



Effective Targeted Therapy Decision
for Your Patients

GCH GENCURIX



Droplex

02

Droplex, is a diagnostic solution designed to provide information that is essential for the safe and effective use of a corresponding drug for specific cancer types. It facilitates the identification of driver mutations to guide treatment and diagnose resistance.

Droplex is a CE-marked and clinically validated assay based on Droplet Digital PCR technology to detect target mutations with fast time-to-results using both tissue and plasma specimens.

Advantages of Plasma-based analyses

- Non-invasive compared to the surgical biopsy
- Shorter turnaround time
- Avoid repeated biopsy due to improved sensitivity

Advantages of Digital PCR [Droplet Digital PCR Platform]



DNA Quality Check

Validated indicator of DNA quality



Broad Application

Option of using either tissue or plasma samples



Quantitative Result

Quantitative information of each target mutation



High Sensitivity

Advanced performance with minimum DNA input



Auto Analysis Software

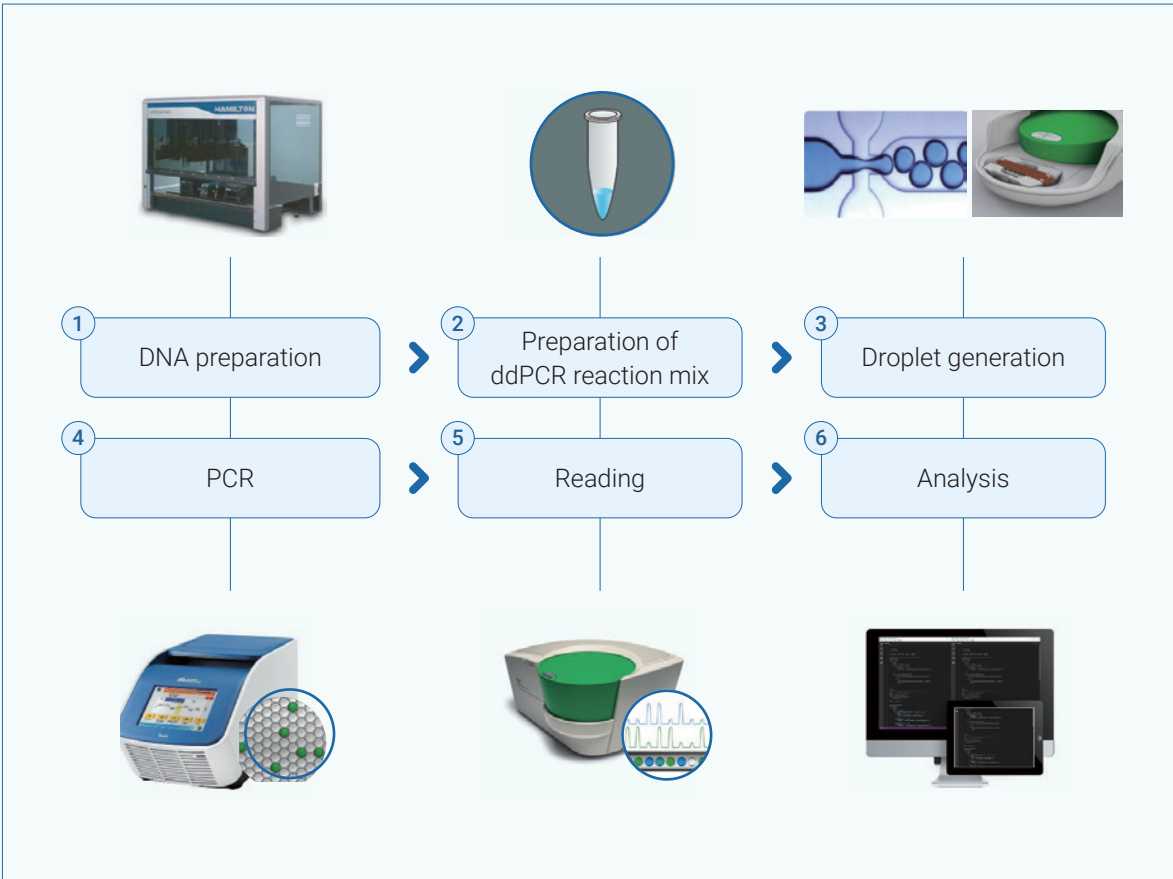
Easy & convenient in result analysis

Droplex provides a comprehensive portfolio for targeted therapy and a strong pipeline capability covering the most dominant cancer types

