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Genetic Analysis AS: Genetic Analysis AS announces CE-IVDR marking for its GA-map® Sample Collection Kit

Oslo, Norway, November 26, 2024 - Genetic Analysis AS (the "Company", Ticker: GEAN) is proud to announce that its GA-map® Sample Collection Kit has obtained CE-IVD marking under the In Vitro Diagnostic Regulation (EU) 2017/746. The GA-map® Sample Collection Kit is a device that simplifies the sample collection process, allowing easy and user-friendly collection of fecal samples at home, without compromising the quality and integrity of the test results. The kit inactivates bacteria and viruses and has documented sample preservation at room temperature for up to four weeks and at -20°C for up to six months. The CE-IVD marking enables broader market access, allowing for increased commercialization opportunities to a wider range of end customers in the European markets.

The GA-map® Sample Collection Kit is now commercially available and will also be offered as a stand-alone product for researchers and laboratories in need of fecal collection sampling, as well as a direct-to-consumer setting. The GA-map® Sample Collection Kit has been designed to be used in conjunction with the GA-map® Dysbiosis Test, a CE-marked probe-based gut microbiota test that can diagnose and characterize dysbiosis in patients with irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD). The market for Microbiome analysis is growing rapidly, and GA is changing the market by lowering the entry barrier for smaller labs to start microbiome testing. The new collection kit is a great complementary product to the Company's offering to the research lab customers.

CEO Ronny Hermansen comments:

"The CE-IVD marking of the GA-map® Sample Collection Kit demonstrates that the product meets the high standards of quality, safety, and performance required by the In Vitro Diagnostic Regulation (EU) 2017/746. Having acquired the certification, we can now expand our commercialization efforts to a significantly broader customer base, thereby enhancing our sales potential and at the same time strengthening our presence in the microbiome analysis field. We believe that our products can make a difference in the diagnosis and management of patients with gut-related disorders, and we look forward to bringing them to more markets and regions in the near future."

For further information, please contact:

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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

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of highly qualified employees with scientific backgrounds and competence in sales, operations, bioinformatics, molecular biology, and bioengineering.

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