SafeSEQ panels and custom solutions

Highly sensitive next-generation sequencing for precision oncology

www.sysmex-inostics.com

Go beyond biopsy with blood

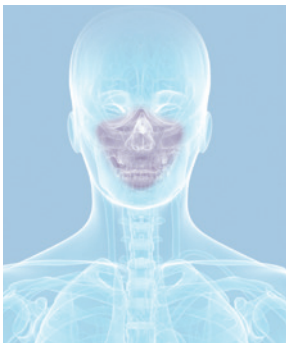
SafeSEQ:
Tailored solutions with market-leading sensitivity

Next-generation sequencing is a balancing act between sensitivity, genomic coverage, available sample input and cost.

'Pan-cancer' and 'universal' NGS tests sacrifice sensitivity and cost in favor of broad coverage and are not able to meet the needs of a wide range of applications.

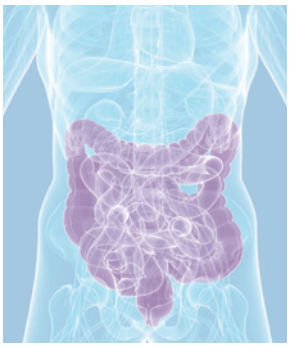
Therefore, Sysmex Inostics has developed SafeSEQ, a highly sensitive, customizable NGS solution for precision oncology:

- proven highly sensitive mutation detection [1]
- disease specific coverage
- optimized cost
- multiple sample types: plasma, tissue/FFPE, cellular DNA, and more
- wide sample input range (>3 ng)
- customizable to your needs



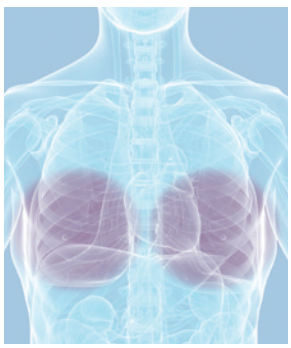
Head and Neck Cancer (HNSCC)

CDKN2A, **HRAS,** PIK3CA, TP53



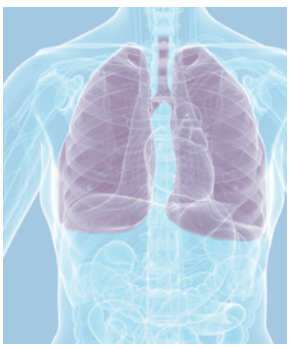
Colorectal Cancer (CRC)

AKT1, **APC, BRAF,** CTNNB1, ERBB3, FBXW7, **KRAS, NRAS, PIK3CA,** POLE, PPP2R1A, RNF43, SMAD4, TP53



Breast Cancer (BC)

AKT1, ERBB2, **ESR1,** KRAS, **PIK3CA,** TP53



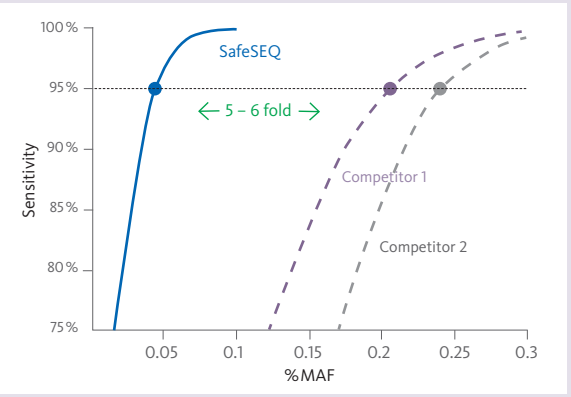
Non Small Cell Lung Cancer (NSCLC)

ALK, AKT1, BRAF, ERBB2, **EGFR,** KRAS, MAP2K1, **MET,** RET, **ROS,** TP53 incl. gene fusions and amplifications

