Com.Pl.i.t DX®

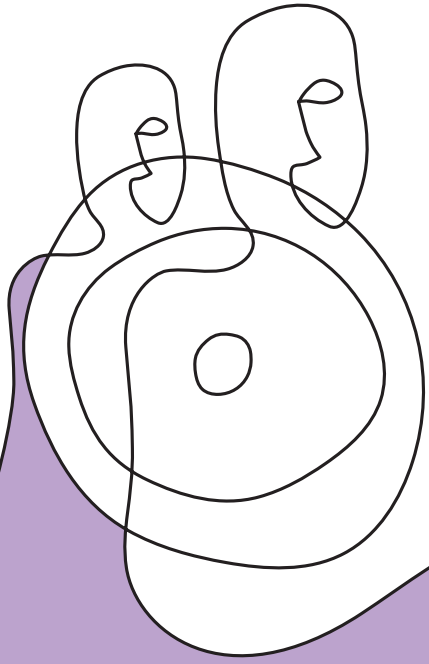
Personalized treatment based on tumor biology

Genekor

Committed to Biotechnological Innovation

in cooperation with

ADEALAB



SHAPING SCIENCE
IMPROVING LIVES

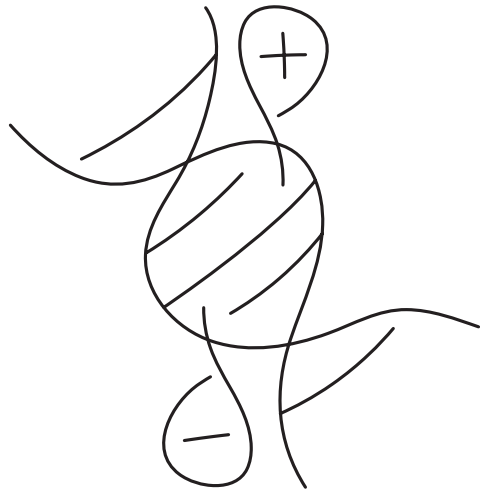
Com.Pl.i.t DX®

Personalized Tumor Profiling

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

Com.Pl.i.t DX® tests are essential in precision oncology by:

- Determining the tumor's molecular profile, including gene alterations, rearrangements, and copy number alterations in both late-stage and early-stage tumors, providing a more comprehensive assessment.
- Identifying approved targeted therapies relevant to the detected molecular alterations or dysregulated pathways.
- Detecting molecular alterations associated with resistance to targeted treatments.
- Supporting therapeutic decision-making by highlighting potential off-label treatment options and identifying relevant ongoing clinical trials.



Technology & Testing Approach

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

Advanced Next Generation Sequencing (NGS) technology is used for the comprehensive analysis of a gene panel related to targeted and personalized therapy.

All findings are systematically categorized using *in silico* analytical algorithms and the OncoKB database, which delivers evidence based insights into the clinical relevance of genomic alterations and associated targeted therapeutic options.

Advantages

- Minimal tumor tissue required
- Simultaneous multi-gene analysis
- Faster and cost-efficient results
- Preservation of valuable biological material

Testing Modalities

Tissue biopsy (FFPE): Provides comprehensive genomic profiling from tumor tissue.

Liquid biopsy (ctDNA): Uses a blood sample to analyze circulating tumor DNA, enabling highly sensitive detection of genomic alterations, including those present at low allele frequencies.

Combined approach (Tissue + Liquid): The parallel use of both methods increases diagnostic sensitivity, improves detection of actionable alterations, and supports faster treatment decisions.

Sample Types & Turnaround Time

Tissue biopsy (FFPE): Sample: Formalin Paraffin-Embedded Tissue (FFPET)

Liquid biopsy (ctDNA): Sample: 10ml of whole peripheral blood in one Cell-Free DNA BCT STRECK vial

Result time: 10 working days

Com.Pl.i.t DX® Lung (FFPE)

