

Abstract #240491**Prospective Clinical Study of Circulating Tumor Cells For Colorectal Cancer Screening**

Podium Presentation On Circulating Tumor Cell Count From A Blood Sample For Colorectal Cancer (CRC) Prevention

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Background: Up to 25% of patients with adenomas progress to having colorectal cancer. If detected early, adenomas can be removed with a diagnostic colonoscopy procedure, preventing cancer. Invasive colonoscopy is the only screening method with the sensitivity to accurately detect adenomas, but has a low compliance rate of 38% for screening. Available non-invasive tests (including stool-based multi-analyte tests) have very limited sensitivity for adenomas. Hence, there is an unmet need for a non-invasive test for adenoma detection.

Methods: IRB-approved prospective study was conducted in 627 subjects 50 year or older- recommended for routine CRC screening- 405 subjects had adenoma or CRC, confirmed by colonoscopy with tumor biopsy. 2mL peripheral blood was processed using the CellMax biomimetic platform (CMx), which uses a microfluidic biochip to enumerate circulating tumor cells (CTCs). Nominal logistic regression was used to assess performance while proportional odds logistic regression and Cuzick's trend test were used to determine association of CTC counts with cancer stage. **Results:** An increase in CTC count was significantly correlated with an increase in disease burden (Cuzick's Test p-value < 0.0001). Furthermore, there was a significant association between CTC counts and stages of adenoma-carcinoma progression (Likelihood ratio p-value < 0.0001). The CTC enumeration was able to differentiate between healthy and diseased patients (adenoma + cancer). Mean CTC Counts, Sensitivity and Specificity by CRC Stage

	Mean CTC (s.e.)	Sensitivity (95% CI)
Precancer	6.1 (0.91)	85.3% (76.5%, 91.7%)
Stage I	6.4 (1.7)	75.7% (64.0%, 85.2%)
Stage II	14.5 (4.5)	90.0% (81.9%, 95.3%)
Stage III	23.6 (7.9)	88.3% (80.8%, 93.6%)
Stage IV	22.3 (10.4)	92.3% (79.1%, 98.4%)
CRC Stage I-IV	16.9 (3.4)	86.5% (82.1%, 90.1%)
Precancer & CRC	14.4 (2.6)	86.2% (82.4%, 89.4%)

Specificity: 89.6% (84.9%, 93.3%). Mean CTC Count for Healthy: 1.7 (s.e. = 0.17) **Conclusions:** To the best of our knowledge, these are the first reported results for a blood test that has high accuracy for adenoma detection, and truly enables colorectal cancer prevention. This test can be administered in the primary care setting and drive high compliance.

Title:

Prospective Clinical Study of Circulating Tumor Cells For Colorectal Cancer Screening

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Is this a late-breaking data submission?

No

Is this abstract a clinical trial?

No

Would like to be considered for a Merit Award:

No

Have the data in this abstract been presented at another major medical meeting?

No

Has this research been submitted for publication in a medical journal?

No

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