Cancer Solutions

Associated Cancer	Category	Droplex Products
Lung Cancer	IVD-CDx	EGFR Mutation Test v2
	IVD-CDx	KRAS Mutation Test v2
	IVD-CDx	cMET Exon14 skipping Mutation Test
Breast Cancer	IVD-CDx	PIK3CA Mutation Test
Melanoma Cancer	IVD-CDx	BRAF Mutation Test v2
Colorectal Cancer	IVD-CDx	KRAS Mutation Test v2
Thyroid Cancer	IVD	BRAF Mutation Test v2
Endometrial Cancer	IVD	POLE Mutation Test

Droplex Workflow

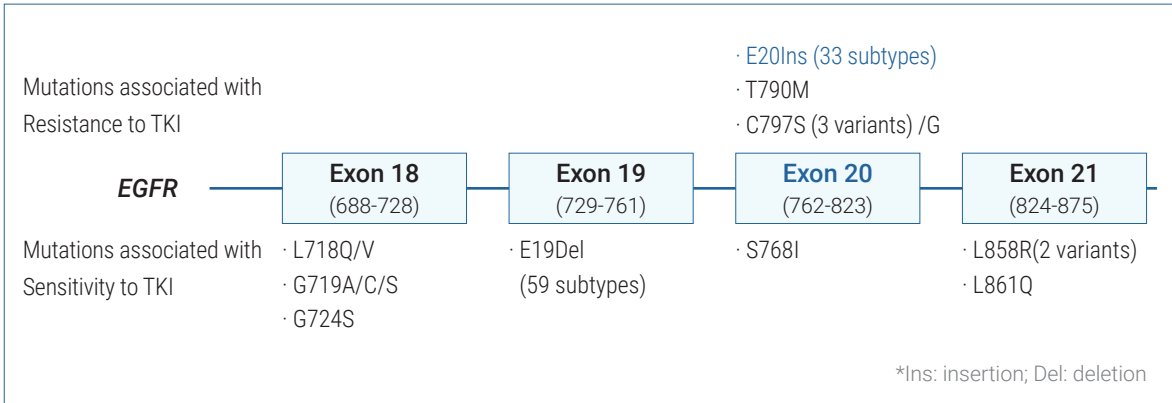


Droplex EGFR Mutation Test v2



Cat No. CD002
Cancer Type Non-Small Cell Lung Cancer
Regulatory status IVD-CDx
Compatible Sample type FFPE tissue
 Plasma
Mutation variants 107
6 well-reactions/test (16 tests/kit)
Storage Temp -20°C (+/- 3°C)

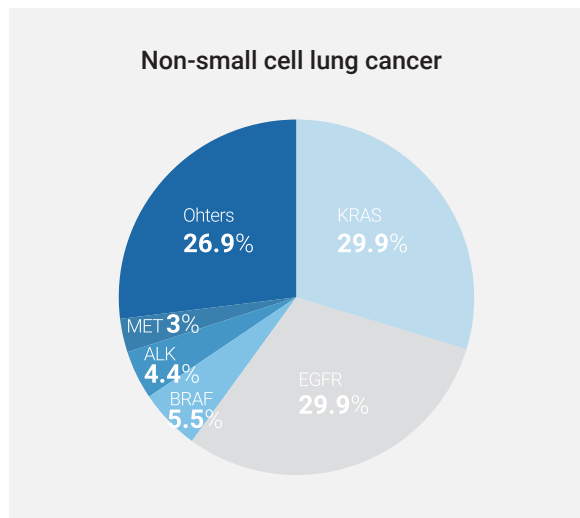
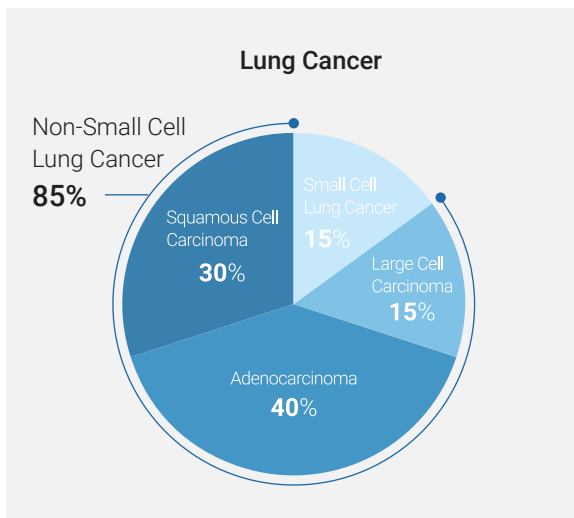
Mutation Coverage