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

77 DNA genes									
ABL1	*AKT1*	*ALK*	*APC*	*ARAF*	*ATM*	*BRAF*	*BRCA2*	*CCNE1**	*CDH1*
*CDKN2A**	*CSF1R*	*CTNNB1*	*DDR2*	*DICER1*	*EGFR**	*EIF1AX*	*ERBB2**	*ERBB3*	*ERBB4*
EZH2	*FBXW7*	*FGFR1**	*FGFR2**	*FGFR3*	*FLT3*	*FOXL2*	*GNA11*	*GNAQ*	*GNAS*
HGF	*HNF1A*	*HRAS*	*IDH1*	*IDH2*	*JAK2*	*JAK3*	*KDR*	*KEAP1*	*KIT*
KRAS	*LAG-3*	*MAP2K1*	*MDM2*	*MET**	*MLH1**	*MPL*	*MTAP**	*MYC*	*NOTCH1*
NPM1	*NRAS*	*NTRK1*	*NTRK2*	*NTRK3*	*PDGFRA*	*PIK3CA*	*PIK3R1*	*POLD1*	*POLE*
*PTEN**	*PTPN11*	*RAC1*	*RAF1*	*RB1*	*RET*	*ROS1*	*SMAD4*	*SMARCA4**	*SMARCB1*
SMO	*SPOP*	*STK11*	*SRC*	*TERT*	*TP53*	*VHL*			
*CNV (amplification/deletion) analysis is included for these genes									

19 RNA genes									
ALK	*BRAF*	*EGFR*	*ERG*	*FGFR1*	*FGFR2*	*FGFR3*	*MET*	*NRG1*	*NTRK1*
NTRK2	*NTRK3*	*PBX1*	*PPARG*	*PRKACA*	*RAF1*	*RET*	*ROS1*	*TFE3*	

IHC biomarkers can be requested as add-on

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

Com.Pl.i.t DX® Lung provides a complete molecular profile for NSCLC patients with prognostic and predictive value, following NCCN guidelines for targeted therapies

Biomarkers with approved therapy

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

Emerging biomarkers

MET amplification (DNA Sequencing)
FGFR1/3 alterations (DNA & RNA Sequencing)
MTAP loss

Biomarkers of immunotherapy resistance

STK11 inactivating mutation
KEAP1 inactivating mutation

Com.Pl.i.t DX® Lung

(Liquid & Combo)

Com.Pl.i.t DX® Liquid analysis provides a minimally invasive approach for selecting optimal targeted therapies for patients. By simultaneously analyzing multiple genes, it generates a comprehensive molecular profile of the tumor's biology. In addition, liquid biopsy analysis is ideal for detecting resistance alterations associated with targeted therapies. This test is particularly valuable when tissue samples are unavailable or insufficient, and it can also be used alongside tissue analysis to enhance clinically relevant information.

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									
9 Fusions									
ALK	*FGFR1*	*FGFR2*	*FGFR3*	*NTRK1*	*NTRK2*	*NTRK3*	*RET*	*ROS1*	
MSI									

Combined Tissue & Liquid Testing

Simultaneous molecular testing of tissue and liquid biopsies in patients with NSCLC 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:

- Increase the possibility of identifying actionable alterations
- Allow for faster initiation of appropriate treatment

Com.Pl.i.t DX® Colon

(FFPE)

Com.Pl.i.t DX® Colon supports physicians in selecting the most appropriate therapy based on the tumor biology in colorectal cancer.

Gene Table

77 DNA genes									
ABL1	*AKT1*	*ALK*	*APC*	*ARAF*	*ATM*	*BRAF*	*BRCA2*	*CCNE1**	*CDH1*
*CDKN2A**	*CSF1R*	*CTNNB1*	*DDR2*	*DICER1*	*EGFR**	*EIF1AX*	*ERBB2**	*ERBB3*	*ERBB4*
EZH2	*FBXW7*	*FGFR1**	*FGFR2**	*FGFR3*	*FLT3*	*FOXL2*	*GNA11*	*GNAQ*	*GNAS*
HGF	*HNF1A*	*HRAS*	*IDH1*	*IDH2*	*JAK2*	*JAK3*	*KDR*	*KEAP1*	*KIT*
KRAS	*LAG-3*	*MAP2K1*	*MDM2*	*MET**	*MLH1**	*MPL*	*MTAP**	*MYC*	*NOTCH1*
NPM1	*NRAS*	*NTRK1*	*NTRK2*	*NTRK3*	*PDGFRA*	*PIK3CA*	*PIK3R1*	*POLD1*	*POLE*
*PTEN**	*PTPN11*	*RAC1*	*RAF1*	*RB1*	*RET*	*ROS1*	*SMAD4*	*SMARCA4**	*SMARCB1*
SMO	*SPOP*	*STK11*	*SRC*	*TERT*	*TP53*	*VHL*			
*CNV (amplification/deletion) analysis is included for these genes									

