sysmex | Together for a better healthcare journey

SYSMEX INOSTICS

Clinical & Biopharma Solutions

Broad & Targeted Panels • Genomic Profiling • Therapy Discovery
Disease Monitoring • Therapy Selection
Companion Dx Development • Accredited Service Lab

Serving our customers

Focused, sensitive genomic sequencing

To expedite oncology studies and provide deeper insights into patient's response to new therapies, we provide a range of targeted and broad NGS panels.

Sysmex Inostics' services are accelerating the pace of drug discovery and therapeutic development, enabling new treatment alternatives and renewed hope for cancer patients.

Our mission and pledge

To uncover actionable molecular insights, with a seamless, end-to-end solution for your clinical trials, without compromise or complexity. **The measure of our success will be in the response our customers have to our business approach.** We commit to unwavering excellence in the delivery of solutions, leading to improved outcomes of patients with cancer.

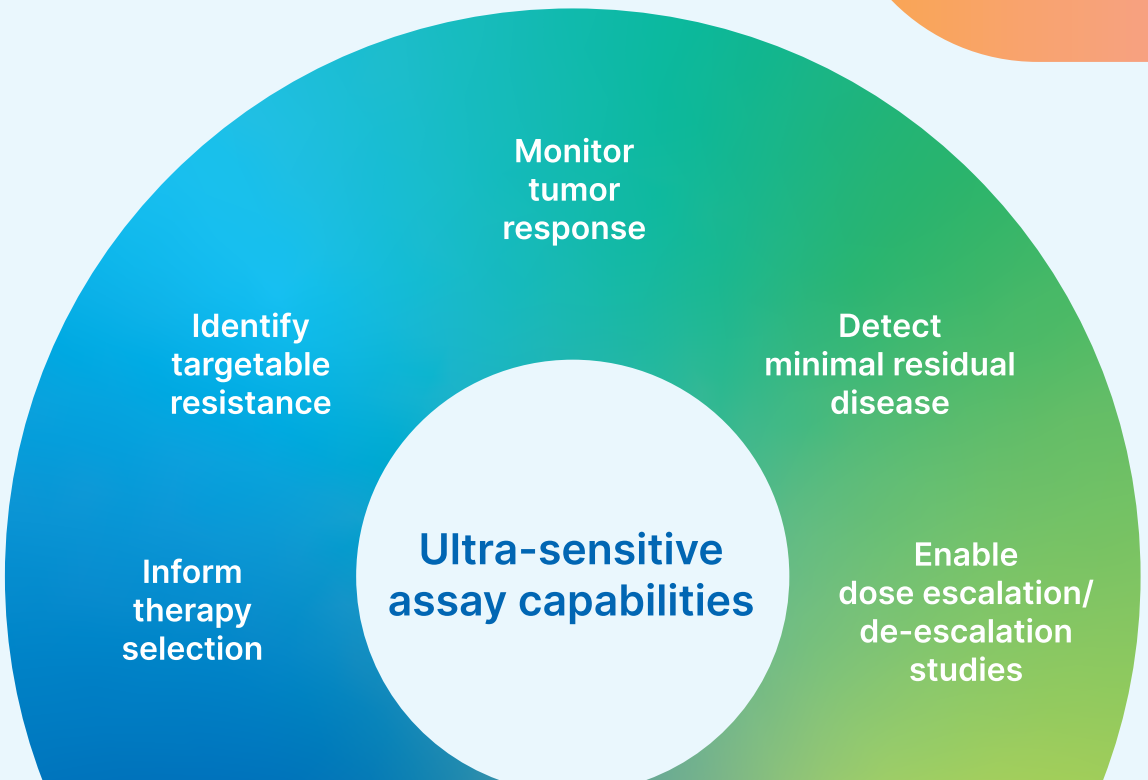
Our experience

- CLIA Certified lab specializing in liquid biopsy since 2012
- Relationships with top pharma companies + our industry expertise have advanced oncology therapies.
- CDx development capabilities + access to powerful somatic variant detection solutions + assay customization

Every Molecule Counts

Every Patient Counts

Every Decision Counts



with Sysmex Inostics laboratory solutions

Working with us

Through our Operational Excellence, Sysmex-Inostics utilizes a partnership model with BioPharma customers. We demonstrate early engagement and shared governance to prioritize and co-manage your studies.

