New Data from Universal DX: Combining Copy Number Variation (CNV) with cfDNA Fragment Size Information Could Serve as Promising New Avenue for Early Detection of Colorectal Cancer (CRC)

Company to present results from the international cohort study at AACR Annual Meeting in Orlando, FL

Results continue Universal DX's demonstration of high-accuracy results for non-invasive testing to detect early-stage CRC

(April 17, 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 cohort study that highlights the role fragment size, specifically on chromosome 18, plays in early-stage CRC detection.

Study results demonstrate that combining copy number variation (CNV) information with cfDNA fragment size information could serve as a new avenue for early detection of colorectal cancer, with early-stage (I-II) CRC sensitivity of 87.5% at 92% specificity. These results were achieved on a prospectively-collected patient sample set from three different populations: Spain, Germany, and Ukraine.

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 (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. And, in early 2023, Universal DX demonstrated that 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.

"These promising results continue to demonstrate the strength, accuracy and robustness of our technology and the role biomarkers play in early-stage CRC detection," said Christian Hense, COO at Universal DX. "The reality that CRC is the third most common cancer diagnosed in the U.S. means we must stay committed to and prioritize screening and the development of new tools that can detect it in its earliest forms, when there are more treatment options available and survival rates are higher."

The aim of the study was to investigate cell-free DNA (cfDNA) fragment sizes in the copy number variation (CNV) regions of the chromosome 18 in the context of early-stage CRC detection.

Study results:

- Training Set analysis exhibited significant differences over whole Chr18q21 region, when comparing CRC and matching control patients.

- Model performance on an independent Testing set reached 83% sensitivity (10/12) at 92% specificity (11/12), with stage I sensitivity being as high as 75% (3/4) and stage IIA 100% (4/4).
- Sensitivity per cancer location was comparable with 83% sensitivity for proximal cancers (5/6) and 83% for distal cancers (5/6).
- Specificity was not affected by presence of benign findings such as hyperplastic polyps, diverticulosis/diverticulitis or hemorrhoids.

Universal DX combines 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 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.

Universal DX will present its findings live at the AACR Annual Meeting in Orlando, FL on April 17th as poster #3353 titled "Cell-free DNA (cfDNA) fragmentation profiles linked to copy number alteration analysis allows for early colorectal cancer detection."

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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