OncoBEAM & Plasma Safe-Sequencing from clinical trials to clinical practice

Dan Edelstein
September 2018
Sysmex Inostics
Agenda

1. Brief introduction to Sysmex Inostics
2. Overcoming technical challenges for ctDNA analysis
3. Clinical applications for liquid biopsies
4. OncoBEAM RAS – from clinical assay to IVD
5. OncoBEAM EGFR – laying the groundwork for clinical adoption of plasma-based testing
6. Plasma Safe-Sequencing: Case study in panel design (HNSCC)
7. Summary
Sysmex Inostics from the pioneer to the gold standard in liquid biopsy

Customers
- Insurances & private payer via oncologists
- Pharma; Biotech; Academics; Other CROs
- Clinical laboratories (private and academic)

Product description
- Biomarker testing service to inform a physician on treatment options (CLIA/IVD)
- Biomarker testing service (RUO/GCP/CLIA)
- IVD and RUO reagents & instruments distributed to clinical testing labs

Business Areas:
- Liquid Biopsy
  - Lab Assay Services
  - Patient testing
  - CRO Service
  - IVD/CDx

BEAMing technology

Safe Sequencing technology

Sysmex Inostics (Germany and US) is a subsidiary of Sysmex Corporation (Japan)
• 120 clinical trials
• >60,000 samples
Sysmex Inostics: Pioneering liquid biopsy in cancer diagnostics

**2002-2007**

**BEAMing**

Bert Vogelstein & colleagues at Johns Hopkins invent and subsequently apply BEAMing digital PCR to detect ctDNA in cancer patients.

**2008-2013**

**Inostics**

Inostics is formed to become the first ctDNA assay provider. CLIA lab certified in 2012 to offer first clinical liquid biopsy for patients.

**2013**

**Sysmex-Inostics**

Sysmex acquires Inostics and supplies IVD expertise, market access and distribution capabilities.

**2014-Current**

**Global delivery of differentiated liquid-biopsy products**

Merck partners with SI to deliver the first CE Mark liquid biopsy kit for RAS detection in CRC patients. SI expands global delivery of focused liquid biopsy solutions.
Released tumor DNA as a clinical biomarker circulating tumor DNA (ctDNA)

Clinical Applications for Liquid Biopsy:

**Diagnosis of molecular status in the absence of tissue biopsy**
- Identification of actionable mutations
- Identification of resistance mutations

**Monitoring**
- Detection of minimal residual disease
- Detection of resistance mutations
- Response to therapy
Liquid biopsy delivers a systemic tumor mutation analysis: Example of NSCLC

EGFR-mutant NSCLC

EGFR activating mutation
EGFR activating mutation plus T790M resistance mutation

Response

First generation EGFRi

T790M-mediated relapse: candidate for T790M therapy

Blood

Reservoir for cancer genome in circulating Tumor DNA

Biopsy

May miss T790M

Time to Results: 5-7 days

Adapted from N. Rosenfeld/D. Tsui

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Overcoming technical difficulties of ctDNA analysis

A short overview
Technical Challenge: Finding the Needle in the Haystack (or the farm in some cases)

2 mutant tumor DNA Fragments in a pool of 10,000 DNA Fragments = 0.02% (BEAMing sensitivity)

Technical Limit of Sensitivity of Traditional Semi-Quantitative PCR is 1%

\[
\text{Mutant Allele Fraction} = \frac{\text{Mutant DNA Molecules}}{\text{Total DNA Molecules}}
\]
Concept of Digital PCR

Digital PCR method can achieve higher analytical sensitivity of mutation detection and enable quantitation of mutant molecule population.