Superior customer service

Sample collection | Collection kit logistics | Sample management | Sample reconciliation | Data reporting

Every Sample Matters

Every Assay Matters

Every Data Point Matters

Proven performance

- We have tested thousands of human samples globally to support clinical trials.
- Individualized Diagnostics; our services are in our name.
- Excellence and precision in our data reporting.

CLIA Certified

Sample types accepted
Peripheral whole blood, BBMCs, Bone marrow, Plasma, FFPE tissue slides, PBMCs

Pre-analytical sample handling
Optional collection shipping kits and temperature loggers available to ensure sample stability

Result turnaround time
Prospective 7-10 days, Retrospective (batch)*

Omic services offered
NGS, dPCR

*Select assays. For batch testing please inquire for more details.

Offer flexible batch processing

Committed to quality, from sample collection to report generation

Prioritize your needs with superior customer service and support

Comply with rigorous regulatory standards: CLIA, GLP, MD, RI, PA, CA

Dedicated to the success of your projects, research, and patients

Partner for success

Produce robust clinical reports

Solutions

Our broad portfolio of molecular assays yields informative data from cfDNA and cfRNA samples, aiding in host immune response evaluation and therapeutic monitoring biomarker identification.

Our scientific expertise and dedicated teams ensure:

- Consistency
- Timeliness
- Reliability on our robust platforms
- Data analysis reporting

Supporting clinical trials in every phase

PHASE 1

- Reveal unknown biomarker dynamics with broad NGS panels
- Biomarker monitoring for initial drug response
- Biomarker mutational profiling

PHASE 2

- Monitor therapy response with broad or targeted NGS panels
- Biomarker mutational profiling to better understand disease
- Clinical trial screening to aid enrollment
- Explore companionDx partnership capabilities

CDx*

PHASE 3

- Clinical trial screening to aid enrollment
- Monitor therapy response in randomized studies
- Coordinate companionDx process & support FDA submission

PHASE 4

- Long term longitudinal biomarker monitoring
- Collect safety/efficacy information
- Long-term sample storage available

*Partnership with QIAGEN

Broad panel assays: Liquid Trace and Profile Plus technology*

Solid tumor and liquid biopsy sample analysis for novel drug and gene variant information.

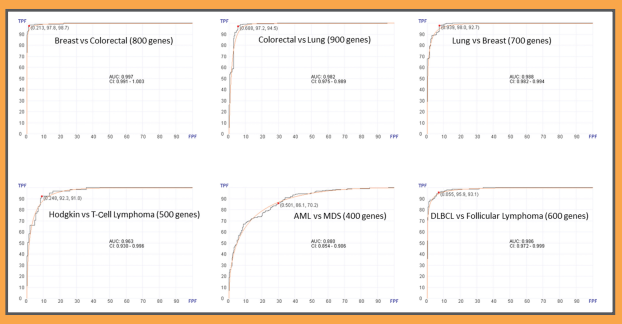
- Accurate disease classification, for patient selection and stratification
- Sample input from cfDNA and cfRNA powered by machine learning
- **Hematology indications:** leukemias, lymphomas, myelomas, viral EBV testing, and more
- **Solid tumor indications:** lung, breast, thyroid, colon, oropharyngeal tumors, ovarian, prostate, HPV, and more

Evaluation with RNA	Implications for biomarkers & therapy development
Exon skipping detection	Understand protein function such as new gene effects, recovery of function, and loss of function. Patient Stratification if using as a biomarker e.g. MET Exon 14 skipping in lung cancer.
Fusion/translocations	RNA provides a reliable method to detect fusions and translocations superior to DNA alone.
RNA complements DNA profiling	RNA testing can confirm mutations found in DNA and will find an additional ~13% of mutations that occur because of transcription errors.
Copy number variation and deletion detection	Helps identify oncogenesis events such as gene amplifications or deletions and can be used to aid in a diagnosis.
Precise diagnosis and classification of disease	RNA can help provide an exact diagnosis and classification of the tumor and identify cell of origin or cancer of unknow primary (CUP).
RNA expression profiling for molecular immunophenotyping	Provides insight into immune cell composition and activation states in the tumor microenvironment. Can identify immune “signatures” associated with treatment response or resistance.