19 RNA genes									
ALK	*BRAF*	*EGFR*	*ERG*	*FGFR1*	*FGFR2*	*FGFR3*	*MET*	*NRG1*	*NTRK1*
NTRK2	*NTRK3*	*PBX1*	*PPARG*	*PRKACA*	*RAF1*	*RET*	*ROS1*	*TFE3*	
MSI									

IHC biomarkers can be requested as add-on

Immunohistochemistry							
HER2							

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

Approved targeted therapies include:

KRAS/NRAS wild type identifies patients eligible for anti-EGFR treatment

KRAS G12C, BRAF V600E, HER2 amplification: guide targeted therapy selection

NTRK1/2/3 & RET fusions: guide targeted therapy selection

MSI, POLE, POLD1: predict response to immune checkpoint inhibitors

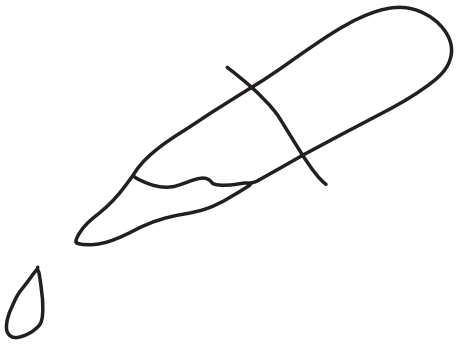
Com.Pl.i.t DX® Colon

(Liquid)

Com.Pl.i.t DX® Liquid analysis provides a comprehensive molecular profile through minimally invasive sampling.

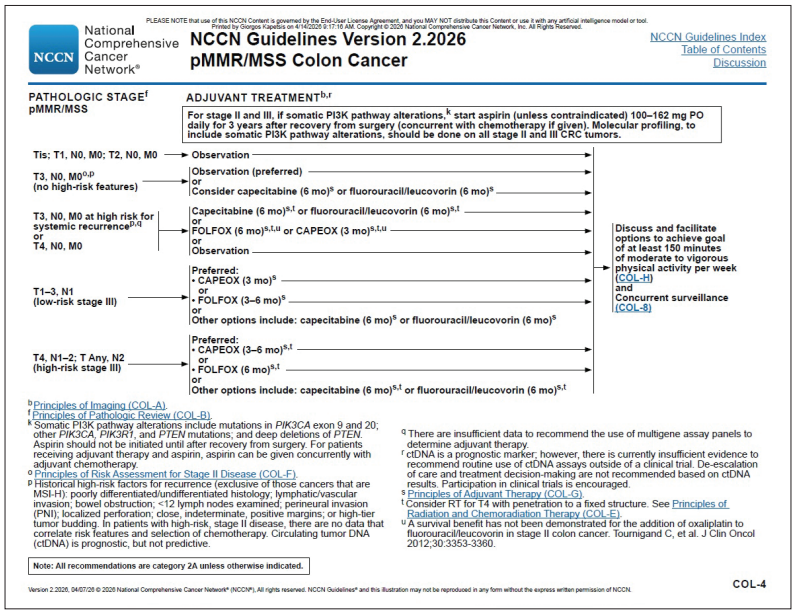
Gene Table

63 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**							
* CNV (amplification/deletion) analysis is included for these genes									
9 Fusions									
ALK	*FGFR1*	*FGFR2*	*FGFR3*	*NTRK1*	*NTRK2*	*NTRK3*	*RET*	*ROS1*	
MSI									



Molecular Profiling in Early Stage Colon Cancer

According to the updated NCCN 2026 guidelines, molecular profiling should be performed in all stage II and III colorectal cancers. Recommended testing includes ***MMR/MSI, POLE/POLD1*** and **PI3K pathway alterations *(PIK3CA, PIK3R1, PTEN)*** which can inform personalized adjuvant treatment decisions.



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National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2026
pMMR/MSS Colon Cancer

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PATHOLOGIC STAGE[f] pMMR/MSS | ADJUVANT TREATMENT[b,r]

For stage II and III, if somatic PI3K pathway alterations,[k] start aspirin (unless contraindicated) 100–162 mg PO daily for 3 years after recovery from surgery (concurrent with chemotherapy if given). Molecular profiling, to include somatic PI3K pathway alterations, should be done on all stage II and III CRC tumors.

