

## Coloscape – A new liquid biopsy based Colorectal Cancer detection assay

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Colorectal cancer is a highly preventable disease as early detection increases rates of patient survival to near 100%. Herein will be reported the development and validation of a novel liquid biopsy based multigene mutation biomarker real-time qPCR assay for qualitative detection of colorectal cancer associated biomarkers that comprise tumor specific mutations in the following genes: APC (Exon 15), KRAS (Exon 2), BRAF (Exon 15) and CTNNB1 (Exon 3) in patients circulating cell-free DNA which is called ColoScape™. The assay allows the sensitive detection of the presence or absence of mutations in the targeted regions of the genes interrogated. The assay was evaluated on prospectively collected whole-blood samples obtained from FIT+ patients enrolled in the CRC screening program of ASL NAPOLI 3 SUD, using colonoscopy as confirmation. The assay's sensitivity for advanced adenomas was evaluated as well as its specificity and other clinical performance criteria. Based on these results which will be reported in this presentation ColoScape™ is a highly promising oncology molecular diagnostic tool and further clinical studies are underway in order to validate its use for the triage of FIT+ patients. The ColoScape™ assay

demonstrates high sensitivity and specificity in detection of colon cancer and advanced adenomas based on the set of biomarkers involved in colorectal cancer genesis and disease progression.

### Speaker Biography

Michael J Powell is a highly recognized scientific and business leader with more than 30 years experience in R&D, technology, business and corporate development. He has held R&D Director positions at IGEN, Inc., Microgenics, Inc., Boehringer Mannheim GmbH and Roche. He was a pioneer and lead scientist and inventor of the electrochemiluminescence (ECL) assay technology and also developed catalytic antibodies at IGEN, Inc. which was acquired by Roche for \$1.4B in 2003. He has held several other R&D senior management positions at Integrated Genetics Inc., Medisense and Celltech PLC, in the UK. Medisense was acquired by Abbott in 1996 for \$900M and Celltech was acquired by UCB Pharma in 2004 for \$1.9B. He has extensive expertise in the fields of molecular diagnostic assay research and development, qPCR and other nucleic acid amplification technologies, high sensitivity detection of cancer biomarkers in body fluids so called 'liquid biopsy' for cancer diagnosis and therapy management and automated in-vitro diagnostics instrumentation platforms. He is currently Chief Scientific Officer at DiaCarta, Inc. a precision diagnostics company.

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