OncoBEAM assays: the gold standard in highly sensitive mutation detection

BEAMing (Beads, Emulsions, Amplification, Magnetics) has shown efficacy in several therapeutic clinical trials as well as in oncology patient testing applications.
Essential elements of Safe-Seq: a low error rate next-generation sequencing technology
Tag starting molecules with endogenous or exogenous unique identifiers (UIDs)
Essential Elements of Safe-Seq

Courtesy of Ken Kinzler
Essential Elements of Safe-Seq

Sequencing or Replication Error
This strategy can decrease error rates by >70-fold.
Pharma’s rigorous comparison of commercial plasma NGS assays

• Comparison of results from 4 plasma NGS vendors presented by AstraZeneca at FDA-AACR Liquid Biopsy Workshop:
  • Rigorous comparisons on paired samples reveal discordance at low mutant allele frequencies <1.0%
  • Commercial plasma NGS providers are all “off-the-shelf” with variant calling not customized to the tumor type of interest

AstraZeneca’s conclusion:
• Most [Plasma NGS assays] are reliable at allele fractions greater than 1%. Our best practices recommend that you should be cautious at allele fractions less than 1%.
High Sensitivity Matters

Distribution of RAS MAFs in mCRC patients

- 0.02-0.1%: 38%
- >0.1-1%: 13%
- >1%: 35%
- >5%: 14%

48% of patients with MAFs <1%

Distribution of EGFR MAFs in EGFR-mutant NSCLC patients with T790M+ resistance

- 0.02-0.1%: 36%
- 0.1-1%: 15%
- >1%: 22%
- >5%: 27%

42% of patients with MAFs <1%

Distribution of PIK3CA MAFs in HR+/HER-recurrent Breast Cancer patients

- 0.02-0.1%: 32%
- 0.1-1%: 23%
- >1%: 23%
- >5%: 32%

45% of patients with MAFs <1%

BEAMing and SafeSeqs assays have analytical sensitivities of >/= 0.02-0.06%

ctDNA clinical development applications

A short overview
ctDNA accelerates clinical development and discovery

- Patients
- Academia
- BioPharma

- Discovery of resistance pathways
- Response monitoring & stratification
- Clinical Adoption
- Design Adaptive Trials

Target Validation
Molecular Target Discovery
OncoBEAM BCP – BELLE2 Clinical Trial

**Critical Results:**

- When PIK3CA mutation status was analyzed with archival tissue, no statistically significant difference in overall response was seen.
- When PIK3CA mutation status was analyzed using the OncoBEAM™ BCP assay from blood samples, PIK3CA mutant patients demonstrated a significant OR benefit (18.4 vs. 3.5 months) with the addition Buparlisib.
OncoBEAM provides greater resolution of disease status than imaging in melanoma patients receiving PD-1 inhibitors

68-year-old female receiving pembrolizumab (anti-PD-1) for metastatic melanoma

<table>
<thead>
<tr>
<th>Time</th>
<th>ctDNA</th>
<th>Imaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Detectable (0.95%)</td>
<td>No Evidence of Disease (NED) Rim enhancing, centrally necrotic 1.5 cm uterine mass</td>
</tr>
<tr>
<td>3 months</td>
<td>Not Assessed</td>
<td>Interval increase in the intra-fibroid lesion, now 3cm in diameter. Still determined NED</td>
</tr>
<tr>
<td>5 months</td>
<td>Detectable (5.7%)</td>
<td>FDG-PET/CT: 5 cm necrotic hypermetabolic lesion within a fibroid uterus. Biopsy = metastatic melanoma.</td>
</tr>
</tbody>
</table>
OncoBEAM shows used for monitoring IDH1 mutations in AML patients treated with ivosidenib

- **Best response:** complete remission or complete remission with partial hematologic recovery, the mean levels of IDH1 mutations in bone marrow mononuclear cells and neutrophils decreased over time.

- **Lack of response:** IDH1 mutations remained stably elevated over time in patients who did not have a complete remission or complete remission with partial hematologic recovery.

- **All patients** with relapsed or refractory AML with clearance of IDH1 mutations had complete remission.

- LOD for BEAMing IDH1 assay is 0.02-0.04% MAF. This is 50-100X more sensitive than “pan-heme” NGS assays!
Exponential interest in ctDNA research

Number of Journal Articles Containing "ctDNA" by Year

649 peer reviewed articles containing “ctDNA” in 2017 and already >400 in 2018

Circulating DNA as a Possible Factor in Oncogenesis

PubMed keyword search “ctDNA” JUL2018

Data & graph courtesy of Jonathan Beer
Liquid biopsy enthusiasm cycle

- Preanalytical standards
- Standardized clinical performance & validity
- Refining intended use population for specific assays
- Clinical utility
- Widespread adoption

- Innovation Trigger
- Trough of Disillusionment
- Peak of Inflated Expectations
- Plateau of Productivity

