The aim of this study was to use a personalized multiplex-PCR NGS platform targeting 16 tumor-specific mutations per patient to assess minimal residual disease post-operatively and to monitor treatment response in CRC.

Methods

- A total of 58 patients with stage IV CRC, treated with adjuvant chemotherapy (ACT) plus or minus systemic therapy were included. Plasma samples were collected longitudinally at baseline prior to surgery and at scheduled control visits after surgery (Figure 1A).

- Whole-exome sequencing identified somatic mutations; following the analytically-validated Signatera 16-plex assay, 16 cancer-specific mutations were monitored along with the Signatera 16-plex assay (Figure 1B).

- A positive ctDNA test result was defined as the presence of ctDNA tumor mutations in the blood sample obtained by week 6 and prior to start of ACT. (A) Kaplan-Meier analysis of recurrence free survival stratified by ctDNA status. Patients without event were censored at 1273 days.

- All samples were collected longitudinally at baseline prior to surgery and at scheduled control visits after surgery (Figure 1A).

- Clinical follow-up was performed for all patients post-operatively. Relapse rates were compared between patients who had a positive and negative ctDNA test result (Figure 1B).

- Figure 6. Plasma ctDNA Analysis Reveals Actionable Mutations During Surveillance

- Actionable mutations were monitored along with the Signatera 16-plex assay (Figure 1B).

- A total of 10 patients post-operative ctDNA-positive prior to treatment with adjuvant chemotherapy.

- Figure 7. Time to Recurrence Based on Radiology, ctDNA and CEA

- Time to recurrence was defined as the time from surgery to recurrence detected by both modalities.

- In conclusion, the personal multiplex-PCR NGS platform targeting 16 tumor-specific mutations per patient is an efficient and effective method to detect minimal residual disease post-operatively and to monitor treatment response in CRC.

- Table 1. Patient Characteristics and Demographics

- Clinical follow-up was performed for all patients post-operatively. Relapse rates were compared between patients who had a positive and negative ctDNA test result (Figure 1B).

- Figure 8. Plasma ctDNA Analysis Reveals Actionable Mutations During Surveillance

- Actionable mutations were monitored along with the Signatera 16-plex assay (Figure 1B).

- A total of 10 patients post-operative ctDNA-positive prior to treatment with adjuvant chemotherapy.

- Figure 7. Time to Recurrence Based on Radiology, ctDNA and CEA

- Time to recurrence was defined as the time from surgery to recurrence detected by both modalities.

- Reference