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Non-Small Cell Lung Cancer

Lung Cancer is a leading cause of cancer deaths, making up almost 25% of all cancer deaths. About 80~85% of lung cancer are Non-Small Cell Lung Cancer (NSCLC) – NSCLC patients are likely to have EGFR mutation, which hinders cancer treatment .

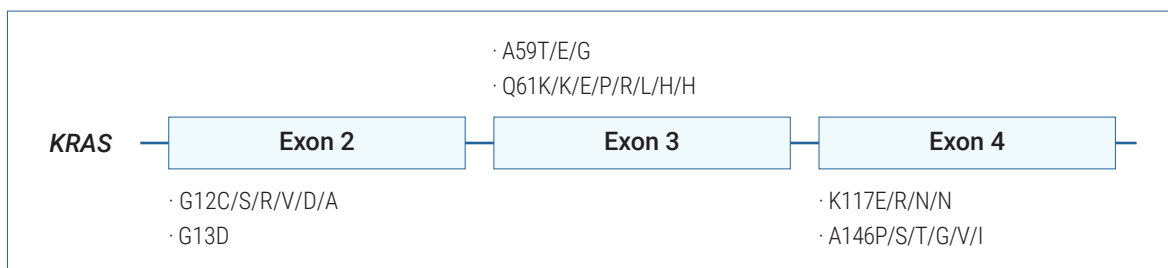


Droplex KRAS Mutation Test v2



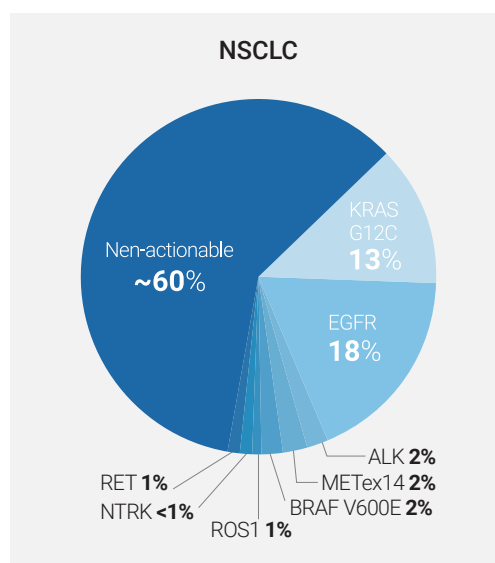
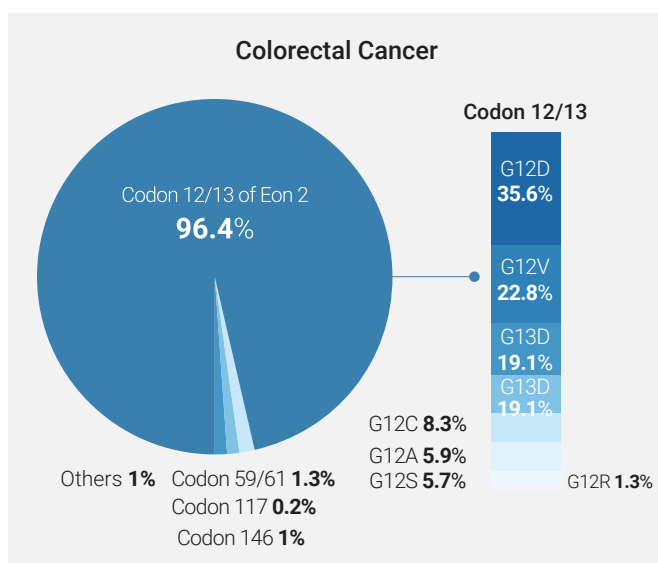
Cat No. CD012
Cancer Type Colorectal Cancer
 Non-Small Cell Lung Cancer
Regulatory status IVD-CDx
Compatible Sample type FFPE tissue
 Plasma
Mutation variants 28
4 well-reactions/test (24 tests/kit)
Storage Temp -20°C (+/- 3°C)

