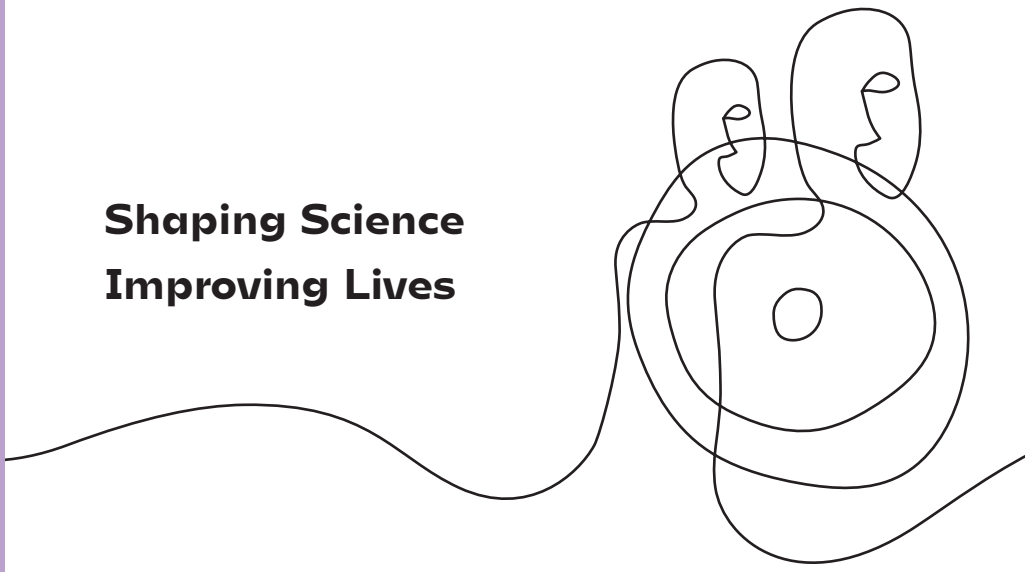
Com.Pl.i.t DX

Personalized treatment based on tumor biology

For patients with lung, colon, and breast cancer



Shaping Science
Improving Lives

Genekor

Committed to Biotechnological Innovation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Com.Pl.i.t DX®

Com.Pl.i.t DX® multi-gene tests provide valuable information that can be used to select the optimal targeted therapy for patients. By analyzing multiple genes simultaneously, they provide a detailed fingerprint of tumor biology, which is used by the treating physician to **personalize** the patient's **treatment plan**.

Com.Pl.i.t DX® tests are essential for personalizing treatment plans.

- Determine the molecular profile of the tumor, such as gene mutations, rearrangements, and copy number variations in inoperable and early-stage tumors, providing a more comprehensive assessment.
- Determine the indicated drugs that target the mutated gene(s) or pathways involved.
- Identify mutations associated with resistance to targeted therapy.
- Recommend off-label therapies and/or indicate therapies currently in clinical trials.

Com.Pl.i.t DX® tests are designed to offer maximum sensitivity and specificity.

All findings are categorized using ***in silico*** analysis algorithms and the **OncoKB (Memorial Sloan Kettering Cancer Center)** database, which provides evidence-based information on the clinical significance of gene mutations and available targeted therapies.

Why are Com.Pl.i.t DX® multigene tests the most appropriate tool for selecting the optimal personalized treatment?

- **They provide reliable information.**

Advanced Next Generation Sequencing (NGS) technology is used for the comprehensive analysis of a panel of genes related to targeted and personalized therapy. **Com.Pl.i.t DX®** also includes the analysis of genetic rearrangements, providing comprehensive and reliable information to both patient and physician. The molecular profile of each patient's tumor allows for a highly personalized therapy selection.

- **Saving Time, Samples, and Costs.**

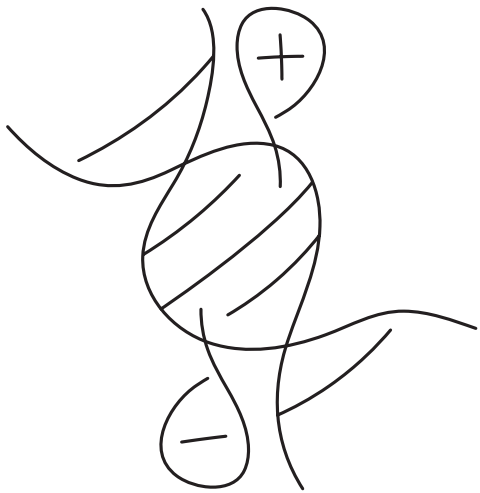
The advantage of the **Com.Pl.i.t DX®** polygenic test is that it uses a minimal tumor sample, in which all cancer-related genes are analyzed simultaneously providing clear,

complete results quickly and at lower cost. Unlike single-gene tests that require larger or multiple samples, this approach saves time and preserves valuable tissue.