- Tis; T1, N0, M0; T2, N0, M0 → Observation
- T3, N0, M0[o,p] (no high-risk features) → Observation (preferred) or Consider capecitabine (6 mo)[s] or fluorouracil/leucovorin (6 mo)[s]
- T3, N0, M0 at high risk for systemic recurrence[p,q] or T4, N0, M0 → Capecitabine (6 mo)[s,t] or fluorouracil/leucovorin (6 mo)[s,t]; or FOLFOX (6 mo)[s,t,u] or CAPEOX (3 mo)[s,t,u]; or Observation
- T1–3, N1 (low-risk stage III) → Preferred: • CAPEOX (3 mo)[s] or • FOLFOX (3–6 mo)[s]; or Other options include: capecitabine (6 mo)[s] or fluorouracil/leucovorin (6 mo)[s]
- T4, N1–2; T Any, N2 (high-risk stage III) → Preferred: • CAPEOX (3–6 mo)[s,t] or • FOLFOX (6 mo)[s,t]; or Other options include: capecitabine (6 mo)[s,t] or fluorouracil/leucovorin (6 mo)[s,t]

→ Discuss and facilitate options to achieve goal of at least 150 minutes of moderate to vigorous physical activity per week (COL-H) and Concurrent surveillance (COL-8)

[b] Principles of Imaging (COL-A).
[f] Principles of Pathologic Review (COL-B).
[k] Somatic PI3K pathway alterations include mutations in *PIK3CA* exon 9 and 20; other *PIK3CA*, *PIK3R1*, and *PTEN* mutations; and deep deletions of *PTEN*. Aspirin should not be initiated until after recovery from surgery. For patients receiving adjuvant therapy and aspirin, aspirin can be given concurrently with adjuvant chemotherapy.
[o] Principles of Risk Assessment for Stage II Disease (COL-F).
[p] Historical high-risk factors for recurrence (exclusive of those cancers that are MSI-H): poorly differentiated/undifferentiated histology; lymphatic/vascular invasion; bowel obstruction; <12 lymph nodes examined; perineural invasion (PNI); localized perforation; close, indeterminate, positive margins; or high-ber tumor budding. In patients with high-risk, stage II disease, there are no data that correlate risk features and selection of chemotherapy. Circulating tumor DNA (ctDNA) is prognostic, but not predictive.
[q] There are insufficient data to recommend the use of multigene assay panels to determine adjuvant therapy.
[r] ctDNA is a prognostic marker; however, there is currently insufficient evidence to recommend routine use of ctDNA assays outside of a clinical trial. De-escalation of care and treatment decision-making are not recommended based on ctDNA results. Participation in clinical trials is encouraged.
[s] Principles of Adjuvant Therapy (COL-G).
[t] Consider RT for T4 with penetration to a fixed structure. See Principles of Radiation and Chemoradiation Therapy (COL-E).
[u] A survival benefit has not been demonstrated for the addition of oxaliplatin to fluorouracil/leucovorin in stage II colon cancer. Tournigand C, et al. J Clin Oncol 2012;30:3353-3360.

Note: All recommendations are category 2A unless otherwise indicated.

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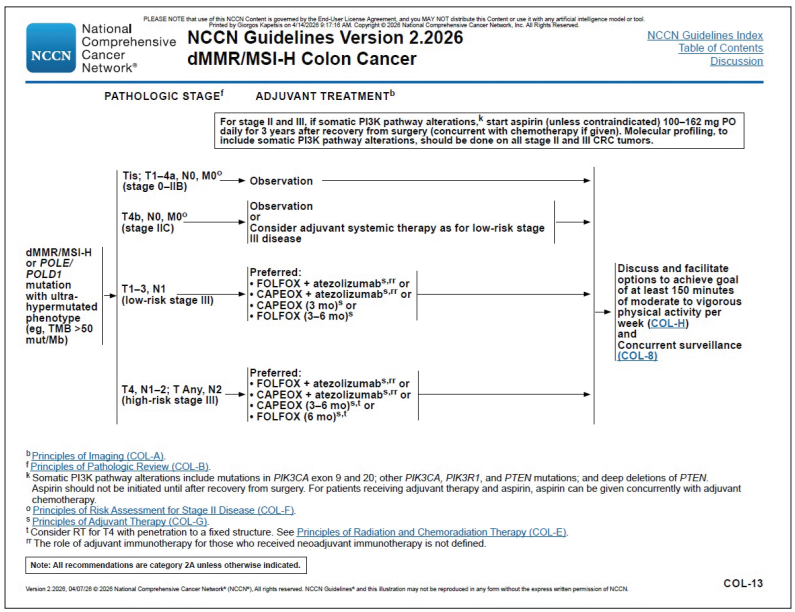
COL-4