Mutation Coverage



Colorectal Cancer & NSCLC

Colorectal Cancer is one of the cancers with the most incidents & mortality rate around the globe. KRAS mutation is the most common driver mutation in colorectal cancer patients which accounts about 30~40% of total cases. KRAS G12C mutation is also an important mutation for NSCLC patients, which occurs in 13% of all NSCLC cases.



Román, M., Baraibar, I., López, I. et al. KRAS oncogene in non-small cell lung cancer: clinical perspectives on the treatment of an old target. Mol Cancer 17, 33 (2018). <https://doi.org/10.1186/s12943-018-0789-x>

Dinu D, Dobre M, Panaitescu E, Birlă R, Iosif C, Hoara P, Caragui A, Boeriu M, Constantinoiu S, Ardeleanu C. Prognostic significance of KRAS gene mutations in colorectal cancer—preliminary study. J Med Life. 2014 Oct-Dec;7(4):581-7. PMID: 25713627; PMCID: PMC4316144.

Droplex cMET Exon 14 Skipping Mutation Test



Cat No. CD007

Cancer Type Non-Small Cell Lung Cancer

Regulatory status IVD-CDx

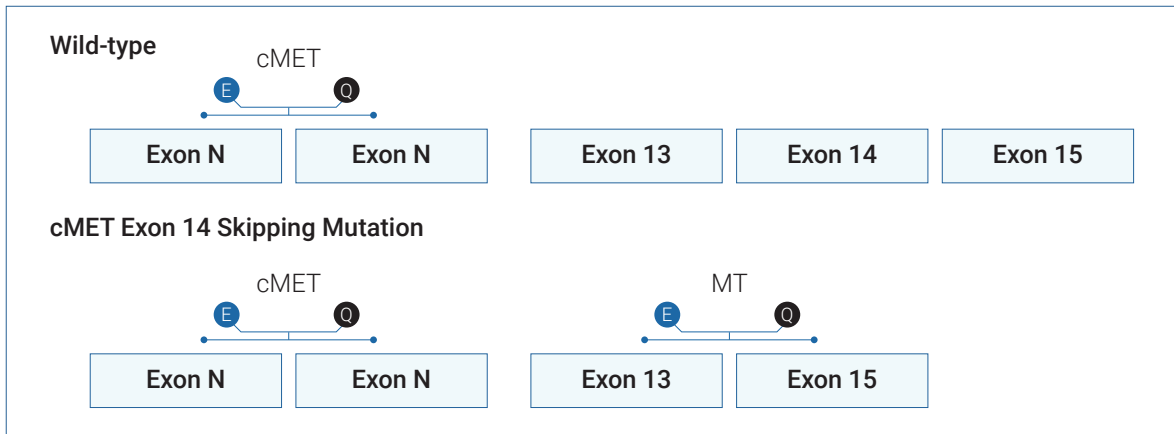
Compatible Sample type FFPE tissue
Whole Blood RNA