Expectations vs. Time

Forced march of enlightenment
Slope of Enlightenment
OncoBEAM RAS

Companion Diagnostic Development: Clinical Evidence & Design to IVD
Sysmex Inostics OncoBEAM™ RAS Kit
(Joint Collaboration: Sysmex | Merck)

Bringing Service based Assays to Hospitals Globally

LDT to IVD

The first CE Mark IVD Liquid Biopsy Assay for Europe & Asia Pacific
Innovative utilization of liquid biopsy testing: Merck CDx for OncoBEAM RAS CRC

**Phase I: Therapy Selection**

- **Tissue**
  - WT: TAT: 15-45 days
  - MUT: TAT: 5-7 days

- **Blood**
  - MUT

**Phase II: RAS Resistance Detection**

- **No tissue**
  - T0
  - T1
  - T2

- Monitoring of RAS mutation status

- Anti-EGFR Re-challenge?

**Concordance of RAS status in blood vs tissue**
OncoBEAM™ RAS CRC kit timeline

Partnership signed in April 2014 to develop a CE marked RAS liquid biopsy mutation test (IVD) based on the BEAMing technology

- RUO kit launched at ASCO 2015 allowed for COE set-up and training as well as concordance studies
- CE marked April 2016
- Build-out COE network
- 34 mutation expanded RAS panel
- Deliver new assays to COE labs, e.g. EGFRv2 & provide global clinical trial support for anti-EGFR re-challenge studies

**KRAS**
- Codon 12
- Codon 13
- Codon 59
- Codon 61
- Codon 117
- Codon 146

**NRAS**
- Codon 12
- Codon 13
- Codon 59
- Codon 61
- Codon 117
- Codon 146
Kit & CDx development: OncoBEAM™ Testing Centers

OncoBEAM™ RAS CRC

Strategic Goal of COE Network
Ensure patient access to high-quality CDx testing on day 1
# OncoBEAM RAS liquid biopsy performance vs tissue

## Studies of OncoBEAM RAS Concordance

<table>
<thead>
<tr>
<th>Study Reference</th>
<th>Pts.</th>
<th>OPA</th>
<th>Comments/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schmiegel 2017</td>
<td>98</td>
<td>91.8%</td>
<td>Australia/Germany; retrospective concordance</td>
</tr>
<tr>
<td>Grasselli 2017</td>
<td>146</td>
<td>89.7%</td>
<td>Spain; mPFS &amp; mOS of RAS+ and WT patients 2nd and 3rd line selected by tissue vs. plasma were comparable.</td>
</tr>
<tr>
<td>Vidal 2017</td>
<td>115</td>
<td>93.0%</td>
<td>Spain; mPFS of WT patients 1st line selected by tissue vs. plasma were comparable.</td>
</tr>
<tr>
<td>Garcia-Foncillas 2017</td>
<td>232</td>
<td>90.5%</td>
<td>Spain; concordance in 10 hospital labs where OncoBEAM is installed.</td>
</tr>
<tr>
<td>Normanno 2017</td>
<td>92</td>
<td>78.3%</td>
<td>Italy; CAPRI-GOIM retrospective; mPFS &amp; mOS of RAS+ and WT patients 1st line selected by tissue vs. plasma results comparable.</td>
</tr>
<tr>
<td>Saunders 2017</td>
<td>95</td>
<td>92.6%</td>
<td>UK; prospective concordance</td>
</tr>
<tr>
<td>Internal cut-off and verification studies</td>
<td>135</td>
<td>93.4%</td>
<td>prospectively collected plasma samples from Germany, France, Belgium, and Spain</td>
</tr>
<tr>
<td>Meta-analysis</td>
<td>913</td>
<td>90.3%</td>
<td>Positive Percent Agreement (PPA) = 88.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Negative Percent Agreement (NPA) = 91.8%</td>
</tr>
</tbody>
</table>
Clinical performance: Blood vs tissue to select patients for anti-EGFR therapy

PFS in RAS WT population by blood or tissue analysis  EGFRi + irinotecan in 2nd or 3rd line