We use machine learning at every step of our Liquid Trace and Profile Plus analyses to make new discoveries and improve patient care.

STUDY

Receiver operating characteristic curves for the prediction of diagnoses using targeted transcriptome according to AI–based models. The area under the curve (AUC) and 95% CI are shown for various diagnostic classes.



Clinical Laboratory Improvement Amendments

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

CE Solid Tumor Profile Plus, Liquid Biopsy Solid Tumor Profile, Hematology Profile Plus, Hematology Profile, are in conformity with Directive 93/42/EEC

FOR MORE INFO ON STUDY:

https://bit.ly/3FjjaLv

*Liquid Trace and Profile Plus technology are CAP accredited, NY state approved and CE marked.

Targeted panel assays: Plasma-Safe-SeqS (PSS) technology

Ultra-sensitive NGS liquid biopsy detecting of cfDNA

Detecting low frequency somatic variants requires ultrasensitive liquid biopsy approaches.

Assays are designed by incorporating literature, public genomic databases, and insights from KOLs.

Our targeted approach balances the primary need for high sensitivity with the breadth of genomic coverage, providing confidence that somatic variants can be detected even at exceedingly low concentrations.

DNA extraction

Pre-analytical process

- Two tubes of blood
- Efficient extraction, quantification and quality control check at each step

Target enrichment, library preparation & sequencing

Target enrichment

- Designed for a broad range of cfDNA input
- UIDs added to enrichment amplicons allow to retain all input cfDNA and exclude sequencing errors from analysis

NGS analysis & reporting

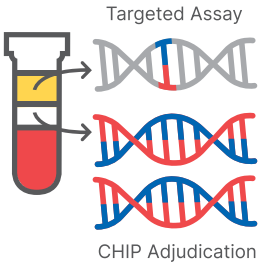
Analysis & reporting

- Limit of Blank (LoB) determined for all potential base changes to reduce noise
- Low assay-wide Limit of Detection (LoD) ensures sub level variants (below 0.03% VAF) can be detected
- CHIP and germline adjudication

Matched germline sequencing reduces clinical false positives

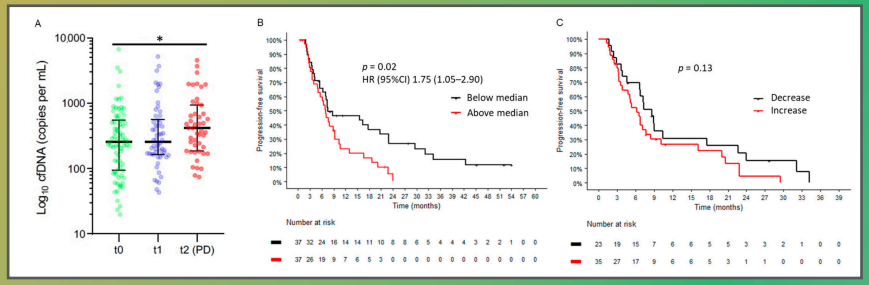
Clonal hematopoiesis of indeterminate potential (CHIP) poses a unique challenge for NGS-based cfDNA assays since it can cause the apparent detection of tumor-associated somatic mutations in the plasma of healthy, aging individuals, leading to clinical false positives.

PSS assays use matched genomic DNA from the buffy coat portion of the blood collection tube to directly adjudicate the status of potential CHIP variants.