Bringing OncoBEAM sensitivity to NGS: SafeSEQ performance data

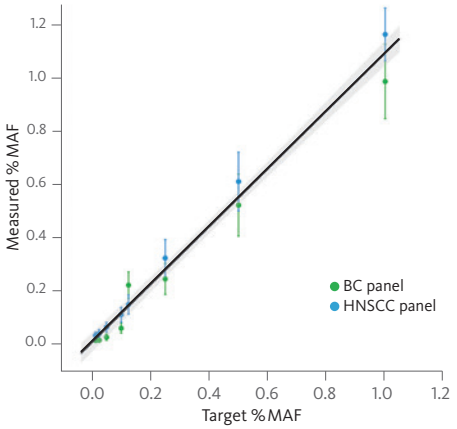
Sensitivity

SafeSEQ sets new standards in sensitivity for NGS assays reaching up to 6 fold higher analytical sensitivity compared to other common liquid biopsy NGS providers. This enables robust mutation detection in more liquid biopsy clinical samples, ~ 60 % of which usually harbour Mutant Allele Frequencies (MAFs) below 1 %.



Precision and accuracy

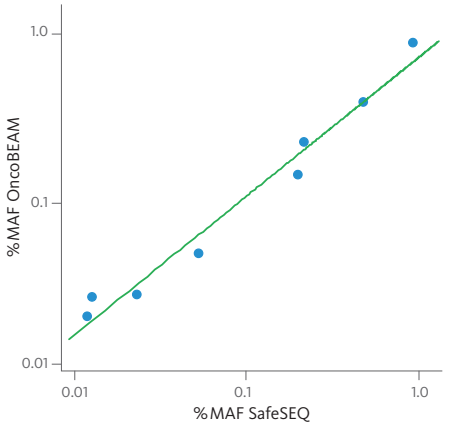
SafeSEQ demonstrates remarkably high precision which is important for robust assay performance especially when sample material is limited. Additionally, applications requiring longitudinal measurements like monitoring and minimal residual disease detection benefit from high precision and accuracy across the entire SafeSEQ assay range.



SafeSEQ and OncoBEAM: high concordance

Built to expand Sysmex Inostics' portfolio of assays with market-leading sensitivity, SafeSEQ was designed to complement the liquid biopsy gold standard OncoBEAM exhibiting similar performance characteristics.

Target mutant molecules	Corresponding MAF [30 ng]	Sensitivity	
		SafeSEQ	OncoBEAM
10	0.1 %	100 %	100 %
5	0.05 %	97.4 %	94.4 %
2.5	0.025 %	82.5 %	81.5 %
1.25	0.0125 %	61.4 %	57.4 %



Therapeutic monitoring:
A novel application with unique needs

The emerging utility of tracking genetic alterations for disease monitoring highlights the need for flexible diagnostic tests.

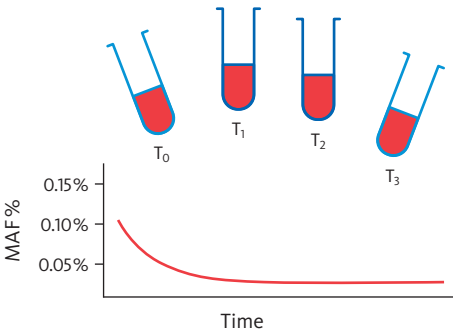
Discovery of cancer-relevant mutations via tissue sequencing requires an assay which interrogates the most relevant set of targets for a particular type of cancer. After somatic mutations have been characterized in the tissue, tracking via ctDNA analysis of serial blood draws requires extremely high sensitivity, and quantitative detection of the selected markers.

NGS tests used for disease monitoring must be able to modulate the balance between sensitivity and genomic coverage to ensure robustness for both discovery as well as tracking of mutations. Through unique design and customization, SafeSEQ is able to fulfill these requirements.

Tissue SafeSEQ disease-specific panels

Tissue for somatic mutation profiling

Plasma SafeSEQ custom panels



Serial ctDNA analysis for monitoring

To learn more about SafeSEQ or discuss your panel requirements, contact us at **info@sysmex-inostics.com**

References

[1] ***Kinde I et al.*** *(2011): Detection and quantification of rare mutations with massively parallel sequencing. Proc Natl Acad Sci USA. 108 (23) : 9530 – 5.*

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