Mutation variants Exon 14 skipping

2 Well-Reactions/Test (24 tests/kit)

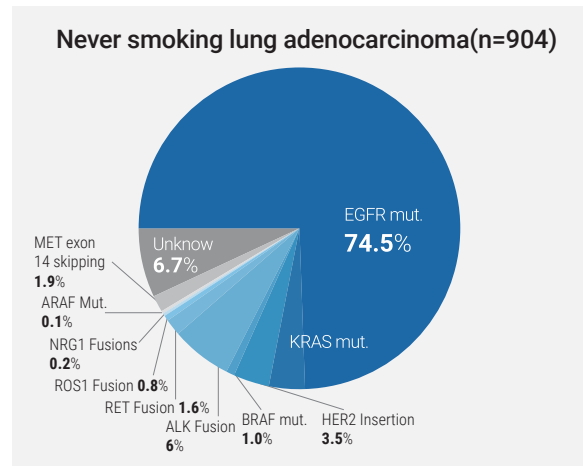
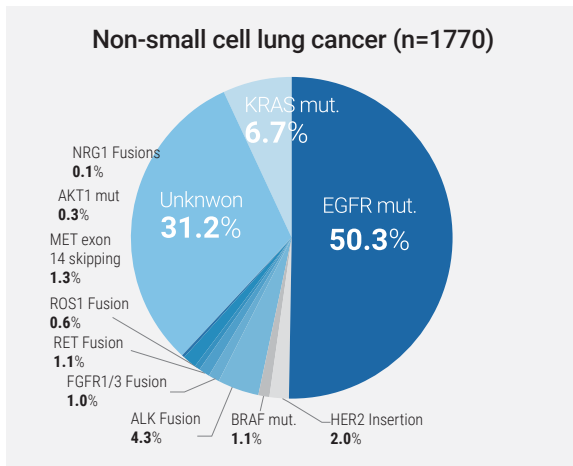
Storage Temp -20°C (+/-3°C)

Mutation Coverage



Non-Small Cell Lung Cancer

In NSCLC, the frequency of cMET Exon14 Skipping mutation is very low (1~4%), but cMET Exon14 Skipping mutation is related with NSCLC-drug resistance. When MET Exon 14 skipping occurs, the MET pathway, which plays an important role in cell signaling, proliferation, and survival, is overstimulated and causes proliferation of cancer cells.



Fujino T, Suda K, Mitsudomi T. Lung Cancer with MET exon 14 Skipping Mutation: Genetic Feature, Current Treatments, and Future Challenges. Lung Cancer (Auckl). 2021 May 20;12:35-50. doi: 10.2147/LCTT.S269307. PMID: 34295201; PMCID: PMC8290191.

Droplex BRAF Mutation Test v2



Cat No. CD011

Cancer Type Papillary Thyroid Cancer
Melanoma

Regulatory status IVD-CDx

Compatible Sample type FFPE tissue

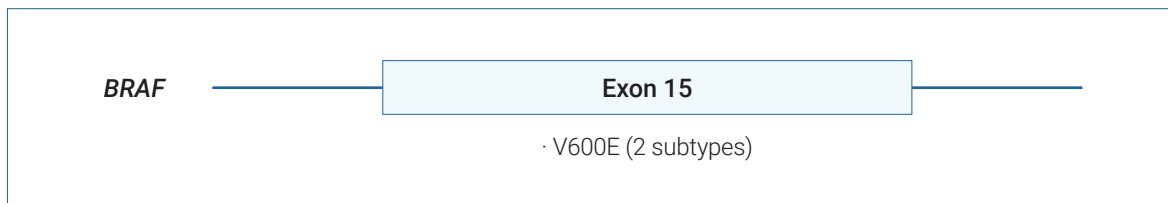
Mutation variants 2

1 well-reaction/test (24 tests/kit)

Storage Temp -20°C (+/-3°C)

