



Cancer Prevention and Early Detection Is One Step Closer as Universal DX Announces Breakthrough Study Results from Its Multi-omics + Computational Biology + Machine Learning Blood Test

New results from the OMICS study, which will be presented at ASCO, show Universal DX's blood test can detect colorectal cancer with extraordinary accuracy (92% sensitivity / 97% specificity), which exceeds currently available non-invasive tests for colorectal cancer screening

Early detection cancer screening via a liquid biopsy is not only critical to save lives, but is a vast market opportunity, ranging between \$30B and \$75B in the U.S. alone

(JUNE 3, 2021) CAMBRIDGE, MA. – Universal Diagnostics (UDX), a bioinformatics and multi-omics company on a mission to transform cancer into a curable disease, today announced the results of an international multicenter observational cohort study: Colorectal cancer detection at 92% sensitivity and 97% specificity was achieved using single targeted sequencing analysis of multi-omics markers, advanced computational biology and machine learning algorithms. The company's approach also demonstrates high levels of accurate detection of early-stage (I, II) colorectal cancer at 89% sensitivity and 97% specificity.

Universal DX is specially focused on identifying cancer in its earliest stages, so that the disease can be cured, and even in its pre-cancerous stage, when cancer can be prevented. The company leverages proprietary, state-of-the-art computational biology tools combined with targeted next generation sequencing (NGS) assay platform for highly sensitive cancer signal scoring of cell-free DNA regions linked to cancer of interest. The company is developing "Signal-X", a platform to detect multiple types of cancer; its first product, "Signal-C", detects early-stage colorectal cancer and adenomatous polyps.

"We have built a test that can "read" cancer's tissue-specific signal in blood on a fragment level," said Christian Hense, managing director at Universal DX. "We know that if we can detect cancer early, or identify pre-cancer stage patients before they develop cancer, the survival rates increase exponentially. In order to do that, we need to develop new screening methods that are simple, non-invasive, accurate, and more accessible and affordable than what's available today. At Universal DX, we are driven by the belief that cancer can be a curable disease, and continue to work tirelessly to develop blood-based tools that can make that a reality."

Multi-omics + Computational Biology + Machine Learning (ML)

Unlike other liquid biopsy-based screening approaches in the market today, Universal DX uses a targeted sequencing approach, which allows the company to look for the specific biomarkers established to have a biological link to cancer development and progression in tissue. Universal DX has previously identified those biomarkers by combining tissue, buffy coat and plasma whole-genome bisulfite sequencing (WGBS) analysis with a proprietary marker-filtering approach and a pattern-based cancer signal threshold calculation.

Given this direct tissue-confirmed link to cancer, Universal DX is able to zero in to the most relevant marker regions when they analyze a blood sample, decreasing the complexity of the data, which in return increases biological signal-to-noise ratio and assures robustness, which is



necessary for blood-based analyses. This combined approach – multi-omics + computational biology + machine learning – has led to early study results, which will be presented at ASCO, showing effective and highly-accurate performance for detecting early-stage colorectal cancer.

“Colorectal is the third most commonly diagnosed cancer globally, and the people at risk are getting younger,” said Michael H. A. Roehrl, MD, PhD, Attending Pathologist at Memorial Sloan Kettering Cancer Center and Member of the Scientific Advisory Board of UDX. “Today, we see patients with later-stage and harder-to-treat disease because they don’t get regular screenings. We need to come up with a better, more accessible approach if we want to alter the course of cancer to something we can prevent and cure.”

Universal DX is focused on finding cancer in its earliest (and pre-cancerous) stages in order to prevent or facilitate more effective treatment of this complex disease. Having worked since its founding in 2012 towards making this a reality, the company brings unique value propositions to the growing liquid biopsy industry:

- **Tissue-first:** Tissue, buffy coat and plasma WGBS profiling combined with proprietary computational biology tools facilitates the discovery of the most informative marker regions and patterns for each individual cancer type;
- **Multi-omics:** Methylomics and Fragmentomics analyze multiple layers of cancer signal and allow to identify pre-cancer and early-stage cancers;
- Combination of **proprietary fragment level cancer signal scoring algorithms with machine learning** achieve high-accuracy in early and pre-cancer detection;
- **Computational biology:** Proprietary novel tools and approaches manage large genomic data with high quality to discover the most relevant biomarker regions and identify cancer and tissue-of-origin-specific signal patterns in tissue and cfDNA;
- **Targeted NGS platform** captures and “reads” hundreds of marker regions with high accuracy and fits seamlessly and economically into any clinical lab;
- **Multi-cancer:** “Signal-X” detects various types of high-burden cancers with high sensitivity and tissue-of-origin specificity;
- Strong focus on **early detection** (stages I and II) **and prevention** (pre-cancerous stage).

Hense continued: “Our blood contains so many signals, that if we don’t know what we’re looking for, it’s easy to become distracted by all the noise. So, we started by analyzing cancer cells in tissue and established patterns, which we call cancer signals, that we can identify in plasma cell-free DNA. Through this process, we say that we learned to speak the language of cancer, to read its signal. We hope that by doing so, we can detect its signal in a person’s body in order to get to a future where cancer is a curable disease.”

The company will be presenting at ASCO on Friday, June 4th; abstract [here](#).

About Universal Diagnostics

Universal DX is on a mission to transform cancer into a curable disease. With its multi-omics + computational biology + machine learning approach, it is cracking the code to “true” early cancer detection, having identified the specific cfDNA sequence regions that capture cancer’s earliest signal with +90% accuracy. Its first single-draw blood test, Signal-C, accurately detects colorectal cancer with a sensitivity rate of 92% and specificity rate of 97%, with extraordinary accuracy for earlier stages (89%/97%). The company’s multi-cancer platform seeks to identify



the unique DNA sequence regions associated with high-burden cancers, such as pancreatic, liver and stomach, with high sensitivity and tissue-of-origin specificity.

For more information about the company, visit <https://www.universaldx.com/>.

Dr. Roehrl has provided advisory services to Universal Diagnostics.

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