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Multi-Cancer Early Detection with a Spectroscopic Liquid Biopsy Platform

DXCOVER
The future of cancer diagnostics

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INTRODUCTION

- Research into liquid biopsies is currently dominated by circulating tumor DNA (ctDNA) and cell-free DNA (cfDNA) testing.
- Not all cancers and sub-types release genetic material; there are generally only small amounts of early-stage tumor cfDNA in a blood sample.[1]
- Even with late-stage metastatic cancers, ctDNA is found in only 75% of cases.[2]
- High sensitivity is vital to effectively detect cancer.
- At early stages non-tumor derived information dominates.[3]

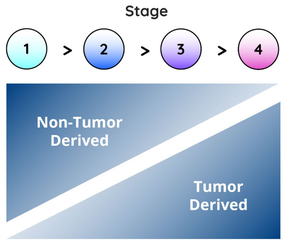

Figure 1. Dxcover® Cancer Liquid Biopsy is sensitive to both tumor and non-tumor derived information.

- Infrared light causes molecules in a blood sample to vibrate and produce a spectrum which characterizes the whole sample.
- The Dxcover® Cancer Liquid Biopsy reaches beyond tumor DNA and is inclusive of the whole spectrum of signals both from tumor molecules and molecules released by the body to fight the disease (non-tumor derived).

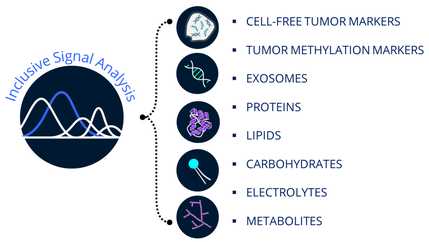

Figure 2. Dxcover® Cancer Liquid Biopsy is a multi-omic inclusive signal analysis and detects a whole range of markers.

SPECTROSCOPIC MCED TEST DETECTS CANCERS IN ASYMPTOMATIC AND SYMPTOMATIC POPULATIONS, WITH AUC OF 0.94 AND 0.86

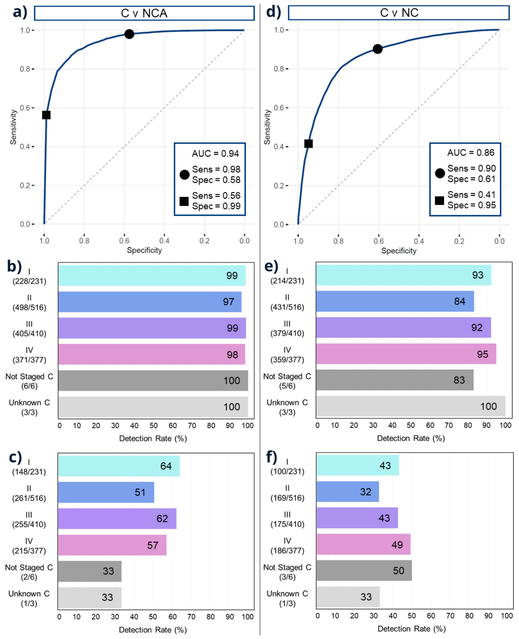

Figure 3. Dxcover® Cancer Liquid Biopsy is highly sensitive in cancer detection within both asymptomatic (C v NCA) and symptomatic (C v NC) populations.

- To effectively improve patient prognosis, a multi-cancer early detection (MCED) test must be capable of detecting early-stage cancers.
- This approach can be fine-tuned to maximize either sensitivity or specificity depending on the requirements from different healthcare systems and cancer diagnostic pathways.
- The cancer versus asymptomatic non-cancer (C v NCA) classification detected:
  - 99% of stage I cancers at 58% specificity **(Fig. 3b)**
  - 64% of stage I cancers at 99% specificity **(Fig. 3c)**
- For cancer versus all non-cancer, including symptomatic patients (C v NC), the sensitivity-tuned model enabled:
  - 90% sensitivity with 61% specificity **(Fig. 3d)**
  - Detection rates of 93% for stage I, 84% for stage II, 92% for stage III and 95% for stage IV **(Fig. 3e)**
- When detected in early stages, 5-years survival rates for certain cancers are > 90%, compared to approximate 15% at late stage (stage IV).[4]

Table 1. Dxcover® Cancer Liquid Biopsy can be tuned for high sensitivity or high specificity based on health and market requirements (CV, cross-validation).