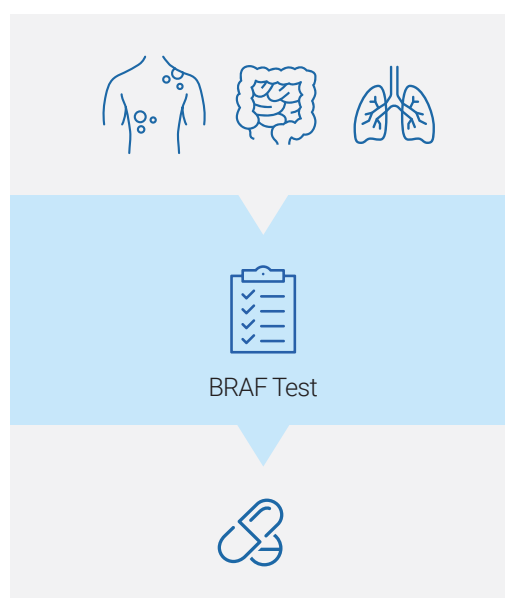
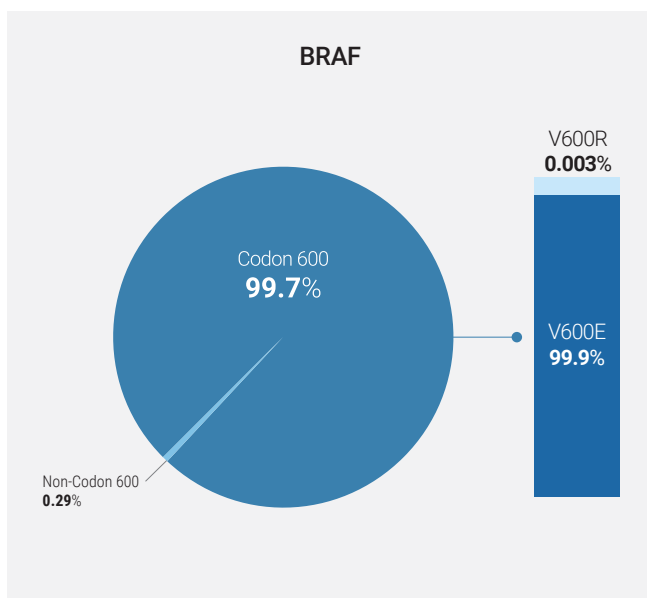
Mutation Coverage

* Melanoma: vemurafenib



Papillary Thyroid Cancer

Thyroid cancer is the most common malignant tumor that occurs in the endocrine system and occurs at a younger age than other malignancies. Papillary Thyroid Carcinoma (PTC) accounts for about 80% of all thyroid cancers and is characterized by spreading along the lymphatic system. About 30~ 60% of PTC patients has BRAF mutation, which is found in codon 600. Melanoma, NSCLC and Colorectal Cancer patients also are guided to screen BRAF mutation for targeted therapy.



Limaiem F, Rehman A, Mazzoni T. Papillary Thyroid Carcinoma. [Updated 2022 Jun 5]. In: StatPearls [Internet]. Bakshi J, Patro SK, Kaur N, Panda NK, Budhiraja G. Understanding Malignancies of the Thyroid Gland: Institutional Experience. Indian J Otolaryngol Head Neck Surg. 2018 Dec;70(4):482-489. doi: 10.1007/s12070-018-1492-3. Epub 2018 Sep 5. PMID: 30464902; PMCID: PMC6224818.

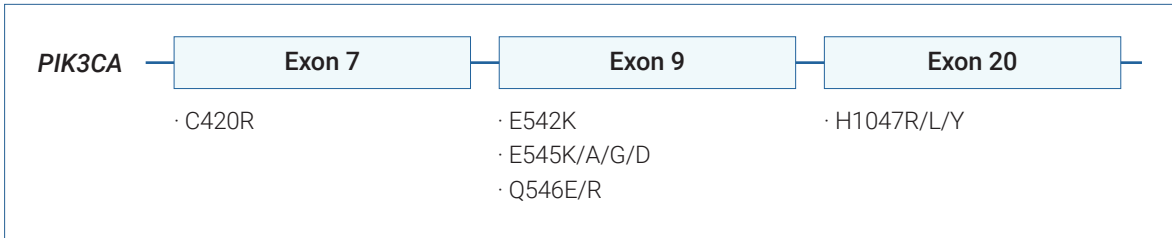
Droplex PIK3CA Mutation Test



Cat No. CD006
Cancer Type Breast Cancer
Regulatory status IVD-CDx
Compatible Sample type FFPE tissue
 Plasma
Mutation variants 11
4 well-reactions/test (24 tests/kit)
Storage Temp -20°C (+/-3°C)

