



Specialists in Endotoxin and Glucan Detection

For Immediate Release

Contact: Celeste Jones
508-274-3637
fungitell@acciusa.com
www.acciusa.com

Introducing Fungitell STAT™ a single sample test used in the diagnosis of Invasive Fungal Infections.

July 31, 2020; East Falmouth, MA – Associates of Cape Cod, Inc. (ACC), an East Falmouth, MA based IVD Company, is pleased to formally launch Fungitell STAT™. Fungitell STAT™ is the first and only single sample format FDA – cleared and CE marked rapid *in vitro* diagnostic screening test for invasive fungal infection (IFI) that detects (1→3)-β-D-glucan in serum within 60 minutes. This near POC test offers the convenience of either a single patient sample test run or up to seven patient samples per test run providing clinicians with a rapid assessment of patient serum Beta Glucan (BG) levels used as an aid in the early diagnosis of IFI. Using an incubating absorbance tube reader and BG Analytics™ software, this single sample test allows for the rapid stratification of patients as diagnostically positive, negative or indeterminate relative to serum BG burden.

(1→3)-β-D-glucan is produced by common primary human fungal pathogens such as *Candida* spp., *Aspergillus* spp. and *Pneumocystis* spp., as well as many opportunistic fungal pathogens. During infection, (1→3)-β-D-glucan produced by certain fungal pathogens may be released into the bloodstream and then detected by the Fungitell STAT™ assay using patient blood serum. This assay is intended for use as a diagnostic aid in clinical situations where rapid results concerning IFI are required; Fungitell STAT™ should be used in conjunction with other diagnostic procedures.

Dr. AJ Meuse, President and Chief Executive Officer of ACC states, “We are pleased to introduce the first and only FDA-cleared and CE Marked single format (1→3)-β-D-glucan assay. ACC believes that Fungitell STAT™ will offer clinicians the flexibility of decreased turnaround time which is vital for clinical utility in the diagnosis of IFI.”

ACC is one of the world's largest manufacturers of products developed to detect and quantify Gram-negative bacterial endotoxins and (1→3)-β-D-glucans. Our products are used worldwide by leading pharmaceutical and medical device companies to ensure the safety of their parenteral drugs, biological products and medical devices. Our goal is to provide the best products and services, as well as the best technical support and customer service, to enhance the productivity and efficiency of all customers. ACC is I.S. EN ISO 13485:2016 and ISO 13485:2016 certified; its laboratories are FDA Inspected and DEA Licensed and our Beacon Diagnostics® laboratory is CLIA certified.

ACC's corporate headquarters are located in East Falmouth, Massachusetts with offices in the UK and Germany. Founded in 1974, ACC was the first to be licensed by the FDA to manufacture LAL for use as a quality control test for endotoxin detection in the pharmaceutical and medical device markets. Over the years, ACC has grown to be an internationally recognized leader in the detection of endotoxin and (1→3)-β-D-glucans, providing our products and services worldwide. Associates of Cape Cod, Inc. is a Seikagaku Corporation group company.