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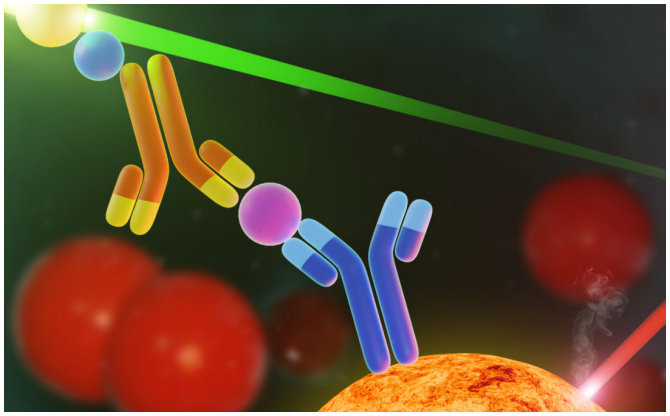
R&D SYSTEMS

Solution Brief

Meeting the Challenges of Early Cancer Detection

Sensitivity Remains Elusive

Detecting cancers at their earliest stage increases the chance of long-term survival. While advances in genomic testing have led to progress in developing tools for early diagnosis, many current tests lack the sensitivity required to detect cancers early. One drawback to gene-expression analysis is that tumors shed cell-free DNA in a stage-dependent manner. In the early stages, when tumor burden is low, there is not much cell-free DNA entering the bloodstream. Moreover, that small amount of cell-free DNA has to be picked out of a higher baseline of other, non-tumor derived cell-free DNA[1].



Cancer Proteomics: the Key to Enhancing Sensitivity

Non-tumor derived signals from the tumor microenvironment are likely to be better indicators of cancer in earlier stages of cancer and more easily detectable. In recent years new proteomic-based technologies have enabled the identification of potential biomarkers that can be used to better detect cancers and tumor progression.

Additional studies have demonstrated the advantages of multiomics (the use of proteins along with nucleic acids) in increasing sensitivity. By adding proteomic algorithmic signature data, you get increased specificity and sensitivity, and increased probability of success for early detection[2].

FIGURE 1. CRC Sensitivity

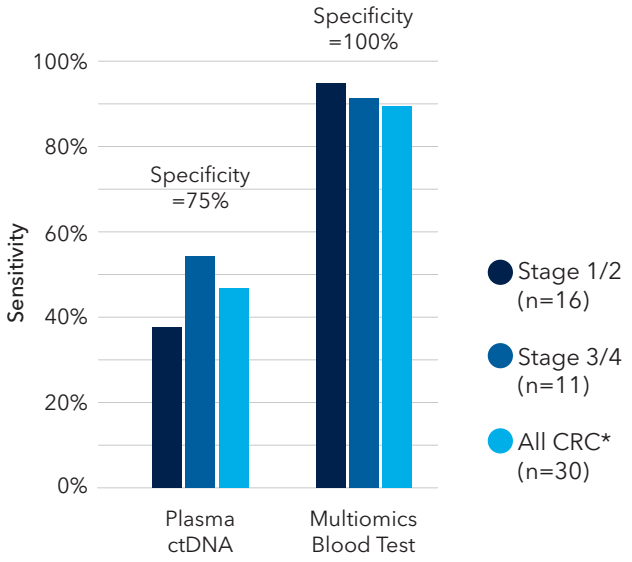


FIGURE 1. The multiomics blood test demonstrated 90% sensitivity and 100% specificity for CRC, whereas ctDNA achieved 47% sensitivity and 75% specificity.

How Are Proteomics Used to Detect Cancer Early and Accurately?

Bladder cancer is a good example. While it is not one of the most common types of cancer, bladder cancer has one of the highest rates of recurrence.

To date, there are no diagnostics capable of detecting bladder cancer prior to clinical presentation. Because of this severe limitation, nearly 30% of patients initially present with stage 2 and higher bladder cancer. Stage 2 bladder cancer has a 5-year survival rate of 50%[3].

That's where new multiplex protein assays are delivering promising results. Case in point is Oncuria®, a first-of-its-kind bladder cancer test from Nonagen Bioscience. Developed using high quality reagents from R&D Systems, this Luminex® multiplex panel detects concentrations of 10 proteins associated with bladder cancer in urine samples. Validated in more than 4,300 patients, Oncuria gives urologists a higher level of certainty compared to existing urine-based cancer and upper tract urothelial diagnostics.

In clinical studies, Oncuria was shown to have 93% sensitivity and 95% specificity for detecting bladder cancer.

FIGURE 2. Diagnostic Performance of Oncuria

	AUROC	Sensitivity	Specificity
Overall	0.95	0.93	0.93
Low-grade tumors	0.94	0.89	0.93
High-grade tumors	0.95	0.94	0.93
Low-grade tumors (NMIBC)	0.93	0.93	0.93
High-grade tumors (MIBC)	0.97	0.94	0.93

FIGURE 2. Diagnostic performance of Oncuria in parients with no personal bladder cancer history: presenting to a urology outpatient clinic for bladder cancer evaluation. 46 patients with de novo bladder cancer and 316 controls. Patients with no history of bladder cancer; n=362.

Charting a Path to LDT Development

To move robust biomarker panels closer toward clinical utility, research trials need sensitive and highly reproducible immunoassay systems that can simultaneously interrogate large numbers of targets per sample, in a short time.

These challenges underscore the importance of working with a trusted partner for assay RUO to LDT development. It's critical to look for a reliable supplier of raw materials with deep immunoassay development and manufacturing experience all conducted in a regulatory compliant environment.

The ability to design custom multiplex panels tailored to your unique needs helps save time, mitigate risk, and accelerate your path to LDT development. In a field defined by constant evolution, it's vital to equip yourself with the best tools to meet tomorrow's needs.

Learn more
bio-techne.com/reagents/luminex-assays/early-cancer-detection

Related Resources

1. Bredno J, Lipson J, Venn O, Aravanis AM, Jamshidi A. Clinical correlates of circulating cell-free DNA tumor fraction. PLoS One. 2021 Aug 25;16(8):e0256436.
2. Klein, Clinical Validation of a Targeted Methylation-based Multi-cancer Early Detection Test Using an Independent Validation Set. Ann Oncol, 2021 Sep;32(9):1167-1177
3. Charles J Rosser, MD, MBA, Hideki Furuya, Cedars-Sinai Medical Center, A Novel Multiplex Immunoassay for the Early Detection of Bladder Cancer, IIT2021-19-Furyua-EarlyDx, 2022-04-29

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