- **Ongoing Support for Patients and Physicians.**

Direct access to scientific and procedural support, as well as useful information, is essential. Genekor provides continuous support through its customer service department and scientific advisors, offering expertise to always enhance the physicians' work.

Next Generation Sequencing (NGS) technology allows simultaneous analysis of multiple genetic mutations in the same sample - saving valuable material.



Com.Pl.i.t DX® Lung

Com.Pl.i.t DX® Lung is designed to help the treating physician select the optimal treatment for patients with Non-Small Cell Lung Cancer (NSCLC) based on tumor biology.

Gene Table

79 unique genes/73 genes full CDS analysed									
ABL1	*AKT1*	*ALK*	*APC*	*ARAF*	*ATM*	*BRAF*	*BRCA2*	*CCNE1*	*CDH1*
CDKN2A	*CSF1R*	*CTNNB1*	*DDR2*	*DICER1*	*EGFR*	*EIF1AX*	*ERBB2*	*ERBB3*	*ERBB4*
EZH1	*EZH2*	*FBXW7*	*FGFR1*	*FGFR2*	*FGFR3*	*FLT3*	*FOXL2*	*GNA11*	*GNAQ*
GNAS	*HNF1A*	*HRAS*	*IDH1*	*IDH2*	*JAK2*	*JAK3*	*KDR*	*KEAP1*	*KIT*
KRAS	*MAP2K1*	*MDM2*	*MET*	*MLH1*	*MPL*	*MYC*	*NOTCH1*	*NPM1*	*NRAS*
NTRK1	*NTRK2*	*NTRK3*	*PDGFRA*	*PIK3CA*	*POLE*	*PTEN*	*PTPN11*	*RAC1*	*RAF1*
RB1	*RET*	*ROS1*	*RC*	*SMAD4*	*SMARCB1*	*SMO*	*SOS1*	*SPOP*	*STK11*
TERT	*TP53*	*VHL*							

18 RNA Genes					
ALK	*BRAF*	*EGFR*	*ERG*	*FGFR2*	*FGFR3*
MET	*NRG1*	*NTRK1*	*NTRK2*	*NTRK3*	*PBX1*
PPARG	*PRKACA*	*RAF1*	*RET*	*ROS1*	*TFE3*

Immunohistochemistry							
PD-L1	*HER2*	*c-MET*					

The NRG1 and FGFR1–3 genes, among others, have been added to the new **Com.Pl.i.t DX® Lung**.

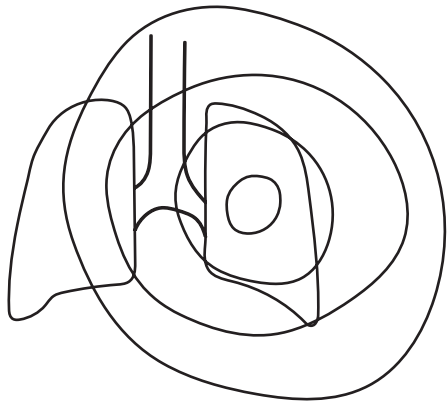
- Patients with NSCLC and **NRG1 rearrangements** represent a rare molecular subgroup with an **approved targeted therapy**.
- Mutations and rearrangements in FGFR1–3 are emerging biomarkers in NSCLC, and patients with these changes could benefit from targeted therapies.

