

New droplet digital PCR for highly sensitive detection of microsatellite instability

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Background & objectives

Management of colorectal cancer (CRC) patients relies on the accurate determination of microsatellite instability (MSI) status. MSI status can have an influence on therapy decisions centered on immune checkpoint inhibitors.

Methods

In this study a novel droplet digital PCR (ddPCR) kit for MSI status determination was validated across 3 separate CRC patient cohorts.: 102 tumor samples from the ALGECOLS cohort, 129 plasma samples from the RASANC cohort and 23 plasma samples plus 17 matched tumor samples from the ADIGYN cohort. Each cohort was assessed for MSI status using the novel ddPCR kit and compared to historical and/or newly obtained results, (either immunohistochemistry analysis or PCR amplification).

Results

Concordance between ddPCR and conventional MSI determination methods for the analysis of tissue samples was 97.1% for ALGECOLS and 100% for ADIGYN cohorts.. When looking at positive ctDNA samples, a concordance of 97.6% was observed for the RASANC cohort and 100% for the ADIGYN cohort .

Conclusion

This study illustrates that ddPCR MSI testing represents a rapid, sensitive and accurate method with a strong correlation to established methods. Moreover, the ability of the described approach to monitor MSI status in both tumor and plasma enhances the potential for the use of MSI status in longitudinal monitoring of CRC patients.