- Tissue RAS WT
  - 10.3 months PFS

- Plasma RAS WT
  - 10.3 months PFS

Expert Taskforce Recommendation for OncoBEAM in Clinical Practice

Incorporating BEAMing technology as a liquid biopsy into clinical practice for the management of colorectal cancer patients: an expert taskforce review

J. García-Foncillas¹, E. Alba², E. Aranda³, E. Díaz-Rubio⁴, R. López-López⁵, J. Tabernero⁶ & A. Vivancos⁷

Table 2. Concordance of RAS mutation status: plasma ctDNA versus tumor tissue analyses

<table>
<thead>
<tr>
<th>Tumor-tissue RAS result</th>
<th>RAS</th>
<th>Mutant</th>
<th>WT</th>
<th>Total</th>
<th>PPA (95% CI)</th>
<th>NPA (95% CI)</th>
<th>OPA (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma ctDNA</td>
<td>Mutant</td>
<td>112</td>
<td>7</td>
<td>119</td>
<td>100×112/121=92.6% (86%, 96%)</td>
<td>100×110/117=94.0% (88%, 97%)</td>
<td>100×222/238=93.3% (89%, 96%)</td>
</tr>
<tr>
<td></td>
<td>WT</td>
<td>9</td>
<td>110</td>
<td>119</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RAS result</td>
<td>Total</td>
<td>121</td>
<td>117</td>
<td>238</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

"The clinical utility of the OncoBEAM RAS test allows patients to benefit from international guideline-recommended expanded RAS testing with rapid turnaround."

"The high degree of concordance of results generated by blood-based OncoBEAM RAS vs. standard tissue testing methods supports the conclusion that detection of RAS mutations in the blood with BEAMing may be a useful replacement to tumor testing."

J. García-Foncillas¹, E. Alba², E. Aranda³, E. Díaz-Rubio⁴, R. López-López⁵, J. Tabernero⁶ & A. Vivancos⁷
Plasma profiling to support the clinical development of EGFR T790M inhibitors for patients with EGFRm NSCLC
Plasma testing for EGFR T790M

EGFR mutant tumor at Dx → T790M Emerging → T790M Mutant Tumor → T790M TKI → T790M+/C797S Mutant Tumor → 3rd Line Therapy

OncoBEAM EGFR assay includes L858R, Exon 19 dels, T790M, & C797S

High ORR in Patients with Tumor or Plasma Positive T790M

**Identical 9.7 month PFS for patients treated with osimertinib based on either tissue or plasma T790M status**

Oxnard et al. JCO 2016

Sysmex Inostics
Clinical Impact of Results Generated with highly sensitive OncoBEAM EGFR

100 EGFR mutation-negative* NSCLC patient plasmas profiled across BEAMing EGFR assays

<table>
<thead>
<tr>
<th>Plasma BEAMing digital PCR</th>
<th>19 del</th>
<th>L858R</th>
<th>T790M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

*As determined by local EGFR tissue test

High sensitivity does not lead to higher rate of false positives

Tumor heterogeneity, not BEAMing assay performance, is the likely cause of the tissue-plasma T790M “discordance”

MUTANT ALLELE FRACTION DISTRIBUTION FOR EGFR T790M

N=167 plasma samples

- 29% MAF: 1% MAF cutoff will not reliably detect 43% of samples
- 28%
- 35%
- 8%
Clinical Adoption of accurate plasma T790M testing

Proposed paradigm for use of plasma diagnostics

1. Acquired resistance to EGFR-TKI
   - FDA approved plasma assay for T790M and sensitizing mutations

2. T790M positive
   - Skip biopsy, start 3rd gen. EGFR-TKI

3. T790M negative
   - Biopsy, FDA approved FFPE assay for T790M

   a. T790M positive
      - 3rd gen. EGFR-TKI
   b. T790M negative
      - Chemotherapy

Recent data suggest that plasma genotyping (also known as liquid biopsy or plasma biopsy) may be considered instead of tissue biopsy to detect whether patients have T790M; however, if the plasma biopsy is negative, then tissue biopsy is recommended if feasible. 627, 628

Disease Specific ctDNA Assay Design & Clinical Development

Head and Neck Cancer Squamous Cell Carcinoma
Four important considerations for NGS-based oncology tests: sensitivity, genomic coverage, amount of sample required, and cost.

