fCAL® turbo RECEIVES 510(K) CLEARANCE IN THE USA

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Gentian Diagnostics AS is pleased to announce that BÜHLMANN has received 510(k) clearance (K190784) from the FDA for the BÜHLMANN fCAL® turbo. BÜHLMANN is Gentian's exclusive commercial partner for the fecal calprotectin products worldwide.

The potential US fecal calprotectin market is of an estimated size of USD ~30 million, while the current market is of an estimated size of USD ~5 million. Hilja Ibert, CEO Gentian Diagnostics AS comments "While the fecal calprotectin market size in the US is still quite small, fecal calprotectin is part of a high annual growth market, as observed in Europe. The already FDA cleared BÜHLMANN fCAL® ELISA has paved the way for BÜHLMANN fCAL® turbo which will allow for high throughput analysis of fecal calprotectin in applicable core laboratories and screening programmes."

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ABOUT GENTIAN DIAGNOSTICS AS:

Gentian Diagnostics AS is a medical diagnostics company listed on Merkur Market, Oslo Stock Exchange with the ticker "GENT-ME".

Gentian is headquartered in Moss, Norway, with a representative office in China and distribution subsidiaries in Sweden and USA.

Gentian designs, develops and markets in vitro diagnostic reagents (IVD) based on its proprietary Nanosense technology. The goal is to offer efficient and accurate reagents for major clinical chemistry platforms with a focus within the areas of kidney disease, cardiac disease, inflammation and veterinary medicine. The Nanosense technology will enable users to move assays from low volume immunology platforms to fully automated, high throughput instruments with shorter turnaround times, better workflow and improved cost efficiency.