With these additions, **Com.Pl.i.t DX® Lung** provides a complete molecular profile for NSCLC patients with prognostic and predictive value, following NCCN guidelines for nine approved targeted therapies:

- ***EGFR, BRAF V600E, KRAS G12C, ERBB2*** **(DNA sequencing)**
- ***ALK, NRG1, NTRK1/2/3, ROS1, RET*** **(RNA sequencing)**
- ***MET*** **exon 14 skipping mutation (DNA & RNA sequencing)**
- **HER2, PD-L1, c-MET overexpression (IHC)**

Sample: Paraffin-embedded tissue

Result time: 10 working days



Com.Pl.i.t DX® Colon

Gene Table

79 unique genes/73 genes full CDS analysed									
ABL1	*AKT1*	*ALK*	*APC*	*ARAF*	*ATM*	*BRAF*	*BRCA2*	*CCNE1*	*CDH1*
CDKN2A	*CSF1R*	*CTNNB1*	*DDR2*	*DICER1*	*EGFR*	*EIF1AX*	*ERBB2*	*ERBB3*	*ERBB4*
EZH1	*EZH2*	*FBXW7*	*FGFR1*	*FGFR2*	*FGFR3*	*FLT3*	*FOXL2*	*GNA11*	*GNAQ*
GNAS	*HNF1A*	*HRAS*	*IDH1*	*IDH2*	*JAK2*	*JAK3*	*KDR*	*KEAP1*	*KIT*
KRAS	*MAP2K1*	*MDM2*	*MET*	*MLH1*	*MPL*	*MYC*	*NOTCH1*	*NPM1*	*NRAS*
NTRK1	*NTRK2*	*NTRK3*	*PDGFRA*	*PIK3CA*	*POLE*	*PTEN*	*PTPN11*	*RAC1*	*RAF1*
RB1	*RET*	*ROS1*	*SMAD4*	*SMARCB1*	*SMO*	*SOS1*	*SPOP*	*STK11*	*SRC*
TERT	*TP53*	*VHL*							

18 RNA Genes					
ALK	*BRAF*	*EGFR*	*ERG*	*FGFR2*	*FGFR3*
MET	*NRG1*	*NTRK1*	*NTRK2*	*NTRK3*	*PBX1*
PPARG	*PRKACA*	*RAF1*	*RET*	*ROS1*	*TFE3*

Immunotherapy
MSI

Com.Pl.i.t DX® Colon helps physicians select the best therapy based on the tumor biology in metastatic colorectal cancer.

In colorectal cancer, somatic mutations occur in genes involved in key signaling pathways related to cancer development and treatment.

Approved targeted therapies include:

KRAS & NRAS: Identify patients unlikely to benefit from anti-EGFR therapies (cetuximab, panitumumab). ~50% of **colorectal cancers** carry these mutations.

BRAF V600E: Found in ~10% of metastatic colorectal cancers and associated with approved targeted treatments.

HER2 amplification: An approved target in ***KRAS/NRAS*** wild-type tumors.

Additional approved biomarkers (any cancer type):

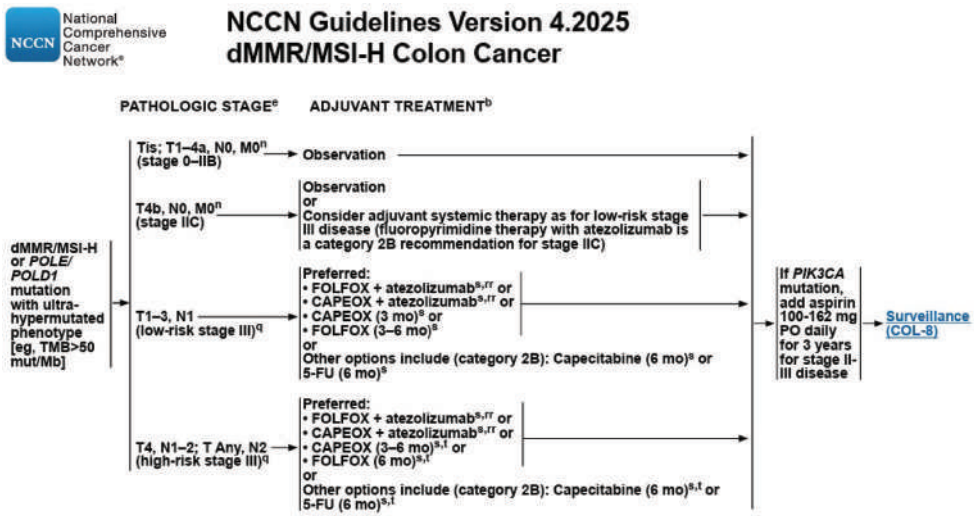
Microsatellite Instability (**MSI**) and ***POLE*** mutations (per NCCN Guidelines) predict response to immune checkpoint inhibitors.