For a given sample input at a fixed amount of sequencing data (cost), an NGS test can achieve coverage of a large number of genomic targets at relatively low sensitivity, or highly sensitive coverage of a well-defined set of targets. If a test is designed to interrogate a large genomic area at high sensitivity, increased sample input requirements and cost are inevitable.
Clinical relevance drives optimal coverage & cost

**Breast Cancer**

- PIK3CA (98.39%)
- KRAS (100.0%)
- ESR1 (98.02%)
- ERBB2 (93.38%)
- AKT1 (97.31%)
- TP53 (81.69%)

**NSCLC**

- KRAS (100.0%)
- MAP2K1 (100.0%)
- MET (89.88%)
- NRAS (100.0%)
- PIK3CA (92.34%)
- ERBB2 (93.25%)
- EGFR (98.68%)
- BRAF (98.18%)
- ALK (100.0%)
- TP53 (84.05%)

**HEAD & NECK SQUAMOUS CELL**

- PIK3CA (95.44%)
- HRAS (100.0%)
- CDKN2A (87.18%)
- TP53 (83.26%)

**COLORECTAL CANCER**

- KRAS (99.92%
- NRAS (100.0%)
- PIK3CA (89.59%)
- POLE (100.0%)
- PPP2R1A (100.0%)
- RNAF43 (84.47%)
- SMAD4 (84.84%)
- APC (74.85%)
- AKT1 (100.0%)
- TP53 (88.35%)

Purpose-designed for maximum sensitivity detection of highly relevant markers at efficient cost
Clinical trial targeting HNSCC patients with HRAS mutations

- HRAS mutation prevalence in HNSCC is ~5% (depending on where you look)
- Molecular testing not a component of HNSCC patient SOC workup
- Archived tumor tissue must be retrieved and analyzed – takes many weeks or months and may not represent current molecular status.
- Archival tissue is not appropriate for patients that have received cetuximab as 20% develop new HRAS mutations
- Patients likely to be unwilling to undergo repeat biopsy procedure for investigative therapy with 5% chance of identifying mutation
- Tissue testing, including biopsy procedure is time consuming and expensive
- ctDNA is present in HNSCC patients, albeit in low quantities

In search of a simple, highly sensitive, well-designed & cost efficient means to identify patients
Detection of somatic mutations and HPV in the saliva and plasma of patients with head and neck squamous cell carcinomas

87% (26/30) of patients present with detectable plasma ctDNA mutant allele fraction <1%

77% (20/30) with ctDNA mutant allele fraction <0.5%
Sensitivity matters for accurate patient selection and clinical trial stratification

Limit of Detection

- 1.0%
- 0.5%
- 0.1%
- 0.05%

Easier patient identification means…
- Rarer targets are optimized
- Smaller studies are empowered
- Fewer patients are screened
- Cost and time savings

Optimal selection of eligible patients
Truncal mutation detection is vital for determining HRAS mutation status from ctDNA in HNSCC patients

There is a need to better define “ctDNA negative” results in clinical reporting & clinical trials

– Scott Kopetz, MD, PhD

Liquid Biopsies in Oncology Drug and Device Development Workshop Part 2, October 2017

Plasma SafeSeq HNSCC panel designed to confidently identify patients with HRAS mutations

Plasma SafeSeq HNSCC seeking HRAS+

- Single gene HRAS+
  - Eligible for Therapy

- Single gene HRAS-
  - ctDNA uninformative

- HRAS-/TP53+
  - HRAS WT

- HRAS-/PIK3CA-/TP53-/CDKN2A-
  - ctDNA uninformative
Plasma testing enables speed & efficiency to identify eligible patients

Tissue timeline for HRAS testing

- Retrieve Tissue (archive or fresh biopsy)
- Test Tissue for HRAS
- Eligibility Decision

~30 – 45 days

Plasma timeline HRAS testing

- Perform Blood Draw
- SafeSeq HNSCC Panel
- Eligibility Decision

10 Days
Improved patient identification & cost savings example

• Biomarker occurs in only 5% of patients with the disease
• ~60% of occurrences are present in ctDNA below 1% MAF and cannot be reliably detected using non-optimized "pan-cancer" NGS tests
• Goal is enrollment of 50 patients in the study
• **Focused**, highly sensitive test is $3,000/ sample
• Large “pan-cancer” test is $5,000/ sample (sequencing of additional non-relevant targets increases cost)