Mutation Coverage

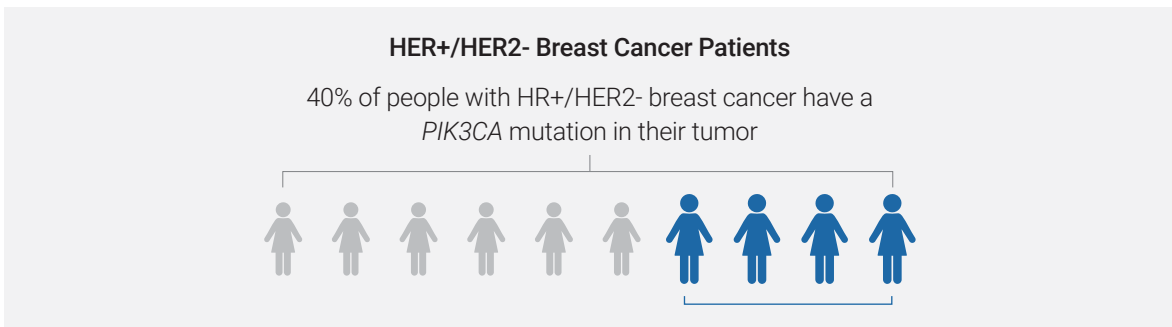
* PIK3CA: Alpelisib



Breast Cancer

Breast Cancer is the most common cancer in women, and is a second leading cause of death in Women. ER+ and HER2- type tumor accounts for about 71% of all Breast cancer patients, and, 40% of those BC patients have PIK3CA mutations

When a patients has PIK3CA mutation, they are likely to be resistant to the chemotherapy. Therefore, knowing the existence of PIK3CA mutation is important in treating breast cancer patients with appropriate drugs.



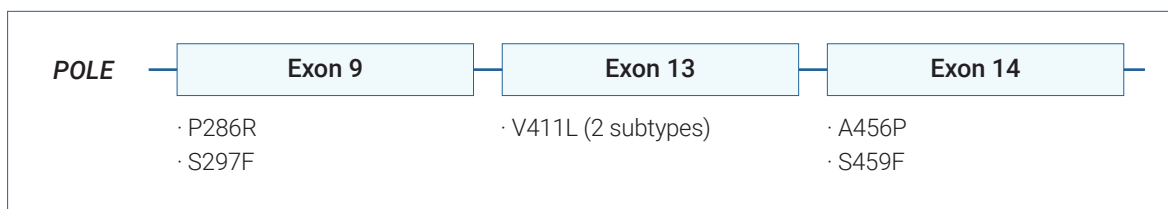
<p>Endocrine Resistance</p> <p>PIK3CA mutations have been identified in patients with endocrine resistance</p>	<p>Shorter mPFS</p> <p>A more aggressive disease can lead to shorter median time to tumor progression or death</p>
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Droplex POLE Mutation Test



Cat No. CD008
Cancer Type Endometrial Cancer
Regulatory status IVDs
Compatible Sample type FFPE tissue
Mutation variants 6
3 well-reactions/test (32 tests/kit)
Storage Temp -20°C (+/-3°C)

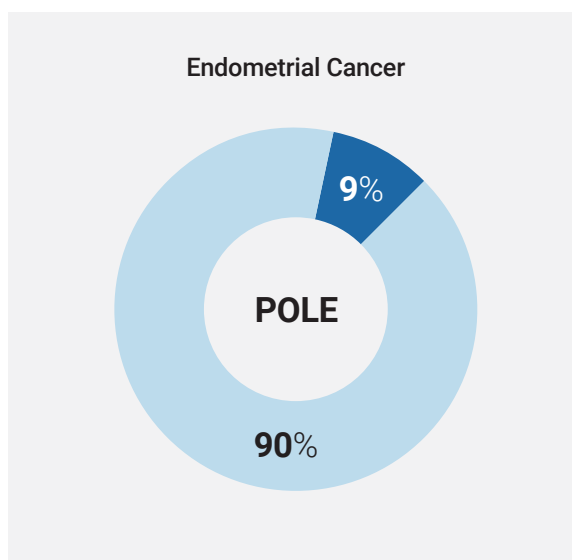
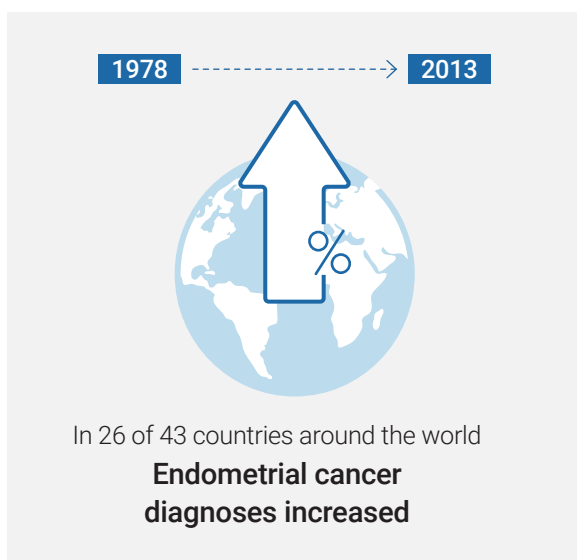
Mutation Coverage



