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NEWS RELEASE

Fungitell® is awarded FDA Breakthrough Device Designation for testing of Cerebrospinal Fluid (CSF) matrix as an aid in the diagnosis of Central Nervous System (CNS) fungal infection

Falmouth, Massachusetts (USA)— August 26, 2024

Associates of Cape Cod, Inc. (ACC), a Falmouth, MA based IVD Company, is delighted to announce that Fungitell® testing in the cerebrospinal fluid (CSF) matrix has been granted Breakthough Device designation from the U.S. Food and Drug Administration (FDA). The diagnosis of fungal infection of the central nervous system (CNS) represents a challenge since it is not associated with specific clinical signs or symptoms, making missed or delayed diagnoses significant contributing factors to high mortality rates. Fungitell® is a protease zymogen-based colorimetric assay that measures (1→3)-β-D-glucan, a major cell-wall component of various medically important fungi. Measurement of CSF (1→3)-β-D glucan titers may be more predictive of disease than serum titers for the diagnosis and clinical management of CNS fungal infection. CSF (1→3)-β-D glucan titers may be detected earlier than positive CSF culture and help guide optimal patient care.

The Breakthrough Devices Program is reserved for certain medical devices and device led combination products that provide for more effective treatment of diagnosis of life threatening or irreversibly debilitating diseases or conditions for which no approved or cleared alternatives exist. The program provides patients and health care providers with timely access to medical devices by speeding up development, assessment, and review for premarket approval, 510(K) clearance and De Novo marketing authorization.

“The Breakthrough Device designation for Fungitell® testing in the CSF matrix will represent a significant milestone in the diagnosis of CNS fungal infection and will have a tremendous impact on the lives of patients around the world.” said Dr. AJ Meuse, President and Chief Executive Officer of ACC. “Once approved, we look forward to introducing the expanded indication of our current Fungitell® product to include testing of the CSF matrix as an aid in the diagnosis of CNS fungal infection.”

About ACC — A Seikagaku Group Company
Specializing in recombinant and traditional chromogenic and turbidimetric reagent technologies, ACC has been a global leader in endotoxin and (1,3)-β-D-glucan detection products and services for 50 years. ACC pioneered modern LAL testing methodology and was the first U.S. FDA-licensed company to manufacture LAL reagents; ACC is today recognized as an international leader in endotoxin and (1,3)-β-D-glucan detection. Visit www.acciusa.com for more information.

About Fungitell®
Fungitell® is the first and **only FDA-cleared and CE marked** rapid *in vitro* diagnostic test for detecting (1→3)-β-D-glucan in serum as an adjunct to diagnosis of invasive fungal infection (IFI) including *Candida*, *Aspergillus* and *Pneumocystis*.

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