A COST-EFFECTIVE DIGITAL PCR DIAGNOSTIC METHOD FOR DETECTION OF MICROSATELLITE INSTABILITY (MSI) IN TISSUES AND BODY FLUIDS OF CANCER PATIENTS

Microsatellite instability (MSI) refers to the hyper mutability of short repetitive sequences of the cancer genome due to loss of DNA mismatch repair activity. MSI is found across several cancer types and has recently emerged as a predictive pan-tumor biomarker of immunotherapy efficacy. The present invention is relevant to the field of oncology and suitable for therapeutics and research applications. Especially it allows detection of MSI from any source of DNA with high sensitivity.

APPLICATION

Drop-off MSI ddPCR assay reliably detects MSI in FFPE tumor tissues as well as plasma and serum samples. The product could be made available as service or as a companion diagnostic kit.

PROBLEM ADDRESSED

Available molecular assays for the testing of MSI positive solid tumors currently fail to meet the need for effective MSI screening methods. The present innovation combines in a single assay the advantages of the PCR and NGS approaches and fulfills the unprecedented medical need for non-invasive large-scale screening of MSI.

COMPETITIVE ADVANTAGES

• Cost-effective, fast, easy and convenient method to detect MSI
• High sensitivity and specificity.
• Detection from any source of DNA, including cfDNA.
• Adoption do not require any change into clinical practice and convenient scale-up into numerous health care center around the world.

Results for high level microsatellite instability (MSI-H) versus microsatellite stable (MSS). The test shows high sensibility and sensitivity in every kind of samples.
DEVELOPMENT STATUS

The test is **reproducible** and has been **validated** on retrospective samples including FFPE and body fluid samples. This cohort includes plasma samples before and during treatment with immunotherapy. The test is currently being further optimized on retrospective samples. Next step is to validate the test on a large prospective trial.

IP STATUS & OWNERS


WHAT ARE WE LOOKING FOR?

Interested industrial partners for **collaboration** to further validate retrospectively and prospectively the test and/or **licensing opportunities** for exploitation and commercialization.

PUBLICATIONS

- Stern et al., *AACR Annual Meeting* 2018 (DOI: 10.1158/1538-7445.AM2018-4599)

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