Endometrial Cancer

Endometrial Cancer is one of the increasing concern cancer type for women over the years. Globally, the risk is also increasing - according to the WHO in 2018, it ranked fourth in the prevalence and mortality of cancer among women.

Although POLE Mutation is shown in only 9% of (Endometrial cancer) EC patients, it is an important subgroup of Endometrial Cancer, because they are indicator of relatively good prognosis for patients



Del Re, M.; Crucitta, S.; Lorenzini, G.; De Angelis, C.; Diodati, L.; Cavallero, D.; Bargagna, I.; Cinacchi, P.; Fratini, B.; Salvadori, B.; et al. PI3K mutations detected in liquid biopsy are associated to reduced sensitivity to CDK4/6 inhibitors in metastatic breast cancer patients. *Pharmacol. Res.* 2021, 163, 105241
 Zhang S, Gong TT, Liu FH, Jiang YT, Sun H, Ma XX, Zhao YH, Wu QJ. Global, Regional, and National Burden of Endometrial Cancer, 1990-2017: Results From the Global Burden of Disease Study, 2017. *Front Oncol.* 2019 Dec 19;9:1440. doi: 10.3389/fonc.2019.01440. PMID: 31921687; PMCID: PMC6930915.

Droplex Portfolio

Droplex EGFR Mutation Test v2



- 1 IVD-CDx for Non-Small Cell Lung Cancer (NSCLC)
- 2 107 mutations in EGFR gene
- 3 6 well-reactions/Test (16 tests/kit)
- 4 Cat. No. CD002

	OM1		OM2		OM3	OM4		OM5		OM6	
Internal Control	E19Del	T790M	L858R	E20Ins	G724S	C797X	S768I	L718X	G719X	L861Q	

Droplex KRAS Mutation Test v2



- 1 IVD-CDx for Colorectal (CRC) and Non-Small Cell Lung Cancer (NSCLC)
- 2 28 mutations in KRAS gene
- 3 4 well-reactions/Test (24 tests/kit)
- 4 Cat. No. CD012

OM1		OM2		OM3		OM4	
G12X, G13D	Internal Control	K117X	G12C	A59X, Q61X	Internal Control	A146X	Internal Control

Droplex cMET Exon14 Skipping Mutation Test



- 1 IVD-CDx for Non-Small Lung Cancer
- 2 over 100 different mutations
- 3 2 well-reactions/Test (24 tests/kit)
- 4 Cat No. CD007

OM1		OM2	
cMET Exon14 Skipping	Internal Control	cMET	Internal Control

Droplex BRAF Mutation Test v2



- 1 IVD for Papillary Thyroid Carcinoma (PTC) and Melanoma
- 2 V600E mutation detection (2 subtypes)
- 3 1 well-reaction/Test (24 tests/kit)
- 4 Cat. No. CD011

OM	
V600E	Internal Control

Droplex POLE Mutation Test



- 1 IVD for Endometrial Cancer (EC)
- 2 6 mutations in POLE gene
- 3 3 well-reactions/Test (32 tests/kit)
- 4 Cat. No. CD008

OM1		OM2		OM3	
P286R	Internal Control	S297F	V411L	S459F	A456P

Droplex PIK3CA Mutation Test



- 1 IVD-CDx for Breast Cancer (BC)
- 2 11 mutations in PIK3CA gene
- 3 4 well-reactions/Test (24 tests/kit)
- 4 Cat. No. CD006

OM1			OM2			OM3			OM4		
E545K	Internal Control	H1047R	E542K	E545A	H1047L	Q546E	E545G	H1047Y	Q546R	C420R	E545D

Droplex

DROP-B-001-EN-R0-2022-09

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