New Data from Universal DX Demonstrates Effective Detection of Early-stage Colorectal Cancer Using Combination of Methylation, Fragmentation and Machine Learning

Company to present results from the international cohort study at ASCO Gastrointestinal Cancers Symposium

(January 20, 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 an international, observational cohort study which evaluated the effectiveness of utilizing a combination of cell-free DNA (cfDNA) methylation, fragmentation and machine learning to detect early-stage colorectal cancer (CRC).

This is the latest in a series of findings from Universal DX; today's news demonstrates 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 (92% sensitivity at 94% specificity). These results were achieved on a prospectively collected patient sample set from four different populations: the U.S., Spain, Germany, and Ukraine.

Universal DX has previously shown that non-invasive blood testing can be used to detect CRC and pre-cancerous advanced adenomas (AA) through both analysis of cell-free circulating tumor DNA (ctDNA) methylation, fragmentation and microbiome patterns 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; the ability to do so could lead to better outcomes and improved survival rates.

"This study further validates and reinforces the work we are doing to develop tests that detect cancer in its earliest stages," said Christian Hense, COO at Universal DX. "With a completely new sample set, we have again demonstrated highly-accurate early-stage CRC detection, further verifying the robustness of our technology and use of biomarkers to find traces of cancer in a person's blood. At Universal DX, we believe early detection is one of the most powerful tools for improving survival rates, and are encouraged to see these promising results once again."

Study results:

- Prediction model that utilized a panel of methylation and fragmentation scores originating from cfDNA biomarkers that belong to relevant cancer development and progression-related pathways correctly classified 92% (87/95) of CRC patients.
- Sensitivity per cancer stage ranged from 91% (21/23) for stage I, 92% (23/25) for stage II, 91% (30/33) for stage III and 93% (13/14) for stage IV.
- Fragmentation signals contributed most to early-stage cancers (I-II), while methylation signals were more significant for late stage (III-IV) detection.
- Specificity of the model was 94% (199/204), with 97% (28/29) NAA (non-advanced adenoma), 93% (116/125) BEN (benign colonoscopy fingings of diverticulosis/diverticulitis, hemmorhoids, hyperplastic/inflammatory polyps*)* and 94% (47/50) cNEG (colonoscopy negative) patients correctly identified.

- Lesion location, gender, age and country of origin were not significantly correlated to prediction outcome.

Universal DX leverages proprietary, state-of-the-art computational biology tools combined with a targeted next generation sequencing assay platform that 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.

Hense continued: “Colorectal cancer is the third most common cancer diagnosed in the U.S.; in 2023, The American Cancer Society estimates there will be more than 150,000 new diagnoses of colon and rectal cancer. This demonstrates the need to not only prioritize screening, but find tools that help us detect cancer in its earliest forms, when there are more treatment options available and survival rates are higher.”

Universal DX will present its findings live at the ASCO Gastrointestinal Cancers Symposium in San Francisco, CA on January 21st as poster #201 titled “Use of methylation and fragmentation signals in the detection of early-stage colorectal cancer.”

In addition to today’s results, the company will be presenting findings from additional studies in the upcoming months.

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, detects colorectal cancer with high sensitivity and specificity, with extraordinary accuracy for earlier stages. The company’s multi-cancer platform seeks to identify the unique DNA sequence regions associated with high-burden cancers, such as pancreatic, liver, lung and stomach, with high sensitivity and tissue-of-origin specificity.

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

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