Tumor Type	AUC	Sens (%) at 45% CV Spec	Spec (%) at 45% CV Sens
Brain	0.90	95	99
Breast	0.75	87	86
Colorectal	0.91	97	97
Kidney	0.91	98	95
Lung	0.91	99	95
Ovary	0.86	93	95
Pancreas	0.85	94	92
Prostate	0.86	93	96

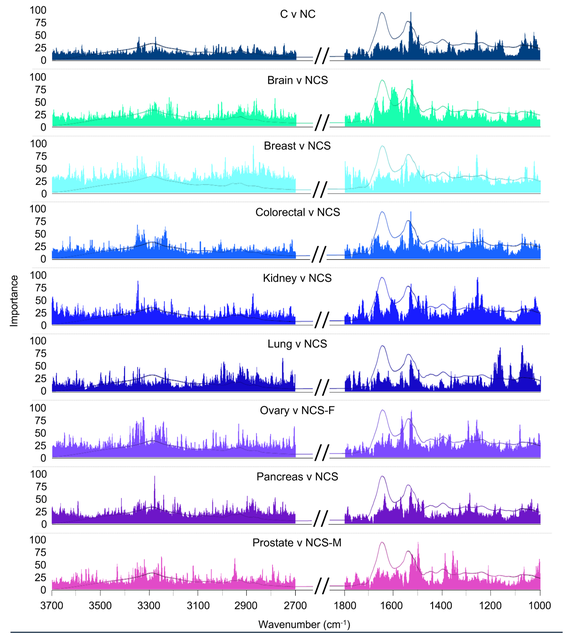

Figure 4. Dxcover® Cancer Liquid Biopsy detects differences between each individual cancer type; different cancers have different infrared signatures (NC, non-cancer; NCS, non-cancer symptomatic; NCS-F, NCS-females only; NCS-M, NCS-males only).

CONCLUSIONS

- A spectroscopic liquid biopsy platform can detect cancer with high accuracy and has significantly high sensitivity for stage I and II disease, enabling the early detection of cancer.
- This approach is cost-effective, simple to use and requires minute volumes of human serum (9 µL).
- Our rapid, low-cost blood test can fit seamlessly into diagnostic pathways due to a low barrier to integration.
- For effective MCED tests both high sensitivity and high specificity are needed.
- Combining this approach with high specificity-based techniques (e.g., next generation sequencing) can enable an effective MCED that can increase patient survival and be economically viable.

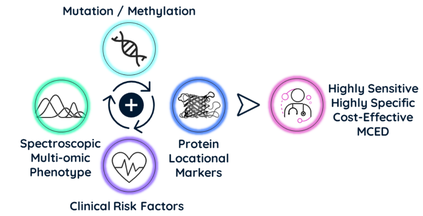

Figure 5. A combination approach of Dxcover® Cancer Liquid Biopsy with other genetic tests and risk factors can provide a highly sensitive, specific and cost-effective MCED.

References

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METHODS

- The cohort was comprised of 2,094 patients, including 1,543 cancer samples (brain, breast, colorectal, kidney, lung, ovarian, pancreatic and prostate), and 551 non-cancer samples, which included a mixture of symptomatic and asymptomatic patients.
- Patient samples were analyzed using the Dxcover® Cancer Liquid Biopsy; this utilizes infrared spectroscopy combined with machine learning algorithms to predict the presence of disease.[5]

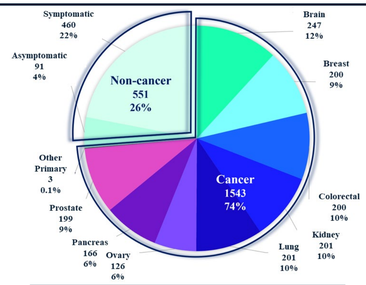

Figure 6. Full MCED patient cohort.

DROP.DRY.DETECT™

- We DROP 3 µL of human blood serum onto three wells of a Dxcover® Sample Slide, leaving well 0 blank for background collection.
- After that, we DRY the slide in less than 10 minutes before inserting it in the Dxcover® Platform for spectral collection.
- We then DETECT the presence of cancer; the spectra are fed into a trained classification algorithm for disease prediction.

Figure 7. Dxcover® Sample Slide (top) and Dxcover® Platform (bottom).

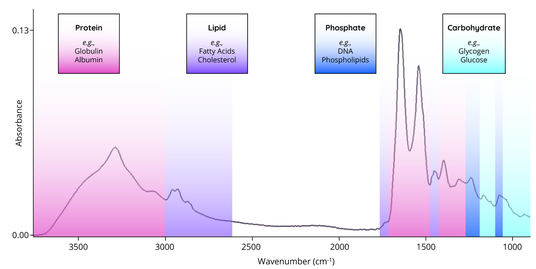

Figure 8. Infrared spectrum detailing main blood serum components.