Approved therapies also exist for ***NTRK1/2/3*** and ***RET*** rearrangements, and for ***KRAS G12C*** mutations.

Com.Pl.i.t DX® Colon integrates all these therapeutic targets into one test, offering a comprehensive molecular profile.

POLE & PIK3CA Testing in Early-Stage Cancer:

Even early-stage colorectal cancers benefit from molecular profiling. NCCN guidelines recommend testing for ***PIK3CA*** and ***POLE*** mutations alongside MSI to guide personalized treatment.



Sample: Paraffin-embedded tissue

Result time: 10 working days

Com.Pl.i.t DX® Liquid

Com.Pl.i.t DX® Liquid analysis provides valuable information that can be used to select the optimal targeted therapy for patients. By analyzing multiple genes simultaneously, it provides a detailed fingerprint of the tumor's biology, which is used by the treating physician to personalize the patient's treatment plan.

Gene Table

64 Genes with SNV/Indels Analyzed									
AKT1	*ALK*	*APC*	*ARAF*	*ATM**	*BRAF*	*BRCA2**	*CDH1*	*CDKN2A**	*CSF1R*
CTNNB1	*DDR2*	*EGFR**	*ERBB2**	*ERBB3*	*ERBB4*	*EZH2*	*FBXW7*	*FGFR1*	*FGFR2**
*FGFR3**	*FLT3*	*FOXL2*	*GNA11*	*GNAQ*	*GNAS*	*HNF1A*	*HRAS*	*IDH1*	*IDH2*
JAK2	*KDR*	*KEAP1*	*KIT*	*KRAS**	*MAP2K1*	*MDM2*	*MET**	*MLH1**	*MYC*
NOTCH1	*NPM1*	*NRAS*	*NTRK1*	*NTRK2*	*NTRK3*	*PDGFRA*	*PIK3CA**	*POLE*	*PTEN**
PTPN11	*RAF1*	*RB1**	*RET*	*ROS1*	*SMAD4*	*SMARCA4*	*SMARCB1*	*SMO*	*SPOP*
STK11	*TERT*	*TP53**	*VHL**						
* CNV (amplification/deletion) analysis is included for these genes									
Fusions									
ALK	*FGFR1*	*FGFR2*	*FGFR3*	*NTRK1*	*NTRK2*	*NTRK3*	*RET*	*ROS1*	
MSI									
15 loci									

Test Description

- A blood sample is taken from the patient, as in a routine blood test.
- Isolation of cancer DNA and RNA detected in the blood, also known as circulating tumor DNA and RNA.
- Ability to detect mutations at very low rates (<1%).
- Advanced Next Generation Sequencing (NGS) technology is used.
- Each genetic locus is read over 10,000 times by the NGS system.
- Specialized software is used to analyze the data and convert raw data into practical information.

Com.Pl.i.t DX® Liquid is designed for patients with colon or lung cancer.

Sample: Blood in 1 vial of 10ml Cell-Free DNA BCT STRECK

Result time: 10 working days

Com.PI.i.t DX® Lung Combo

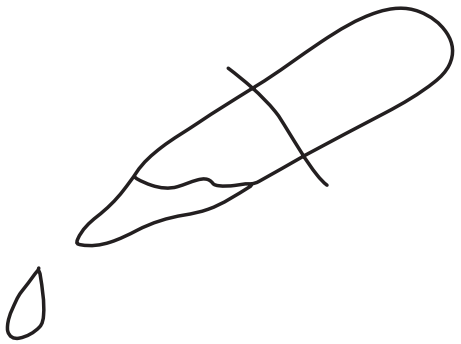
Simultaneous molecular testing of tissue and liquid biopsies in patients with **NSCLC** (Non-Small Cell Lung Cancer) **is the optimal diagnostic approach**.

Each method has a certain rate of **false negatives;** therefore, **combining** them increases **diagnostic sensitivity** and leads to the **detection of more actionable molecular alterations**.

