



Universal DX Presents Data from Large, 1,000-patient, Multi-Cohort Study Proving 93% Sensitivity for Colorectal Cancer and 54% Sensitivity for Advanced Adenoma at 92% Specificity

Findings highlight company's approach is highly accurate for early-stage (I-II) detection: CRCs (91% sensitivity) and AA (54% sensitivity) at 92% specificity

Data offer hope for the future of blood-based early cancer detection

(May 9, 2023) CAMBRIDGE, Mass.—Universal Diagnostics (Universal DX), a bioinformatics and multi-omics company on a mission to transform cancer into a curable disease, today announced the results of a large international multi-cohort case-control study, which demonstrate that cell-free DNA methylation and fragmentation signals combined with machine-learning can be used to detect early-stage colorectal cancer (CRC) with 93% and pre-cancerous advanced adenomas (AA) with 54% sensitivity at 92% specificity.

The findings offer an optimistic glimpse into the future of early-stage CRC detection and cancer prevention via AA detection through a simple blood test. Such promising results within a large, international, prospectively collected patient cohort (U.S. and Europe) showcase the potential of Universal DX's unique, proprietary technological platform Signal-X, which combines signal-enhancing NGS-Assay, biologically-relevant biomarkers, and fit-for-purpose computational biology.

"We have every reason to be positive about the future of early cancer detection based on these results," said Christian Hense, COO at Universal DX. "Our research continues to build on itself, demonstrating in study after study that our unique combination of methylation and fragmentation signals and machine learning algorithm can detect colorectal cancer in its earliest stages with high accuracy. These findings on such a large sample set get us one giant step closer to a future where cancer can be a curable disease."

This is the latest in a series of findings from Universal DX. Previously, the company has shown that [non-invasive blood testing can be used to detect CRC and pre-cancerous advanced adenomas](#) through both analysis of cell-free circulating tumor DNA (ctDNA) methylation, fragmentation with single targeted sequencing analysis and combining it with advanced computational biology and machine learning algorithms. In 2022, the company extended [early-stage colorectal cancer detection to prognostics and stratification](#) and [demonstrated the analysis of microbiome signatures in plasma can assist in early detection of colorectal cancer](#). And, in 2023, Universal DX demonstrated the use of [methylation and fragmentation characteristics of cancer-related cfDNA regions](#), combined with a machine-learning algorithm, is highly accurate for early-stage CRCs. Last month, the company revealed that the [combination of copy number variation \(CNV\) with cfDNA fragment size information](#) could serve as a new avenue for early detection of colorectal cancer.

"Colorectal cancer is the third deadliest cancer in the United States. But when it is detected early, the 5-year survival rate increases from 60% to 90%," said Dr. Aasma Shaukat, Director of Gastroenterology, NYU School of Medicine. "Universal DX's data are incredibly promising, signaling a future where we will be able to detect precancerous adenomas that have a high likelihood of progressing to cancer, thereby increasing the number of early diagnoses and



decreasing those in the late stages when treatment options are fewer and outcomes less optimistic. These impressive findings position Universal DX as a leader in early CRC detection, amongst both fecal- and- blood-based tests.”

Study Results:

This was a prospective, international (Spain, Ukraine, Germany and USA), observational cohort study, co-authored by Aasma Shaukat, MD, MPH NYU Langone Health, New York, and James Kinross, MD, Consultant Surgeon and Senior Lecturer at Imperial College, London. Plasma samples from 997 patients were collected either prior to a scheduled screening colonoscopy or prior to colonic surgery for primary CRC.

- The use of methylation and fragmentation characteristics of cancer-related cfDNA regions, combined with a machine-learning algorithm is highly accurate for early-stage (I-II) CRCs (91% sensitivity) and AA (54% sensitivity) at 92% specificity.
- Prediction model utilizing a panel of methylation and fragmentation scores correctly classified 93% (276/298) of CRC patients and 54% (81/149) AA patients.
- Sensitivity per cancer stage ranged from 85% (48/56) for stage I, 94% (107/114) stage II, 94% (90/96) stage III and 97% (31/32) stage IV.
- Fragmentation signals contributed most to early-stage cancers (I-II) and pre-cancerous AA; methylation signals were more significant for late stage (III-IV) detection.
- High-grade dysplasia AA sensitivity was 52% (33/63), while low grade >1cm AA sensitivity was 57% (48/84), sensitivity for different histological types ranged from 47% for tubulovillous to 69% for serrated adenomas.

Kristi Kruusmaa, Chief Scientific Officer at Universal DX added: “The uniqueness of our technology – the combination of deep expertise of cancer biology and tissue/plasma-based marker discovery, proprietary, state-of-the-art computational biology tools and a targeted next-generation sequencing assay platform – allows for simultaneous detection of methylation, fragmentation and microbiome signals for highly-sensitive cancer signal scoring of cell-free DNA regions linked to cancer of interest. Today’s findings validate our approach. Universal DX is on a pathway to cracking the code to early cancer detection.”

The data will be presented at [Digestive Disease Week](#), taking place in Chicago, May 6-9:

- Presentation title: *Large Multi-cohort study shows accurate detection of early-stage colorectal cancer and advanced adenoma patients using cell-free DNA methylation and fragmentation signals*
- Session title: *AGA Strategies for Early Diagnosis and Monitoring of GI Cancers*
- May 9th at 4:00pm CT
- Location: W190b (McCormick Place)

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/>.

Media Contact:

Kristin Faulder (on behalf of Universal DX)

kristin@heurisay.com