**Focused, highly sensitive test:** Must screen 1,000 patients at $3,000/ sample = $3M to enroll 50 patients

**Large “pan-cancer” test:** Must screen 2,500 patients at $5,000/ sample = $12.5M to enroll 50 patients
Summary
OncoBEAM and SafeSeq liquid biopsy: clinical value & utility

- High concordance vs tissue testing for therapy selection
- Real-time mutation status assessments enable individualized treatment decisions
  - Detection of resistance prior to imaging
  - Clearance of plasma mutations indicate favorable outcome
  - Track tumor burden changes more quickly than CT scans
  - Predict durable responses to immunotherapy

Tumor Load

Surgery

Therapy

Traditional threshold

OncoBEAM threshold

ctDNA testing with high sensitivity
Sysmex Inostics’ Validated Ambient Temperature Shipping Kit

- Insulated shipping required for ctDNA blood samples

Sysmex Inostics’ validated a specimen shipping box to maintain a defined temperature range for up to 72 h.

- Stabilization of cfDNA
- Prevention of WBC lysis and release of genomic DANN
- Comfortable operating temperature range for validated shipping solution
- Readily implemented into clinical trials

Medina Diaz et al., PLOS ONE, 2016
## Current ctDNA clinical trial partnerships

<table>
<thead>
<tr>
<th>Institution</th>
<th>Clinical Research Aim</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>The University of Chicago Medicine of the Pritzker School of Medicine</td>
<td>Immunotherapy &amp; post-surgical disease monitoring</td>
<td>HNSCC</td>
</tr>
<tr>
<td>MD Anderson Cancer Center</td>
<td>Low Frequency RAS to predict response to therapy</td>
<td>CRC</td>
</tr>
<tr>
<td>Johns Hopkins Medicine</td>
<td>Evaluation of neoadjuvant therapy complete response</td>
<td>Breast</td>
</tr>
<tr>
<td>Johns Hopkins Medicine</td>
<td>Immunotherapy (Vaccine) Monitoring of Response</td>
<td>Pancreatic</td>
</tr>
<tr>
<td>Johns Hopkins Medicine</td>
<td>Resistance detection during 1st &amp; 2nd line EGFR TKI therapy</td>
<td>NSCLC</td>
</tr>
<tr>
<td>Johns Hopkins Medicine</td>
<td>PD-1 inhibitor monitoring of response and recurrence</td>
<td>Melanoma</td>
</tr>
<tr>
<td>Hospital Universitario Ramón y Cajal</td>
<td>Monitoring Timing of EGFR T790M emergence</td>
<td>NSCLC</td>
</tr>
<tr>
<td>Hospital Universitario Ramón y Cajal</td>
<td>IDH1 &amp; IDH2 mutation detection in CSF &amp; plasma</td>
<td>Glioma</td>
</tr>
</tbody>
</table>
The BloodPAC consortium aims to accelerate the development and validation of liquid biopsy assays.

BloodPAC provides a collaborative infrastructure that enables sharing of information between stakeholders in industry, academia, and regulatory agencies focused on improving the outcome of patients with cancer.
Sysmex Inostics’ Highly Sensitive Liquid Biopsy Technologies

**OncoBEAM™ digital PCR**
- 2 mL of plasma, FFPE/frozen tissue, blood cells
- Consistently high sensitivity (analytical sensitivities of 0.02% - 0.04%) and high concordance between tissue and plasma
- Different validation status: GCP/CLIA (RUO)
- Validated for samples collected in BD Vacutainer® K2EDTA tubes as well as Streck Cell-Free DNA BCT®

- HNSCC panel
- MRD CRC panel
- TP53
- cKIT
- NSCLC panel*
- Breast Cancer v1**

* In development
** v2 expanded panel in development

**SafeSeq NGS**
- 2-4 mL of plasma, FFPE/frozen tissue, blood cells
- Consistently high sensitivity (analytical sensitivity of 0.06% and lower)
- Validation status: RUO (CLIA, GCP validation possible)

OncoBEAM™ and SafeSeq assays also available as customized panels
Thank you!

*Lighting the way with diagnostics!*