NEWS RELEASE

# Inbiome Receives FDA Breakthrough Device Designation for Revolutionary Molecular Culture ID Technology, Transforming Bacterial Diagnostics

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- More precise diagnostics lead to quicker, more accurate patient treatment, saving lives and improving patient outcomes
- US market introduction foreseen early 2026

Amsterdam, The Netherlands, 26 September, 2024 – **inbiome**, a leading innovator in diagnostic technologies, today announced that its Molecular Culture ID has been granted **Breakthrough Device Designation** by the U.S. Food and Drug Administration (FDA). This grant highlights the FDA's recognition of the potential impact of inbiome's technology in transforming the landscape of infectious disease diagnostics. The prestigious and highly competitive Breakthrough Device designation is awarded in exceptional cases, to devices that offer significant improvements over existing options.

Bacterial infections significantly impact public health, causing one in five human deaths worldwide. Current diagnostic methods often require several days to yield results. With hospitals typically performing hundreds of bacterial diagnostic tests every day, this delay is problematic, as it delays correct treatment, prolongs hospital stays and negatively impacts patient outcomes.

**Molecular Culture ID** is a new diagnostic test that addresses these challenges by combining advanced chemistry with AI, to rapidly detect and identify over 200 bacterial species from various bodily samples. This first-of-its-kind technology provides same-day, highly accurate diagnoses, significantly reducing waiting times, improving patient

outcomes, and lowering healthcare costs. By enhancing the diagnosis of critical infections, including pleural, peritoneal, joint, bone, pericardial, and surgical wound infections, Molecular Culture ID represents a major advancement in the timely and effective treatment of bacterial infections.

Inbiome plans to introduce its technology to the U.S. market by early 2026 and is currently partnering with leading U.S. hospitals on implementation studies. This will facilitate seamless integration into U.S. hospital workflows.

Perspective of Carl Wittwer, member of inbiome's Advisory Board

To help make inbiome's ambitious vision a reality, the company recently welcomed industry veteran Professor Carl Wittwer to its Advisory Board, bringing invaluable expertise at a crucial time. Professor Wittwer, inventor of modern PCR technology (among others LightCycler®) and co-founder of Idaho Diagnostics (later: Biofire), will offer both technical guidance and business acumen. His experience will be instrumental in advancing inbiome's mission to revolutionize bacterial diagnostics and expand its global impact.

"inbiome's PCR technology provides a unique analysis, capable of distinguishing hundreds of bacterial pathogens in a single multiplex test. The U.S. FDA's Breakthrough Device Designation will speed this innovative technology into the U.S. market. I look forward to more interaction with the ground-breaking team at inbiome," said Professor Carl Wittwer.

"We are honored to receive this designation from the FDA," said Dries Budding, CEO of inbiome. "With Molecular Culture ID our ambition is to revolutionize diagnostics of infectious diseases. This recognition by the FDA will help us bring this innovation to patient care as soon as possible."

A Future-Focused Vision

The Molecular Culture ID is the first in a series of new diagnostic technologies that inbiome plans to introduce over the coming years. The company's vision is to achieve same-day diagnostics for all infectious diseases by 2030, which promises to enhance global healthcare delivery and patient care radically.

"Our vision of achieving same-day diagnostics for all infectious diseases by 2030 is ambitious but within reach," added Jord Budding, COO of inbiome. "This milestone will not only enhance patient outcomes but also play a crucial role in the fight against the global threat of antimicrobial resistance, by ensuring antibiotics are used appropriately and effectively."

Support from the European Innovation Council (EIC)

Inbiome's groundbreaking work has been recognized and supported by the European Innovation Council (EIC). The company received an EIC Accelerator grant in 2023 to support the go-to-market strategy of its first in vitro diagnostic (IVD) device. This funding has been important in advancing the development and commercialization of

Molecular Culture ID.

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About Breakthrough Device Designation

The FDA's Breakthrough Devices Program is designed to expedite the development and review of medical devices that offer significant advantages over existing options in diagnosing or treating life-threatening or irreversibly debilitating diseases. This designation not only accelerates the regulatory review process but also facilitates more efficient reimbursement pathways. The goal of the program is to provide patients and healthcare providers with timely access to important medical innovations, consistent with the Agency's mission to protect and promote public health.

About inbiome

Founded with a mission to revolutionize the diagnostics industry, inbiome leverages cutting-edge molecular technologies in combination with modern AI to develop diagnostic solutions that are fast, accurate, and accessible. The company's groundbreaking work is poised to set new standards in the field of infectious disease diagnostics, contributing significantly to patient care and the global fight against antimicrobial resistance.

Inbiome co-operates with US and European industry leaders across the medical, technology and biotechnology industries, as well as prestigious academic institutions, on both clinical and commercial research and product development.

For more information, visit **inbiome's website**.

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Attachment

- **Inbiome Molecular Culture**

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Inbiome Molecular Culture

Inbiome Molecular Culture ID box