

**FUNGITELL<sup>®</sup> ASSAY**  
THE GOLD STANDARD IN  
(1→3)-β-D-GLUCAN TESTING  
FOR RAPID INVASIVE FUNGAL  
INFECTION SCREENING



Quality Matters... Trust Fungitell<sup>®</sup>

**Not all (1→3)-β-D-Glucan assays are created equal – Accept no imitations.**

Fungitell<sup>®</sup> is the first and **the only CE Marked AND FDA-Cleared** serum test *in vitro* diagnostic for detecting (1→3)-β-D-Glucan as an aid to the diagnosis of invasive fungal infection.

- **Excellent Negative Predictive Value (NPV) with Demonstrated Patient Safety**<sup>123</sup>
- **Over a decade of proven clinical use in the marketplace**
- **100+ peer-reviewed clinical papers**

# (1→3)-β-D-GLUCAN ASSAY COMPARISONS: RAPID SCREENING FOR INVASIVE FUNGAL INFECTION IN A CLINICAL SETTING

	Associates of Cape Cod, Inc.	Dynamiker®	ERA Biology
<b>Assay Name</b>	<b>Fungitell®</b>	Fungus	Goldstream® Fungus
<b>Model No.</b>	<b>FT001</b>	DNK-1401-1	GCT-110T, GKT-12M, GKT-25M
<b>FDA Cleared</b>	✓	✗	✗
<b>Over a decade of proven clinical use in the marketplace</b>	✓	✗	✗
<b>100+ peer-reviewed clinical papers</b>	✓	✗	✗
<b>Excellent NPV with Demonstrated Patient Safety<sup>123</sup></b>	✓	✗	✗
<b>Limulus Amebocyte Lysate (LAL) original manufacturer</b>	✓	✗	✗
<b>ISO 13485:2003</b>	✓	✓	✓
<b>EN ISO 13485:2012</b>	✓	✓	✓
<b>CE Marked</b>	✓	✓	✓
<b>Main reagent can be frozen?</b>	✓	✓	Not disclosed
<b>Qualitative Agreement Between Fungitell® and Dynamiker® Fungus Kit</b>	Recognized Reference Standard	Fair (Kappa: 0.5) <sup>4</sup>	No Published Comparison
<b>Quantitative Correlation Between Fungitell® and Dynamiker® Fungus Kit</b>	Recognized Reference Standard	Weak (Spearman's Coefficient: 0.3874) <sup>4</sup>	No Published Comparison

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2. Posteraro, B., Tumbarello, M., De Pascale, G., Liberto, E., Vallecocchia, M.S., De Carolis, E., Di Gravio, V., Treccarichi, E.M., Sanguinetti, M. and Antonelli, M., (1→3)-β-D-Glucan-based antifungal treatment in critically ill adults at high risk of candidaemia: an observational study, Journal of Antimicrobial Chemotherapy Advance Access published April 28, 2016
3. Prattes, J., Hoenigl, M., Rabensteiner, J., Raggam, R.B., Pruessner, F., Zollner-Schwetz, I., Valentini, T., Hönigl, K., Fruhwald, S., and Krause, R., Serum 1,3-beta-D-glucan for the antifungal treatment stratification at the intensive care unit and the influence of surgery, Mycoses Diagnosis, Therapy and Prophylaxis of Fungal Diseases, June 2014
4. White, P.L., Price, J.S., Poos, R.B., & Barnes, R.A., An evaluation of the performance of the Dynamiker® Fungus (1→3)-β-D-Glucan Assay to assist in the diagnosis of invasive aspergillosis, invasive candidiasis and Pneumocystis pneumonia Received 26 September 2016; Revised 24 November 2016; Accepted 6 January 2017; Editorial Decision 29 November 2016

Fungitell® is a trademark of Associates of Cape Cod, Inc. Dynamiker® is a trademark of Dynamiker Biotechnology (Tianjin) Co., Ltd. Goldstream® is a trademark of Tianjin ERA Biology Engineering Co., Ltd.



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