STUDY

Liquid biopsy monitoring in metastatic breast cancer patients treated with endocrine agents after exposure to aromatase inhibitors



cfDNA levels at baseline and early dynamics. (A) Increase in cfDNA levels at progression. (B,C) Prognostic and predictive value of baseline cfDNA levels. *, p < 0.05.

FOR MORE INFO ON STUDY:

https://bit.ly/46BCG1y

Ultra-sensitive cfHPV DNA detection and quantification: HPV-SEQ

cfHPV DNA represents a promising surrogate of disease burden in patients with HPV-driven cancers. Applying ultra-sensitive technology to detect and quantify circulating HPV-DNA using HPV-SEQ is an innovative and exciting step forward in the development of more targeted approaches when managing HPV-associated cancers.

Advantages of HPV-SEQ

- High analytical and clinical sensitivity, with the ability to reliably and consistently detect as low as 2 copies of HPV 16 and HPV 18 DNA
- Quantitative detection of HPV DNA across a broad dynamic range
- Low quantitative variability
- Low background (<0.04 copies), indicating high specificity

HPV-related cancer patient journey

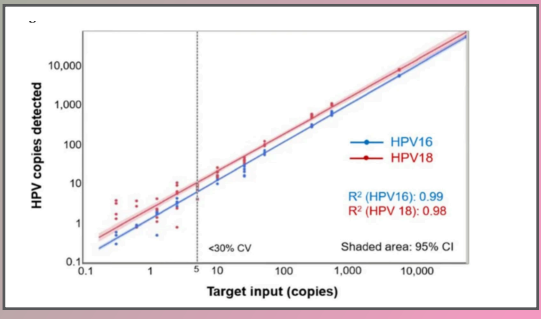
Cancer treatment → **Cancer treatment completion** → **Post-treatment surveillance**

HPV-SEQ may be used during treatment to assess dynamic changes in cfHPV-DNA as a surrogate of disease response. The robust quantitative performance demonstrated by HPV-SEQ enables accurate and reliable detection, which is critical to inform patient management and therapeutic decision-making.

HPV-SEQ may also be used following treatment to monitor for the presence cfHPV-DNA as an indication of disease recurrence. Exquisite sensitivity is key to enabling the detection of low-level cfHPV-DNA in the post-treatment surveillance setting.

STUDY

Prospective study evaluating dynamic changes of cell-free HPV DNA in locoregional viral-associated oropharyngeal cancer treated with induction chemotherapy and response-adaptive treatment



FOR MORE INFO ON STUDY:

https://bit.ly/3PXB2QZ

Technical specifications

For more info on all panels: https://sysmex-inostics.com/assay-details-and-specifications/

FOR MORE INFO ON ALL PANELS:

Broad gene panels

Solid Tumor Profile Plus™, Hematology Profile Plus™,
GTC Liquid Trace Solid Tumor™, GTC Liquid Trace Hematology™

>430 genes for DNA
>1600 genes for RNA

All exons targeted
(Scan QR code for more info)

FFPE: 1 H&E slide and
6-10 unstained slides
Peripheral blood: 5 mL EDTA tube
Bone marrow: 2 mL

Sample type; Inquire for additional types

0.1% VAF, tumor agnostic
0.001% VAF, tumor informed

Limit of detection

7-10 days available

Turnaround time

Targeted gene panels

BC-SEQ, RAS-RAF-SEQ, HNSCC-SEQ, AML-MRD-SEQ, AML-SEQ

5-68 targets

Gene regions targeted
(Scan QR code for more info)

≥0.035% VAF

Limit of detection

7-10 days available

Turnaround time

Peripheral blood: (x2) 8-10 mL
Bone marrow: 2 mL

Sample type

HPV monitoring

HPV-SEQ

HPV 16 & HPV 18

Strains

Qualitative:
>2 copies HPV 16 & HPV 18

Qualitative reporting

Quantitative:
HPV 16: 10 to 500,000 copies
HPV 18: 20 to 500,000 copies

Quantitative reporting

7-10 days available

Turnaround time

Peripheral blood: (x2) 8-10 mL
Streck BCT

Sample type

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