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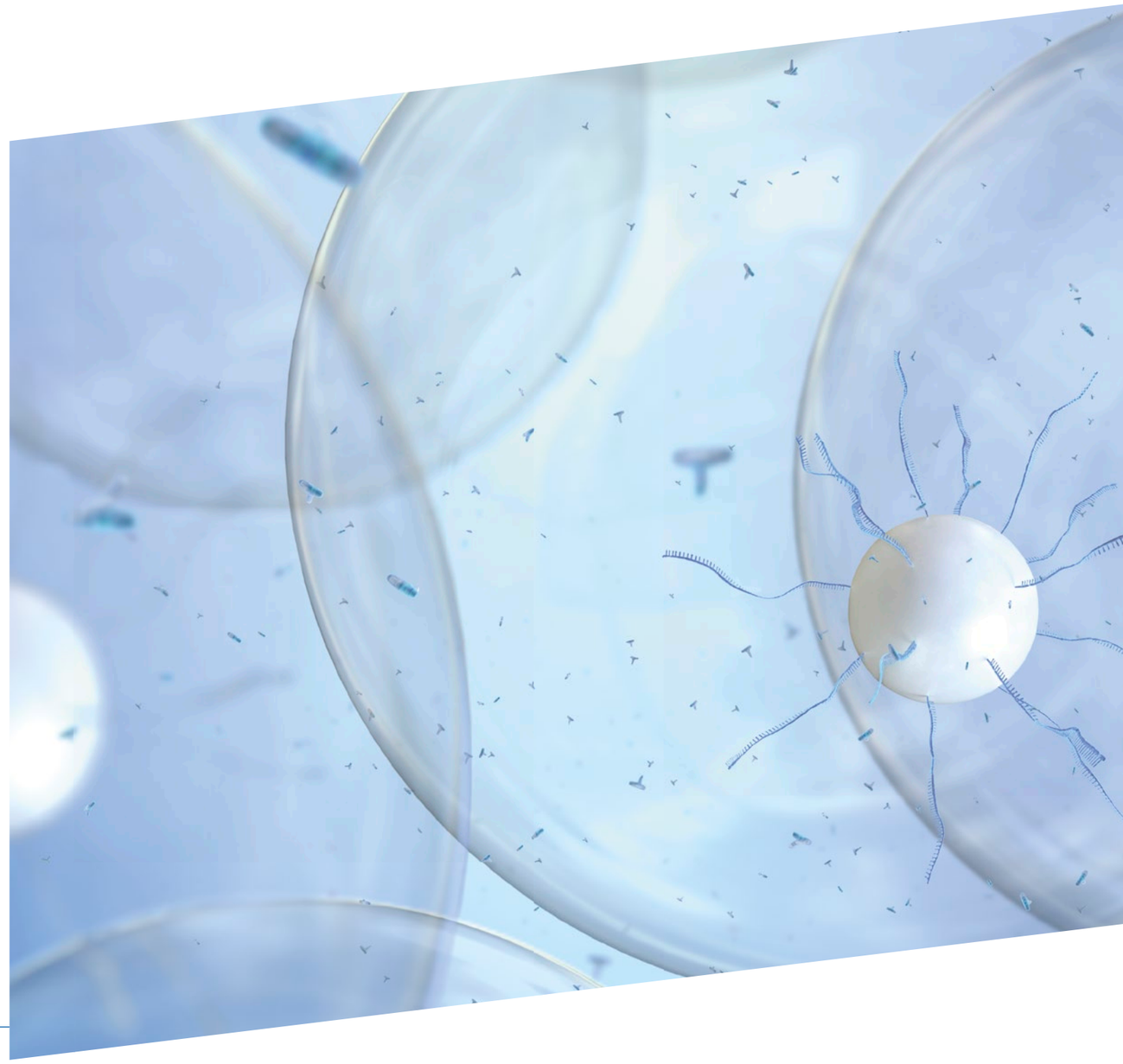
BEAMing Digital PCR Technology



