



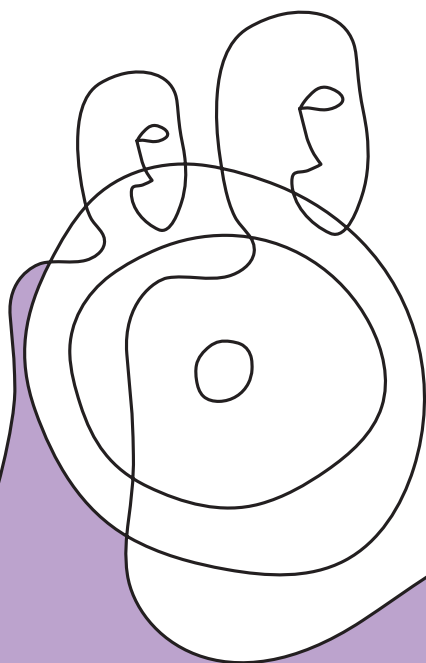
Com.Pl.i.t DX[®]

Personalized treatment based on tumor biology



Genekor

Committed to Biotechnological Innovation



SHAPING SCIENCE
IMPROVING LIVES

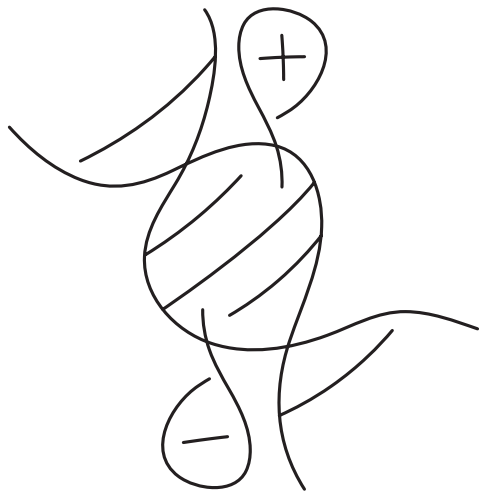
Com.Pl.i.t DX[®]

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

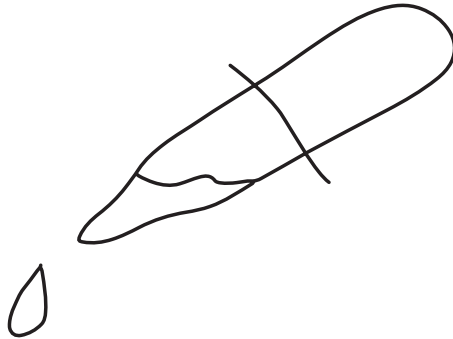
Com.Pl.i.t DX[®] Colon

(Liquid)

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


Gene Table

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									



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.



National Comprehensive Cancer Network®


NCCN Guidelines Version 2.2026 pMMR/MSS Colon Cancer

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PATHOLOGIC STAGE [†]	ADJUVANT TREATMENT [§]	
For stage II and III, if somatic PI3K pathway alterations, [§] 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	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)
T3, N0, M0 [¶] (no high-risk features)	Observation (preferred) or Consider capecitabine (6 mo) [§] or fluorouracil/leucovorin (6 mo) [§]	
T3, N0, M0 at high risk for systemic recurrence ^{¶¶} or T4, N0, M0	Capecitabine (6 mo) ^{§,†} or fluorouracil/leucovorin (6 mo) ^{§,†} or FOLFOX (6 mo) ^{§,†,‡,§} or CAPEOX (3 mo) ^{§,†,§} or Observation	
T1–3, N1 (low-risk stage III)	Preferred: • CAPEOX (3 mo) [§] or • FOLFOX (3–6 mo) [§] or Other options include: capecitabine (6 mo) [§] or fluorouracil/leucovorin (6 mo) [§]	
T4, N1–2, T Any, N2 (high-risk stage III)	Preferred: • CAPEOX (3–6 mo) ^{§,†} or • FOLFOX (6 mo) ^{§,†} or Other options include: capecitabine (6 mo) ^{§,†} or fluorouracil/leucovorin (6 mo) ^{§,†}	
<p>[†]Principles of Imaging (COL-A). [‡]Principles of Pathologic Review (COL-8). [§]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. [¶]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. ^{¶¶}There are insufficient data to recommend the use of multigene assay panels to determine adjuvant therapy. ^{††}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. ^{‡‡}Principles of Radiation and Chemoradiation Therapy (COL-5). ^{§§}Consider RT for T4 with penetration to a fixed structure. See Principles of Radiation and Chemoradiation Therapy (COL-5). A survival benefit has not been demonstrated for the addition of oxaliplatin to fluorouracil/leucovorin in stage II colon cancer. Toumang C, et al. J Clin Oncol 2012;30:3363–3369.</p> <p>Note: All recommendations are category 2A unless otherwise indicated.</p>		

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COL-4



National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2026 dMMR/MSI-H Colon Cancer

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PATHOLOGIC STAGE [†]	ADJUVANT TREATMENT [§]	
For stage II and III, if somatic PI3K pathway alterations, [§] 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; T1–4a, N0, M0 [¶] (stage 0–IIb)	Observation	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)
T4b, N0, M0 [¶] (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 ^{§,††} or • CAPEOX + atezolizumab ^{§,††} or • CAPEOX (3 mo) ^{§,†} or • FOLFOX (3–6 mo) [§]	
T4, N1–2, T Any, N2 (high-risk stage III)	Preferred: • FOLFOX + atezolizumab ^{§,††} or • CAPEOX + atezolizumab ^{§,††} or • CAPEOX (3–6 mo) ^{§,†} or • FOLFOX (6 mo) ^{§,†}	
<p>[†]Principles of Imaging (COL-A). [‡]Principles of Pathologic Review (COL-8). [§]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. [¶]Principles of Risk Assessment for Stage II Disease (COL-F). ^{¶¶}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. ^{††}Consider RT for T4 with penetration to a fixed structure. See Principles of Radiation and Chemoradiation Therapy (COL-5). ^{‡‡}The role of adjuvant immunotherapy for those who received neoadjuvant immunotherapy is not defined.</p> <p>Note: All recommendations are category 2A unless otherwise indicated.</p>		

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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									

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.*

Genekor Medical S.A.

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5/2026