

PRESS RELEASE

Universal Diagnostics Presents New Promising Data on Early (Pre) Cancer Detection from Cell Free DNA at European Society for Medical Oncology (ESMO)

Seville, Spain, September 21, 2020 – [Universal Diagnostics](#) (UDX), an in-vitro diagnostics company developing minimally-invasive, blood-based solutions for detecting cancer early, announced today that promising new data for its investigational advanced adenoma (precursor lesions of colorectal cancer) detection blood test and multi-cancer detection test was presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020.

Despite the fact that more than 80% of colorectal cancers (CRC's) originate from advanced adenomas (AA), current screening methods are not accurate enough to provide detection early enough to prevent CRC. The data presented at ESMO 2020, shows that the evaluation of a panel of cell free DNA (cfDNA) open chromatin regions in plasma can be successfully used for AA detection with high accuracy. These results are further supporting the companies previous findings on using cfDNA derived methylation signals for AA and early colorectal cancer detection.

“Only about a quarter of colorectal cases are caught in the very early, precancerous stages. By screening and detecting molecular changes early, there is a better chance of effectively treating patients or even preventing cancer altogether. Previous research suggests that kinetic analysis and molecular profiling of cfDNA could potentially be used in non-invasive cancer detection and management. The data presented at ESMO 2020 supports this proposition, particularly in screening for colorectal adenomas,” said Michael H. A. Roehrl, MD, PhD, Director, Precision Pathology Center at Memorial Sloan Kettering Cancer Center and Member of the Scientific Advisory Board of UDX. “We urgently need a population-scale colon cancer screening that is cost-effective and blood based, to encourage higher patient compliance and to detect patients with precancerous lesions. The UDX approach could potentially provide that platform.”

In Poster ID 479P titled “Open chromatin region (OCR) based model predicts advanced adenoma in plasma cell-free DNA whole genome bisulfite sequencing data”, the researchers validated an OCR panel performance on plasma cfDNA samples. The results show that 50% of AA samples being correctly identified at 90% specificity. The test is able to detect 100% serrated adenoma, 50% tubulovillous adenoma and 25% tubular adenoma patients. More importantly, the detection rate is comparable for patients with high grade dysplasia (50%) and with low grade but >1cm findings (50%). With this abstract UDX confirms the test's ability to pick up the signal coming from advanced adenomas. The ability to add open chromatin information to its panel could potentially enhance the already strong results presented at ESMO GI in July 2020, which showed 62.5% sensitivity and 88% specificity.

A second poster (ID 97P), titled “A panel of methylation markers for multi-cancer detection from plasma”, shows performance data of UDX's blood test in the detection of four cancer types – colorectal (CRC), lung (LC), pancreatic (PaC) and breast (BC) cancer. The methylation marker panel based test is able to detect 100% of the CRC, 80% of the PaC, 75% of the BC and 73% of LC with low false-positive rate at 90% specificity. Importantly, the sensitivity for early, stage I cancers is 75%, further solidifying the tests potential. Further on, for cancers detected, the test also identifies where the cancer is located in the body with 80% of CRC, 78% of LC, 75% of PaC and 62% of BC cases correctly assigned to tissue of origin.

“Building on encouraging preliminary data in colorectal cancer and adenomas, the data presented at ESMO 2020 suggests that the UDX test may also have an application in the early detection of lung,

pancreatic and breast cancers,” said Dr. James Kinross, Senior Lecturer in Surgery at Imperial College Healthcare NHS Trust and co-author of the study. “Of course these data need now to be validated in larger prospective cohorts but it does suggest that UDX are developing a highly promising and minimally invasive blood-based cancer screening test to detect and ultimately prevent multiple cancers.”

“These data presented at ESMO 2020 continue to show that our cfDNA panels have potential for use in the early, blood-based detection of colorectal cancer, our lead indication, but also in other cancers types, all with high sensitivity and specificity,” said Juan Martínez-Barea, Co-Founder and President of Universal Diagnostics. “We intend to complete our ongoing verification study by end of 2020 and plan to finalize internal validation of our CRC/AA test by the end of 2021. In parallel, we will expand our cancer diagnostic platform to create more substantial data for other cancers, for example, the most frequently diagnosed cancers such as lung cancer.”

About the Colorectal Cancer and Advanced Adenoma Test

UDX’s first product is a simple, non-invasive and accurate blood-based screening test that allows early stage colorectal cancer detection and cancer prevention through advanced adenoma detection. Using profiling of DNA methylation changes in large number of tissue and plasma samples, UDX has identified and quantified a proprietary panel of biomarkers that has been combined into targeted assays that have shown 77% sensitivity for colorectal cancer, 62.5% sensitivity of adenomas and 88-90% specificity and tissue of origin accuracy across different verification studies.

About Universal Diagnostics

Universal Diagnostics (UDX) is a Spanish in-vitro diagnostics company developing minimally-invasive, blood-based tests for detecting cancer early when treatment options are more plentiful. The tests rely on proprietary methylation marker panels. A simple blood sample collected as part of a routine check-up, can be processed at a reference laboratory or hospital using standard equipment and the data uploaded to the UDX cloud for analysis and condition assignment. To date, UDX has raised €20 million in equity financing and a further €5 million in grants and non-dilutive funding. The Company employs a team of 25 professionals.

Further details can be found at <http://www.universaldx.com>.

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