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Genetic Analysis AS and Pangea Laboratory LLC announces the launch of GA-map® MHI GutHealth in the USA

OSLO, NORWAY/IRVINE, CA, USA – 29 July 2025: Microbiome DX company Genetic Analysis AS ("GA") and Pangea Laboratory LLC ("Pangea") announces the launch of the GA-map® MHI GutHealth as a Research Use Only (RUO) test in the USA. As part of the collaboration Pangea will perform analysis in their CLIA-certified, CAP-accredited laboratory in Tustin, California.

The GA-map® MHI GutHealth is the first microbiome-based diagnostic test providing clinically actionable insights into antibiotic-induced microbiome imbalances. The test has been developed by GA in collaboration with Ferring Pharmaceuticals and combines GA's proprietary GA-map® technology with Ferring's Microbiome Health Index™ (MHI). MHI* is a validated biomarker measuring the ratio of pro-inflammatory versus anti-inflammatory bacteria in the patient's gut, demonstrated in recurrent *Clostridioides difficile* (rCDI) infected patients¹.

Initially the test will be targeted towards patients with rCDI, providing clinicians with a rapid tool for baseline microbiome imbalance assessment and for monitoring the effect during microbiome restoration treatment. rCDI infection impacts approximately 500,000 patients annually in the United States, and up to 35% of initial CDI cases will experience a recurrence, which is associated with up to 30,000 deaths annually.

Beyond rCDI, the test has the potential to support clinical decision-making in patient groups where antibiotic-associated microbiome imbalance plays a critical role (ie . Graft-versus-Host Disease (GvHD), infectious diseases, immunocompromised patients and patients colonized with multidrug-resistant organisms.

The test will now be available for analysis at Pangea. As part of the collaboration, GA will supply reagent kits to Pangea. The agreement outlines an ongoing partnership without predefined order volumes or minimum delivery commitments. Revenues for GA will be generated based on the number of tests sold. GA is not obliged to make any additional financial investments as part of the collaboration.

John Moore, CEO of Pangea comments:

"Partnering with Genetic Analysis to offer the GA-map® MHI GutHealth test in the U.S. supports our commitment to advancing microbiome diagnostics and improving patient care. This molecular test has the capability to bring much-needed clarity to managing recurrent C. difficile infections by quantifying microbiome disruption."

CEO Ronny Hermansen comments:

"We are thrilled to have entered into an agreement with Pangea and by this adding an excellent partner for the launch of the GA-map® MHI GutHealth test in the U.S., marking an important milestone for GA. Given that CDI affects approximately 500,000 patients annually in the U.S., this launch represents a substantial commercial opportunity and paves the way for further clinical applications in other disease areas linked to microbiome health. We are driving vital changes in microbiome diagnostics, where there is a need for standardized and rapid testing of the human microbiomes."

^{*}The MHI™ is owned by Ferring Pharmaceuticals and licensed to Genetic Analysis on a non-exclusive basis.

¹ https://www.frontiersin.org/journals/microbiology/articles/10.3389/fmicb.2021.781275/full

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About Pangea Laboratory LLC

Founded in 2014, Pangea Laboratory is a Clinical Laboratory Improvement Amendments (CLIA) certified, and College of American Pathologists (CAP) accredited diagnostics company dedicated to simplifying diagnosis for critical health conditions.

For more information, visit https://pangealab.com

About Genetic Analysis

Genetic Analysis AS (GA) is a science-based diagnostic company and pioneer in the human microbiome field with more than 15 years of expertise in research and product development. The unique GA-map® platform is based on a pre-determined multiplex targets approach specialized for simultaneous analysis of a large number of bacteria in one reaction. The test results are generated by utilizing the clinically validated cutting edge GA-map® software algorithm. This enables immediate results without the need for further bioinformatics work. GA's vision is to become the leading company for standardized gut microbiota testing worldwide, and GA is committed to help unlocking and restoring the human microbiome through its state-of-the-art technology. GA employs a team of highly qualified employees with scientific backgrounds and competence in sales, operations, bioinformatics, molecular biology, and bioengineering.

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