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An evaluation of the analytical performance of the Dynamiker ® Fungus (1-3)- ß-D- Glucan assay in comparison to the Cape Cod Fungitell ® 1,3 beta-D glucan assay for the diagnosis of invasive fungal infections

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AN EVALUATION OF THE ANALYTICAL PERFORMANCE OF THE DYNAMIKER® FUNGUS (1-3)-*B*-D-GLUCAN ASSAY IN COMPARISON TO THE CAPE COD FUNGITELL® 1,3 BETA-D-GLUCAN ASSAY FOR THE DIAGNOSIS OF INVASIVE FUNGAL INFECTIONS.

Abstract

Background:

Left untreated invasive fungal infections (IFI) carry a high mortality rate. The broad fungal biomarker 1,3 beta-D-glucan (BDG) has become increasingly recognized as an adjunct diagnostic test, with the capability of producing results earlier than gold standard culture and is useful in directing clinicians to appropriate initiation of therapy. The Associates of Cape Cod Fungitell® is a widely used BDG assay however it serves predominantly larger laboratories. Alternative options should be sought to implement at lower throughput laboratories to avoid a delay in diagnosis.

Objectives:

We aimed to evaluate the performance of Dynamiker® Fungus assay in comparison to Fungitell® and to assess its precision in our setting.

Methods:

In this prospective laboratory-based study 100 patient serum samples were analysed on both Fungitell® and Dynamiker®. Quantitative and qualitative results were compared to Fungitell®. Additionally, both assays were assessed against gold standard culture and/ or *Pneumocystis jirovecii* PCR (PJP PCR) (60/100). The Dynamiker® precision was determined over 5 days, using the manufacturer's standard material.

Results:

The observed agreement was 74% (80% with a cut-off of 96 pg/ml), with a moderate categorical agreement (Kappa= 0.582, $P < 0.05$). Sensitivity and specificity were 63.64% and 92.86% respectively when compared to Fungitell®, and 75% and 69% for fungal culture respectively. Dynamiker® had excellent repeatability and reproducibility with no significant difference to the manufacturer's means.

Conclusion:

Although Dynamiker® was found to be less sensitive than Fungitell®, it is precise with moderate overall categorical agreement. Further clinical studies are warranted.