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National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2026
dMMR/MSI-H Colon Cancer

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PATHOLOGIC STAGE[f] | ADJUVANT TREATMENT[b]

For stage II and III, if somatic PI3K pathway alterations,[k] start aspirin (unless contraindicated) 100–162 mg PO daily for 3 years after recovery from surgery (concurrent with chemotherapy if given). Molecular profiling, to include somatic PI3K pathway alterations, should be done on all stage II and III CRC tumors.

dMMR/MSI-H or *POLE/POLD1* mutation with ultra-hypermutated phenotype (eg, TMB >50 mut/Mb)

- Tis; T1–4a, N0, M0[o] (stage 0–IIB) → Observation
- T4b, N0, M0[o] (stage IIC) → Observation or Consider adjuvant systemic therapy as for low-risk stage III disease
- T1–3, N1 (low-risk stage III) → Preferred: • FOLFOX + atezolizumab[s,rr] or • CAPEOX + atezolizumab[s,rr] or • CAPEOX (3 mo)[s] or • FOLFOX (3–6 mo)[s]
- T4, N1–2; T Any, N2 (high-risk stage III) → Preferred: • FOLFOX + atezolizumab[s,rr] or • CAPEOX + atezolizumab[s,rr] or • CAPEOX (3–6 mo)[s,t] or • FOLFOX (6 mo)[s,t]

→ Discuss and facilitate options to achieve goal of at least 150 minutes of moderate to vigorous physical activity per week (COL-H) and Concurrent surveillance (COL-8)

[b] Principles of Imaging (COL-A).
[f] Principles of Pathologic Review (COL-B).
[k] Somatic PI3K pathway alterations include mutations in *PIK3CA* exon 9 and 20; other *PIK3CA*, *PIK3R1*, and *PTEN* mutations; and deep deletions of *PTEN*. Aspirin should not be initiated until after recovery from surgery. For patients receiving adjuvant therapy and aspirin, aspirin can be given concurrently with adjuvant chemotherapy.
[o] Principles of Risk Assessment for Stage II Disease (COL-F).
[s] Principles of Adjuvant Therapy (COL-G).
[t] Consider RT for T4 with penetration to a fixed structure. See Principles of Radiation and Chemoradiation Therapy (COL-E).
[rr] The role of adjuvant immunotherapy for those who received neoadjuvant immunotherapy is not defined.

Note: All recommendations are category 2A unless otherwise indicated.

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COL-13

Com.Pl.i.t DX® Breast

(FFPE/Liquid & Combo)

Com.Pl.i.t DX® Breast is designed to help treating physicians in selecting the optimal treatment based on the biology of each patient's 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 including biomarkers with approved treatments as well as emerging biomarkers according to international guidelines.

Biomarkers with Approved Treatment

HR+, HER2– Breast Cancer:

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

All breast cancer subtypes:

- *BRCA1/2*
- *PALB2*
- *NTRK1/2/3 fusions*
- *RET fusions*
- *MSI*

Liquid Biopsy Utility

- Patients with limited or insufficient tissue
- Disease monitoring during or after treatment
- Detection of treatment resistance

Combined Testing

The combination of tissue and liquid biopsy increases diagnostic sensitivity and supports optimally targeted therapy selection.

Com.Pl.i.t DX® in Additional Tumor Indications

Beyond lung, colon, and breast cancer, Com.Pl.i.t DX® is also available for additional tumor types, including GIST, prostate cancer, cholangiocarcinoma, and melanoma.

The assay enables comprehensive genomic profiling in accordance with international guidelines (e.g. NCCN, ESMO) and can be performed on both tissue and liquid biopsy samples.

