EarlySignal-BC: MSRE-ddPCR cfDNA Methylation Assay for Early Breast Cancer Screening

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Technology

- Methylation-sensitive restriction enzyme (MSRE) selectively cleave unmethylated cfDNA, enriching intact methylated sequences that reflect tumor-specific epigenetic signals
- Digital droplet PCR (ddPCR) provides absolute counting of rare methylated alleles from low cfDNA input, achieving analytical sensitivity and specificity amid excess unmethylated DNA
- AI-guided analysis of epigenetic data from >1,200 individuals across tumors, adjacent normals, and blood, capturing tissue-specific, early arising BC signals
- An AI-algorithm integrates multi-gene methylation levels to generate a calibrated, quantitative breast cancer risk score for clinician decision support

Key Advantages

- High analytical performance: detects rare methylated molecules from low cfDNA inputs
- Early, tissue-specific signal: leverages tumor-specific DNA methylation that arises early in carcinogenesis
- Non invasive and accessible: simple blood draw enables cost-effective population screening
- Data and AI advantage: build a longitudinal methylation atlas to continuously improve models and enable new panels across other cancers
- Scalable commercialization path: LDT available near-term with transition to IVD kit; compatible with market-ready ddPCR systems and supported by leading IVD partners

Intellectual Property

- File an early provisional covering core inventions before any disclosure, then a PCT at 12 months and enter key national phases (CN, JP, KR, US, EP)
- Build multiple claim families: (1) biomarker panel and CpG loci; (2) assay methods; (3) kits/primers/probes and controls; (4) clinical use claims; (5) algorithmic risk scoring
- Keep AI training data, feature engineering, model weights/hyperparameters, QC thresholds, and certain workflow parameters as trade secrets
- Freedom-to-operate and licensing: run FTO on MSRE enzymes, ddPCR platforms, cfDNA extraction, and methylation detection methods

Stage of Development

- Discovery: AI-selected 4-gene methylation panel; established proprietary MSRE-ddPCR workflow; initiated pilot plasma runs to confirm sensitivity/specificity (completed)
- Analytical validation and optimization: lock primers/probes and MSRE conditions on commercial ddPCR platforms; define LoD/LoQ, precision, linearity, and interference; standardize sample handling; train/lock AI risk model (*in progress*)
- Clinical validation and commercialization readiness: initiate multi-center clinical studies with IRB approvals; preparing NMPA Class III submission dossier; LDT launch in certified labs; IVD design control, QMS, and supply chain setup with leading industry partners (in planning)

Opportunities

- Pharma and co-development: partner for companion diagnostics, trial stratification, and real-world evidence; co-market with IVD platform and enzyme suppliers
- Population screening and adjunct use: fill gaps where mammography underperforms, triage indeterminate imaging, and reduce unnecessary biopsies
- Clinical expansion: extend to MRD and treatment response monitoring, surveillance in high-risk cohorts, and pre-/post-operative decision support
- Geographic and channel scale: launch as LDT, then IVD kit leveraging existing ddPCR install base; expand across APAC, then US/EU with public health and hospital partnerships; targeting global cfDNA cancer screening market valued at >US$5B in 2025 and an expected CAGR of 20%

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