In addition, the parallel use of the two methods can:

- **Reduce the time to diagnosis.**
- **Allow for faster initiation of appropriate treatment.**

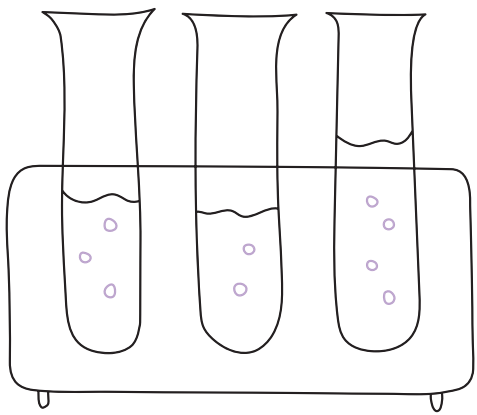
This is particularly important in cases where **the tissue sample is insufficient or unsuitable**, which could otherwise delay patient management.



Com.Pl.i.t DX® Colon Combo

Although there is usually sufficient material for molecular analysis in colon cancer, in some cases (and especially after recurrence) the simultaneous use of liquid biopsy and tissue analysis can significantly increase the sensitivity of mutation detection, particularly resistance mechanisms.

Combined tissue and blood testing improves sensitivity covers the intratumoral heterogeneity of metastasis, enables dynamic monitoring of the disease, and supports personalized treatment selection for patients with metastatic colorectal cancer.



Com.Pl.i.t DX® Breast & Liquid Breast

Com.Pl.i.t DX® Breast is designed to help the treating physician select the optimal treatment based on the biology of the patient's breast cancer tumor.

Gene Table

23 Genes with SNV/Indels Analyzed									
AKT1	*BRCA1**	*BRCA2**	*CDH1*	*CDK4**	*CDK6**	*CCND1**	*EGFR**	*ERBB2*(HER2)*	*ERBB3*
ESR1	*FBXW7*	*FGFR1*	*FGFR2**	*FGFR3**	*GATA3*	*KRAS**	*NF1*	*PALB2**	*PIK3CA**
*PTEN**	*RB1**	*TP53**							
* CNV (amplification/deletion) analysis is included for these genes									
7 Fusions									
FGFR1	*FGFR2*	*FGFR3*	*NTRK1*	*NTRK2*	*NTRK3*	*RET*			
MSI									
15 loci									

It provides a complete molecular profile for breast cancer patients, including all biomarkers with approved treatments as well as emerging biomarkers according to international guidelines (NCCN).

Biomarkers with Approved Treatment

HR+, HER2–:

- *AKT1*
- *ESR1*
- *PIK3CA*
- *PTEN*

All breast cancer subtypes:

- *BRCA1/2*
- *PALB2*
- *NTRK fusions*
- *RET fusions*
- *MSI*

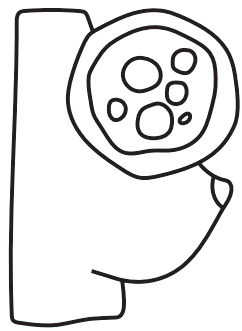
Com.Pl.i.t DX® Liquid Breast

The **Com.Pl.i.t DX® Liquid Breast** test analyzes the same genes and is designed for:

- Patients with inoperable tumors or limited/insufficient biopsy material
- Patients with multiple metastases
- Patients undergoing or post-treatment, to identify emerging targetable or resistant mutations

Recommended for Targeted Treatment Decisions

- Women with advanced or metastatic ER+/HER2– breast cancer after relapse, to determine on-label therapies based on mutations in *ESR1*, *PIK3CA*, *AKT1*, *PTEN*.
- Women with advanced or metastatic breast cancer after relapse, to consider off-label targeted therapies or enrollment in clinical trials.
- In selected cases, the test can guide the use of PARP inhibitors (based on *BRCA1/2*, *PALB2* mutations) or immunotherapy (based on MSI analysis).



Com.PI.i.t DX® Breast Combo

Simultaneous molecular testing of tissue and liquid biopsies in patients with breast cancer is the optimal diagnostic approach, especially in cases where patients have not undergone comprehensive molecular testing at the initial diagnosis of advanced or metastatic disease in biopsy tissue.

Each method has a certain false-negative rate, so combining them increases diagnostic sensitivity and leads to the detection of more actionable molecular alterations.

This is particularly important in breast cancer, as for certain biomarkers such as ***ESR1***, international guidelines recommend testing in liquid biopsy.

Therefore, the parallel use of both methods enhances the overall accuracy of the molecular profile, contributing to:

- The optimal selection of targeted therapies, and
- The personalization of the therapeutic approach.

Sample: Blood in 1 vial of 10ml Cell-Free DNA BCT STRECK

Result time: 10 working days

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