Com.Pl.i.t DX® Cholangiocarcinoma

(FFPE/Liquid)

Gene Table

14 DNA genes									
BRAF	*CDKN2A**	*CTNNB1*	*ERBB2**	*IDH1*	*IDH2*	*KRAS*	*MET*	*NF1*	*PTEN**
TERT	*TSC1*	*TSC2*	*TP53**						
*CNV (amplification/deletion) analysis is included for these genes									
7 Fusions									
FGFR1	*FGFR2*	*FGFR3*	*NTRK1*	*NTRK2*	*NTRK3*	*RET*			
MSI									

Biomarkers with Approved Treatment:

IDH1
FGFR2 fusions

Includes tissue-agnostic biomarkers:

BRAF
ERBB2 (HER2) amplification
RET fusions
NTRK1/2/3 fusions
MSI

Com.Pl.i.t DX® Prostate

(FFPE/Liquid)

Gene Table

30 DNA genes									
AR	*ATM**	*ATR*	*BARD1*	*BRAF*	*BRCA1**	*BRCA2**	*BRIP1*	*CDK12*	*CHEK1*
CHEK2	*ERBB2**	*FANCA*	*FANCL*	*FOXA1*	*MLH1**	*MRE11*	*MSH2**	*MSH6**	*NBN*
*PALB2**	*PMS2*	*PTEN**	*RAD51B*	*RAD51C*	*RAD51D*	*RAD54L*	*RB1**	*SPOP*	*TP53**
*CNV (amplification/deletion) analysis is included for these genes									
9 Fusions									
ALK	*FGFR1*	*FGFR2*	*FGFR3*	*NTRK1*	*NTRK2*	*NTRK3*	*RET*	*ROS1*	
MSI									

Biomarkers with Approved Treatment in metastatic Castration Resistant Prostate Cancer:

BRCA1/2
17 Homologous Recombination Repair (HRR) pathway genes in total

Includes tissue-agnostic biomarkers:

BRAF
ERBB2 (HER2) amplification
RET fusions
NTRK1/2/3 fusions
MSI

Biomarkers with Approved Treatment in metastatic Castration Sensitive Prostate Cancer:

BRCA2

Com.Pl.i.t DX® Melanoma
(FFPE/Liquid)

Gene Table

21 DNA genes									
ARID2	*BAP1*	*BRAF*	*CDKN2A**	*CTNNB1*	*EIF1AX*	*ERBB2**	*GNA11*	*GNAQ*	*IDH1*
IDH2	*KIT*	*KRAS**	*MAP2K1*	*MAP2K2*	*NF1*	*NRAS*	*PTEN**	*SF3B1*	*TERT*
*TP53**									
*CNV (amplification/deletion) analysis is included for these genes									
9 Fusions									
ALK	*FGFR1*	*FGFR2*	*FGFR3*	*NTRK1*	*NTRK2*	*NTRK3*	*RET*	*ROS1*	
MSI									

Biomarkers with Approved Treatment:

BRAF

Includes tissue-agnostic biomarkers:

ERBB2 (HER2) amplification
RET fusions
NTRK1/2/3 fusions
MSI

Com.Pl.i.t DX® GIST

(FFPE/Liquid)

Gene Table

17 DNA genes									
*ARID1A**	*ATRX**	*BRAF**	*ERBB2**	*KIT**	*KRAS**	*NF1**	*PDGFRA**	*PIK3CA**	*PTEN**
*RB1**	*SDHA**	*SDHAF2**	*SDHB**	*SDHC**	*SDHD**	*TP53**			
*CNV (amplification/deletion) analysis is included for these genes									
9 Fusions									
ALK	*FGFR1*	*FGFR2*	*FGFR3*	*NTRK1*	*NTRK2*	*NTRK3*	*RET*	*ROS1*	
MSI									

Biomarkers with Approved Treatment:

KIT
PDGFRA

Includes tissue-agnostic biomarkers:

BRAF
ERBB2 (HER2) amplification
RET fusions
NTRK1/2/3 fusions
MSI

Additional clinically relevant biomarkers:

SDH deficiency (SDHA, SDHB, SDHC, SDHD)

Accreditations & Certifications

Clinical Reliability: ISO 15189:2022 (Cert. No. 822)* & **CAP Accredited Laboratory.**

Data Security: Certified according to **ISO/IEC 7001:2022** for Information Security Management.

Quality Management:
ISO 9001:2015 Certified Quality Management System.

Method Reliability: Com.Pl.i.t DX® is performed using **CE-IVD** marked reagents/software, in compliance with IVDR.

** Within the official scope of accreditation.*

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