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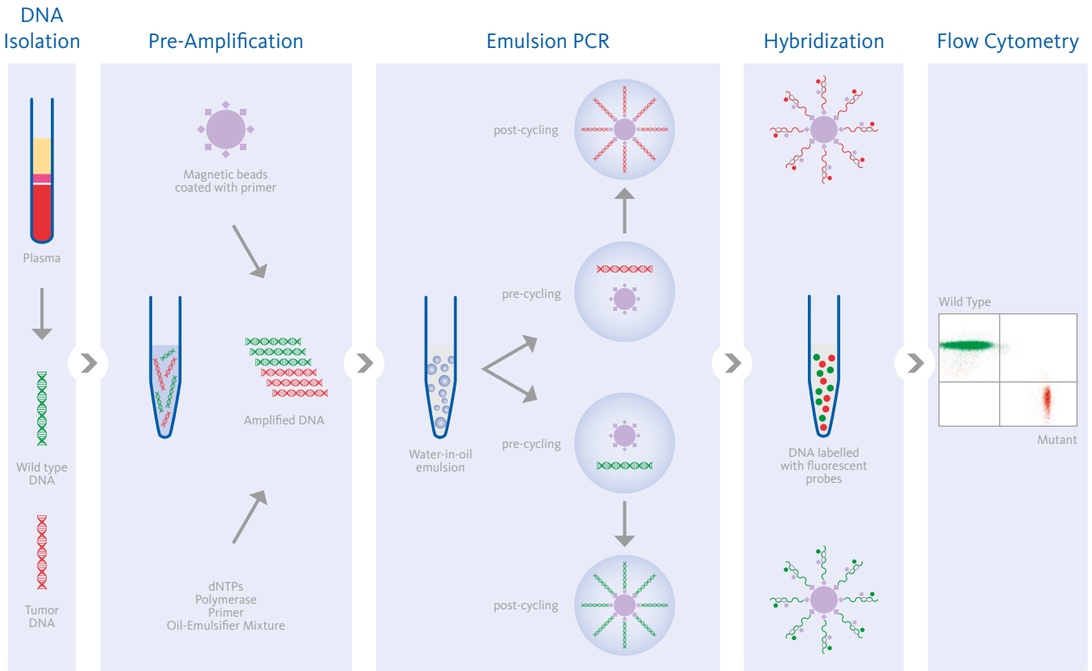
Go Beyond Biopsy with Blood

OncoBEAM™ Technology: BEAMing Digital PCR



Sysmex Inostics' BEAMing Digital PCR technology combines emulsion PCR with magnetic beads and flow cytometry for the highly sensitive detection of mutant tumor DNA molecules.

OncoBEAM™ Advantage: Unparalleled Sensitivity with High Multiplexing Capabilities

Blood-based mutation analysis requires a sensitive technology. Our BEAMing technology delivers increased sensitivity compared to other liquid biopsy methods providing reliable molecular information for timely and non-invasive treatment selection and enhanced prediction of resistance to therapy.

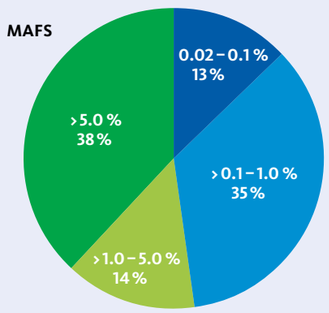


Fig. 1 *48 % of the analyzed mCRC patients showed ctDNA at < 1 % fraction*

- Data shown at SABCS 2015 highlighted the fact that the OncoBEAM™ PIK3CA blood test was a better predictor of therapy response than the standard of care (SOC) tissue test.[1]
- In lung cancer patients, eligible for 3rd generation TKIs, the OncoBEAM™ EGFR blood test accurately identified patients who would benefit from T790M targeted therapy even when tissue as not available for treatment decisions.[2]
- A meta-analysis of data generated with the OncoBEAM™ CRC assay showed that 48 % of the analyzed mCRC patients had a mutant allele fraction (MAF) of between 0.02 % – 1.00 % (see Fig.1).[3,4,5]

OncoBEAM™: Analytical Sensitivity

Assay (Mutation Number)		Analytical Sensitivity — Cut-Off (% Mutant Fraction)
EGFR (10)	L858R / Del19	0.03
	T790M / C797S	0.04
KRAS (15) / NRAS (18) / BRAF (2) / HRAS (2)		0.03
AKT1 (1) / ESR1 (12) / PIK3CA (9)		0.02
ALK (12) / ROS1 (3)		0.02 – 0.04*
IDH1 (5) IDH2 (5)		0.02 – 0.04*

* Depending on mutation

OncoBEAM™ Snapshot: Published Performance

Cancer	Marker	Stage	Patient No.	Tissue Analysis	Concordance (%)
NSCLC	EGFR	IV	78	SOC	99[6]
	KRAS	IV	78	SOC	92[6]
	EGFR		38	SOC	95[7]
mCRC	Extended RAS	IV	238	SOC	93.3[8]
Breast Cancer	PIK3CA	IV	34	BEAMing	100[9]
Melanoma	BRAF V600E	IV	42	Sanger	93[10]

OncoBEAM™: The Gold Standard for Blood-Based Molecular Cancer Testing of ctDNA

2/3 of the top 15 global pharmaceutical oncology companies are repeat customers

35,000+ samples analyzed across multiple cancer types

Development & Commercialization of first blood-based **ALL-RAS IVD KIT** for mCRC patients

Chosen technology for

OPUS, CRYSTAL, TIGER, CORRECT, BELLE, AURA

and a multitude of other landmark trials