavailable. Timely diagnosis is also essential for monitoring resistance patterns and responding effectively in high-risk environments, such as during pandemics or natural

disasters, where cost-effective and rapid diagnostic methods are crucial (5).

Addressing the global burden of fungal infections requires the urgent implementation of rapid and accurate diagnostic tools. Although rapid antigen tests are available for some key fungal pathogens, the introduction of molecular testing at the point of care (POC) could significantly accelerate fungal diagnosis and improve clinical and public health outcomes. Molecular tests, with their high sensitivity, specificity, ease of use, and quick results, have the potential to fulfill this critical need (6).

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