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Clifford Morris, PhD, FAAMM

Kihealth, Saint Augustine, FL, USA

Clinical Applications of Monitoring Unmethylated Insulin cfDNA Associated with Beta-Cell Death for Diabetes and Metabolic Diseases

Abstract:

Metabolic disorders, including Type 1 and Type 2 Diabetes, are significant global health challenges. The CDC estimates that 37.3 million Americans have diabetes, and another 96 million adults are diagnosed with prediabetes each year. Among individuals in Stage 2 diabetes, 75% will progress to full-blown diabetes within five years, highlighting the urgent need for early-stage monitoring tools. Current diagnostics rely on indirect markers, such as blood glucose and insulin levels, which do not capture real-time cellular damage. By the time of diagnosis, up to 60% of beta cell function may already be lost.

Our proprietary ßeta Test™ uses droplet digital PCR (ddPCR) technology to directly measure beta cell function by detecting unmethylated insulin cfDNA released when beta cells break down. This process can identify metabolic changes up to 625 days earlier than current methods, offering a critical advantage in early detection and prevention. Research shows that insulin cfDNA levels correlate with early-stage beta-cell stress in prediabetes and metabolic syndrome, autoimmune destruction in Type 1 Diabetes, and progressive beta-cell loss in Type 2 Diabetes. This technology also helps track treatment responses, including therapies like GLP-1 receptor agonists and immunotherapies.

Early intervention based on this technology can reduce beta-cell stress, improve metabolic flexibility, and delay or prevent disease progression. It enables early identification of high-risk patients, therapeutic efficacy monitoring, and personalized diabetes management. By integrating INS cfDNA testing into clinical practice, providers can enhance detection, optimize treatments, and ultimately reduce complications, providing a new non-invasive approach to metabolic disease management.

Keywords: diabetes, beta-cell, diagnostic, early detection, cfDNA, liquid biopsy